Case No. 85369

In the Supreme Court of Nevada

SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.,

Appellant,

vs.

SANDRA L. ESKEW, as special administrator of the Estate of William George Eskew,

Respondent.

Appeal from the Eighth Judicial District Court, Clark County
The Honorable Nadia Krall, District Judge
District Court No. A-19-788630-C

JOINT APPENDIX
Volume 15 of 18

D. LEE ROBERTS, JR. (SBN 8877)
PHILLIP N. SMITH (SBN 10233)
RYAN T. GORMLEY (SBN 13494)
WEINBERG, WHEELER, HUDGINS, GUNN & DIAL, LLC
6385 S. Rainbow Blvd., Ste. 400
Las Vegas, Nevada 89118
(702) 938-3838
rgormley@wwhgd.com

THOMAS H. DUPREE JR.
(*admitted pro hac vice*)
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Ave. NW
Washington, DC 20036
(202) 955-8500
tdupree@gibsondunn.com

Attorneys for Appellant

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Sierra Health and Life, Inc. is accredited with the National Committee for Quality Assurance (NCQA), an independent, not-for-profit organization dedicated to measuring the quality of America's healthcare. Accreditation is for the Commercial PPO product line in Nevada effective May 12, 2014.

WILLIAM G ESKEW
5825 EGAN CREST DR
LAS VEGAS NV 89149

PLAN BENEFIT INFORMATION

OFF EXCHANGE
10003502
07012016

PROCESSED ON 09/03/2021 15:20 EDT

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

P.O. Box 15645
Las Vegas, Nevada 89114-5645

Reference Guide

Your complete plan benefit information packet includes your evidence of coverage, benefit schedule, applicable endorsements and riders, and exclusions of coverage. These documents explain your benefits in detail. They also outline the health plan's obligations to you. We encourage you to read all materials carefully, because the more you know about us, the better we can serve you.

Our Philosophy

Sierra Health and Life is committed to high standards of professional conduct. We are a caring team of health insurance professionals, dedicated to improving the health insurance experience for the people we serve.

Online Member Center

With Sierra Health and Life you have an online member center to help manage your health plan needs. You'll be surprised how easy it is to get answers to your claims and benefit questions. Access the online member center at **mySHLonline.com** to:

- Change your address
- Request a replacement health plan ID card.
- View or email your virtual health plan ID card.
- Verify what coverage you have for pharmacy, dental or vision services
- Look at your cost sharing amounts for medical services
- Review the status of your claim
- Find out who is on record as your primary care provider (PCP)
- Check if your prior authorization request has been received by the health plan
- Inquire how much you have applied toward your deductible, if applicable

Visit us at **mySHLonline.com.** Your medical information is confidential and only available to you and your providers.

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

Important Contact Information

Member Services	
	702-242-7700 or 1-800-888-2264 8 a.m. – 5 p.m. Monday through Friday, Pacific Time
	P.O. Box 15645 Las Vegas, NV 89114-5645
Medical Claims Administration	
	SHL Claims P.O. Box 15645 Las Vegas, NV 89114-5645
24- Hour Telephone Advice Nurse	
	702-242-7330 or 1-800-288-2264
Health Education and Wellness	
702-877-5356 or 1-800-720-7253	myHEWonline.com
Behavioral Healthcare Options	
702-364-1484 or 1-800-873-2246 bhoptions.com	
Southwest Medical Associates	
702-877-5199	smalv.com

P.O. Box 15645
Las Vegas, Nevada 89114-5645

Notice to Members

This is to provide notice as required under recent federal law

(the Women´s Health and Cancer Rights Act, effective October 21, 1998).

Under this health plan, coverage will be provided to a member who is receiving benefits for a medically necessary mastectomy and who elects breast reconstruction after the mastectomy, for:

1. reconstruction of the breast on which a mastectomy has been performed;

2. surgery and reconstruction of the other breast to produce a symmetrical appearance;

3. prostheses; and

4. treatment of physical complications of all stages of mastectomy, including lymphedemas.

This coverage will be provided in consultation with the attending physician and the covered patient, and will be subject to the same terms and conditions of your evidence of coverage, including any required copayments, annual deductibles or coinsurance provisions that apply for the mastectomy.

If you have any questions about our coverage of mastectomies and corresponding reconstructive surgery, please contact the Member Services number on the back of your ID card.

HEALTH PLAN NOTICES OF PRIVACY PRACTICES

MEDICAL INFORMATION PRIVACY NOTICE

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Effective January 1, 2016

We1 are required by law to protect the privacy of your health information. We are also required to send you this notice, which explains how we may use information about you and when we can give out or "disclose" that information to others. You also have rights regarding your health information that are described in this notice. We are required by law to abide by the terms of this notice.

The terms “information” or “health information” in this notice include any information we maintain that reasonably can be used to identify you and that relates to your physical or mental health condition, the provision of health care to you, or the payment for such health care. We will comply with the requirements of applicable privacy laws related to notifying you in the event of a breach of your health information.

We have the right to change our privacy practices and the terms of this notice. If we make a material change to our privacy practices, we will provide to you, in our next annual distribution, either a revised notice or information about the material change and how to obtain a revised notice. We will provide you with this information either by direct mail or electronically, in accordance with applicable law. In all cases, if we maintain a website for your particular health plan, we will post the revised notice on your health plan website, www.myHPNonline.com or www.mySHLonline.com. We reserve the right to make any revised or changed notice effective for information we already have and for information that we receive in the future.

UnitedHealth Group collects and maintains oral, written and electronic information to administer our business and to provide products, services and information of importance to our enrollees. We maintain physical, electronic and procedural security safeguards in the handling and maintenance of our enrollees’ information, in accordance with applicable state and federal standards, to protect against risks such as loss, destruction or misuse.

How We Use or Disclose Information
We must use and disclose your health information to provide that information:

- To you or someone who has the legal right to act for you (your personal representative) in order to administer your rights as described in this notice; and
- To the Secretary of the Department of Health and Human Services, if necessary, to make sure your privacy is protected.

We have the right to use and disclose health information for your treatment, to pay for your health care and to operate our business. For example, we may use or disclose your health information:

- **For Payment** of premiums due us, to determine your coverage, and to process claims for health care services you receive, including for subrogation or coordination of other benefits you may have. For example, we may tell a doctor whether you are eligible for coverage and what percentage of the bill may be covered
- **For Treatment.** We may use or disclose health information to aid in your treatment or the coordination of your care. For example, we may disclose information to your physicians or hospitals to help them provide medical care to you.
- **For Health Care Operations.** We may use or disclose health information as necessary to operate and manage our business activities related to providing and managing your health care coverage. For example, we might talk to your physician to suggest a disease management or wellness program that could help improve your health or we may analyze data to determine how we can improve our services.
- **To Provide You Information on Health Related Programs or Products** such as alternative medical treatments and programs or about health-related products and services, subject to limits imposed by law.
- **For Plan Sponsors.** If your coverage is through an employer sponsored group health plan, we may share summary

health information and enrollment and disenrollment information with the plan sponsor. In addition, we may share other health information with the plan sponsor for plan administration purposes if the plan sponsor agrees to special restrictions on its use and disclosure of the information in accordance with federal law.

- **For Underwriting Purposes.** We may use or disclose your health information for underwriting purposes; however, we will not use or disclose your genetic information for such purposes.
- **For Reminders.** We may use or disclose health information to send you reminders about your benefits or care, such as appointment reminders with providers who provide medical care to you.

We may use or disclose your health information for the following purposes under limited circumstances:

- **As Required by Law.** We may disclose information when required to do so by law.
- **To Persons Involved With Your Care.** We may use or disclose your health information to a person involved in your care or who helps pay for your care, such as a family member, when you are incapacitated or in an emergency, or when you agree or fail to object when given the opportunity. If you are unavailable or unable to object, we will use our best judgment to decide if the disclosure is in your best interests. Special rules apply regarding when we may disclose health information to family members and others involved in a deceased individual's care. We may disclose health information to any persons involved, prior to the death, in the care or payment for care of a deceased individual, unless we are aware that doing so would be inconsistent with a preference previously expressed by the deceased.
- **For Public Health Activities** such as reporting or preventing disease outbreaks to a public health authority.
- **For Reporting Victims of Abuse, Neglect or Domestic Violence** to government authorities that are authorized by law to receive such information, including a social service or protective service agency.
- **For Health Oversight Activities** to a health oversight agency for activities authorized by law, such as licensure, governmental audits and fraud and abuse investigations.
- **For Judicial or Administrative Proceedings** such as in response to a court order, search warrant or subpoena.
- **For Law Enforcement Purposes.** We may disclose your health information to a law enforcement official for purposes such as providing limited information to locate a missing person or report a crime.
- **To Avoid a Serious Threat to Health or Safety** to you, another person, or the public, by, for example, disclosing information to public health agencies or law enforcement authorities, or in the event of an emergency or natural disaster.
- **For Specialized Government Functions** such as military and veteran activities, national security and intelligence activities, and the protective services for the President and others.
- **For Workers' Compensation** as authorized by, or to the extent necessary to comply with, state workers compensation laws that govern job-related injuries or illness.
- **For Research Purposes** such as research related to the evaluation of certain treatments or the prevention of disease or disability, if the research study meets federal privacy law requirements.
- **To Provide Information Regarding Decedents.** We may disclose information to a coroner or medical examiner to identify a deceased person, determine a cause of death, or as authorized by law. We may also disclose information to funeral directors as necessary to carry out their duties.
- **For Organ Procurement Purposes.** We may use or disclose information to entities that handle procurement, banking or transplantation of organs, eyes or tissue to facilitate donation and transplantation.
- **To Correctional Institutions or Law Enforcement Officials** if you are an inmate of a correctional institution or under the custody of a law enforcement official, but only if necessary (1) for the institution to provide you with health care; (2) to protect your health and safety or the health and safety of others; or (3) for the safety and security of the correctional institution.
- **To Business Associates** that perform functions on our behalf or provide us with services if the information is necessary for such functions or services. Our business associates are required, under contract with us and pursuant to federal law, to protect the privacy of your information and are not allowed to use or disclose any information other than as specified in our contract and as permitted by federal law.
- **Additional Restrictions on Use and Disclosure.** Certain federal and state laws may require special privacy protections that restrict the use and disclosure of certain health information, including highly confidential information about you. "Highly confidential information" may include confidential information under Federal laws governing alcohol and drug abuse information and genetic information as well as state laws that often protect the following types of information:
    1. HIV/AIDS;
    2. Mental health;
    3. Genetic tests;
    4. Alcohol and drug abuse;
    5. Sexually transmitted diseases and reproductive health information; and
    6. Child or adult abuse or neglect, including sexual assault.

If a use or disclosure of health information described above in this notice is prohibited or materially limited by other laws that apply to us, it is our intent to meet the requirements of the more stringent law. Attached to this notice is a "Federal and State Amendments" document.

Except for uses and disclosures described and limited as set forth in this notice, we will use and disclose your health information only with a written authorization from you. This includes, except for limited circumstances allowed by federal privacy law, not using or disclosing psychotherapy notes about you, selling your health information to others, or using or disclosing your health information for certain promotional communications that are prohibited marketing communications under federal law, without your written authorization. Once you give us authorization to release your health information, we cannot guarantee that the recipient to whom the information is provided will not disclose the information. You may take back or "revoke" your written authorization at any time in writing, except if we have already acted based on your authorization. To find out where to mail your written authorization and how to revoke an authorization, contact the phone number listed on your ID card.

What Are Your Rights

The following are your rights with respect to your health information:

- **You have the right to ask to restrict** uses or disclosures of your information for treatment, payment, or health care operations. You also have the right to ask to restrict disclosures to family members or to others who are involved in your health care or payment for your health care. We may also have policies on dependent access that authorize your dependents to request certain restrictions. **Please note that while we will try to honor your request and will permit requests consistent with our policies, we are not required to agree to any restriction.**
- **You have the right to ask to receive confidential communications** of information in a different manner or at a different place (for example, by sending information to a P.O. Box instead of your home address). We will accommodate reasonable requests where a disclosure of all or part of your health information otherwise could endanger you. In certain circumstances, we will accept your verbal request to receive confidential communications, however, we may also require you confirm your request in writing. In addition, any requests to modify or cancel a previous confidential communication request must be made in writing. Mail your request to the address listed below.
- **You have the right to see and obtain a copy** of certain health information we maintain about you such as claims and case or medical management records. If we maintain your health information electronically, you will have the right to request that we send a copy of your health information in an electronic format to you. You can also request that we provide a copy of your information to a third party that you identify. In some cases you may receive a summary of this health information. You must make a written request to inspect and copy your health information or have your information sent to a third party. Mail your request to the address listed below. In certain limited circumstances, we may deny your request to inspect and copy your health information. If we deny your request, you may have the right to have the denial reviewed. We may charge a reasonable fee for any copies.
- **You have the right to ask to amend** certain health information we maintain about you such as claims and case or medical management records, if you believe the health information about you is wrong or incomplete. Your request must be in writing and provide the reasons for the requested amendment. Mail your request to the address listed below. If we deny your request, you may have a statement of your disagreement added to your health information.
- **You have the right to receive an accounting of certain** disclosures of your information made by us during the six years prior to your request. This accounting will not include disclosures of information made: (i) for treatment, payment, and health care operations purposes; (ii) to you or pursuant to your authorization; and (iii) to correctional institutions or law enforcement officials; and (iv) other disclosures for which federal law does not require us to provide an accounting.
- **You have the right to a paper copy of this notice.** You may ask for a copy of this notice at any time. Even if you have agreed to receive this notice electronically, you are still entitled to a paper copy of this notice. If we maintain a website for your particular health plan, you may also obtain a copy of this notice on your website, www.myHPNonline.com or www.mySHLonline.com

Exercising Your Rights

- **Contacting your Health Plan.** If you have any questions about this notice or want information about exercising your rights, **please call the toll-free member phone number on your health plan ID card or you may contact a Health Plan of Nevada/Sierra Health and Life Member Services Representative at 1-800-777-1840 (TTY 711).**

- **Submitting a Written Request.** Mail to us your written requests to exercise any of your rights, including modifying or cancelling a confidential communication, requesting copies of your records, or requesting amendments to your record, at the following address:

  Health Plan of Nevada/Sierra Health and Life
  Member Services – Privacy Unit
  PO Box 15645
  Las Vegas, NV 89114-5645

- **Filing a Complaint.** If you believe your privacy rights have been violated, you may file a complaint with us at the address listed above.

You may also notify the Secretary of the U.S. Department of Health and Human Services of your complaint. We will not take any action against you for filing a complaint.

[1]This Medical Information Notice of Privacy Practices applies to the following health plans that are affiliated with UnitedHealth Group: ACN Group of California, Inc.; All Savers Insurance Company; All Savers Life Insurance Company of California; AmeriChoice of Connecticut, Inc.; Inc.; AmeriChoice of New Jersey, Inc.; Arizona Physicians IPA, Inc.; Care Improvement Plus of Maryland, Inc.; Care Improvement Plus of Texas Insurance Company; Care Improvement Plus South Central Insurance Company; Care Improvement Plus Wisconsin Insurance Company; Dental Benefit Providers of California, Inc.; Dental Benefit Providers of Illinois, Inc.; Golden Rule Insurance Company ;Health Plan of Nevada, Inc.; MAMSI Life and Health Insurance Company; MD – Individual Practice Association, Inc.; Medica Health Plans of Florida, Inc.; Medica Healthcare Plans, Inc.; National Pacific Dental, Inc.; Neighborhood Health Partnership, Inc.; Nevada Pacific Dental; Optimum Choice, Inc.; Oxford Health Insurance, Inc.; Oxford Health Plans(CT), Inc.; Oxford Health Plans (NJ), Inc.; Oxford Health Plans (NY), Inc.; PacifiCare Life and Health Insurance Company; PacifiCare Life Assurance Company; PacifiCare of Arizona, Inc.; PacifiCare of Colorado, Inc.; PacifiCare of Nevada, Inc.; Physicians Health Choice of Texas, LLC; Preferred Care Partners, Inc.; Sierra Health and Life Insurance Company, Inc.; UHC of California; U.S. Behavioral Health Plan, California; Unimerica Insurance Company; Unimerica Life Insurance Company of New York; Unison Health Plan of Delaware, Inc.; Unison Health Plan of the Capital Area, Inc.; UnitedHealthcare Benefits of Texas, Inc.; UnitedHealthcare Community Plan of Georgia, Inc.; UnitedHealthcare Community Plan of Ohio, Inc.; UnitedHealthcare Community Plan, Inc.; UnitedHealthcare Community Plan of Texas, L.L.C.; UnitedHealthcare Insurance Company; UnitedHealthcare Insurance Company of Illinois; UnitedHealthcare Insurance Company of New York; UnitedHealthcare Insurance Company of the River Valley; UnitedHealthcare Life Insurance Company; UnitedHealthcare of Alabama, Inc.; UnitedHealthcare of Arizona, Inc.; UnitedHealthcare of Arkansas, Inc.; UnitedHealthcare of Colorado, Inc.; UnitedHealthcare of Florida, Inc.; UnitedHealthcare of Georgia, Inc.; UnitedHealthcare of Illinois, Inc.; UnitedHealthcare of Kentucky, Ltd.; UnitedHealthcare of Louisiana, Inc.; UnitedHealthcare of the Mid-Atlantic, Inc.; UnitedHealthcare of the Midlands, Inc.; UnitedHealthcare of the Midwest, Inc.; United Healthcare of Mississippi, Inc.; UnitedHealthcare of New England, Inc.; UnitedHealthcare of New Mexico, Inc.; UnitedHealthcare of New York, Inc.; UnitedHealthcare of North Carolina, Inc.; UnitedHealthcare of Ohio, Inc.; UnitedHealthcare of Oklahoma, Inc.; UnitedHealthcare of Oregon, Inc.; UnitedHealthcare of Pennsylvania, Inc.; UnitedHealthcare of Texas, Inc.; UnitedHealthcare of Utah, Inc.; UnitedHealthcare of Washington, Inc.; UnitedHealthcare of Wisconsin, Inc.; UnitedHealthcare Plan of the River Valley, Inc.

FINANCIAL INFORMATION PRIVACY NOTICE

THIS NOTICE DESCRIBES HOW FINANCIAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED. PLEASE REVIEW IT CAREFULLY.

Effective January 1, 2016

We[2] are committed to maintaining the confidentiality of your personal financial information. For the purposes of this notice, "personal financial information" means information about an enrollee or an applicant for health care coverage that identifies the individual, is not generally publicly available, and is collected from the individual or is obtained in connection with providing health care coverage to the individual.

Information We Collect

Depending upon the product or service you have with us, we may collect personal financial information about you from the following sources:

- Information we receive from you on applications or other forms, such as name, address, age, medical information and Social Security number;
- Information about your transactions with us, our affiliates or others, such as premium payment and claims history; and
- Information from a consumer reporting agency.

Disclosure of Information

We do not disclose personal financial information about our enrollees or former enrollees to any third party, except as required or permitted by law. For example, in the course of our general business practices, we may, as permitted by law, disclose any of the personal financial information that we collect about you, without your authorization, to the following types of institutions:

- To our corporate affiliates, which include financial service providers, such as other insurers, and non-financial companies, such as data processors;
- To nonaffiliated companies for our everyday business purposes, such as to process your transactions, maintain your account(s), or respond to court orders and legal investigations; and
- To nonaffiliated companies that perform services for us, including sending promotional communications on our behalf.

Confidentiality and Security

We maintain physical, electronic and procedural safeguards, in accordance with applicable state and federal standards, to protect your personal financial information against risks such as loss, destruction or misuse. These measures include computer safeguards, secured files and buildings, and restrictions on who may access your personal financial information.

Questions About this Notice

If you have any questions about this notice, please call the toll-free member phone number on your health plan ID card or contact Health Plan of Nevada/Sierra Health and Life Member Services at 1-800-777-1840 (TTY 711).

[2] For purposes of this Financial Information Privacy Notice, "we" or "us" refers to the entities listed in footnote 1, beginning on the sixth page of the Health Plan Notices of Privacy Practices, plus the following UnitedHealthcare affiliates: Alere Women's and Children's Health, LLC; AmeriChoice Health Services, Inc.; Connextions HCI, LLC; LifePrint East, Inc.; Life Print Health, Inc.; Dental Benefit Providers, Inc.; HealthAllies, Inc.; MAMSI Insurance Resources, LLC; Managed Physical Network, Inc.; OneNet PPO, LLC; OptumHealth Care Solutions, Inc.; OrthoNet, LLC; OrthoNet of the Mid-Atlantic, Inc.; OrthoNet West, LLC; OrthoNet of the South, Inc.; Oxford Benefit Management, Inc.; Oxford Health Plans LLC; Spectera, Inc.; UMR, Inc.; Unison Administrative Services, LLC; United Behavioral Health; United Behavioral Health of New York I.P.A., Inc.; United HealthCare Services, Inc.; UnitedHealth Advisors, LLC; UnitedHealthcare Service LLC; UnitedHealthcare Services Company of the River Valley, Inc.; UnitedHealthOne Agency, Inc. This Financial Information Privacy Notice only applies where required by law. Specifically, it does not apply to (1) health care insurance products offered in Nevada by Health Plan of Nevada, Inc. and Sierra Health and Life Insurance Company, Inc.; or (2) other UnitedHealth Group health plans in states that provide exceptions for HIPAA covered entities or health insurance products.

UNITEDHEALTH GROUP HEALTH PLAN NOTICE OF PRIVACY PRACTICES: FEDERAL AND STATE AMENDMENTS

Revised: January 1, 2016

The first part of this Notice, which provides our privacy practices for Medical Information (pages 1-5), describes how we may use and disclose your health information under federal privacy rules. There are other laws that may limit our rights to use and disclose your health information beyond what we are allowed to do under the federal privacy rules. The purpose of the charts below is to:

1. show the categories of health information that are subject to these more restrictive laws; and
2. give you a general summary of when we can use and disclose your health information without your consent.

If your written consent is required under the more restrictive laws, the consent must meet the particular rules of the applicable federal or state law.

Summary of Federal Laws

Alcohol & Drug Abuse Information
We are allowed to use and disclose alcohol and drug abuse information that is protected by federal law only (1) in certain limited circumstances, and/or disclose only (2) to specific recipients.
Genetic Information
We are not allowed to use genetic information for underwriting purposes.

Summary of State Laws

General Health Information	
We are allowed to disclose general health information only (1) under certain limited circumstances, and /or (2) to specific recipients.	CA, NE, PR, RI, VT, WA, WI
HMOs must give enrollees an opportunity to approve or refuse disclosures, subject to certain exceptions.	KY
You may be able to restrict certain electronic disclosures of health information.	NC, NV
We are not allowed to use health information for certain purposes.	CA, IA
We will not use and/or disclose information regarding certain public assistance programs except for certain purposes	KY, MO, NJ, SD
We must comply with additional restrictions prior to using or disclosing your health information for certain purposes	KS
Prescriptions	
We are allowed to disclose prescription-related information only (1) under certain limited circumstances, and /or (2) to specific recipients.	ID, NH, NV
Communicable Diseases	
We are allowed to disclose communicable disease information only (1) under certain limited circumstances, and /or (2) to specific recipients.	AZ, IN, KS, MI, NV, OK
Sexually Transmitted Diseases and Reproductive Health	
We are allowed to disclose sexually transmitted disease and/or reproductive health information only (1) under certain limited circumstances and/or (2) to specific recipients.	CA, FL, IN, KS, MI, MT, NJ, NV, PR, WA, WY
Alcohol and Drug Abuse	
We are allowed to use and disclose alcohol and drug abuse information (1) under certain limited circumstances, and/or disclose only (2) to specific recipients.	AR, CT, GA, KY, IL, IN, IA, LA, MN, NC, NH, OH, WA, WI
Disclosures of alcohol and drug abuse information may be restricted by the individual who is the subject of the information.	WA

Summary of State Laws

Genetic Information	
We are not allowed to disclose genetic information without your written consent.	CA, CO, KS, KY, LA, NY, RI, TN, WY
We are allowed to disclose genetic information only (1) under certain limited circumstances and/or (2) to specific recipients.	AK, AZ, FL, GA, IL, IA, MD, ME, MA, MO, NJ, NV, NH, NM, OR, RI, TX, UT, VT
Restrictions apply to (1) the use, and/or (2) the retention of genetic information.	FL, GA, IA, LA, MD, NM, OH, UT, VA, VT
HIV / AIDS	
We are allowed to disclose HIV/AIDS-related information only (1) under certain limited circumstances and/or (2) to specific recipients.	AZ, AR, CA, CT, DE, FL, GA, IA, IL, IN, KS, KY, ME, MI, MO, MT, NY, NC, NH, NM, NV, OR, PA, PR, RI, TX, VT, WV, WA, WI, WY
Certain restrictions apply to oral disclosures of HIV/AIDS-related information.	CT, FL
We will collect certain HIV/AIDS-related information only with your written consent	OR
Mental Health	
We are allowed to disclose mental health information only (1) under certain limited circumstances and/or (2) to specific recipients.	CA, CT, DC, IA, IL, IN, KY, MA, MI, NC, NM, PR, TN, WA, WI
Disclosures may be restricted by the individual who is the subject of the information.	WA
Certain restrictions apply to oral disclosures of mental health information.	CT
Certain restrictions apply to the use of mental health information.	ME
Child or Adult Abuse	
We are allowed to use and disclose child and/or adult abuse information only (1) under certain limited circumstances, and/or disclose only (2) to specific recipients.	AL, CO, IL, LA, MD, NE, NJ, NM, NY, RI, TN, TX, UT, WI

NEVADA LIFE AND HEALTH INSURANCE GUARANTY ASSOCIATION

GUARANTY ASSOCIATION ACT SUMMARY DOCUMENT
Effective June 14, 2016

Residents of Nevada who purchase life insurance, annuities or health insurance should know that the insurance companies licensed in the state to write these types of insurance are members of the Nevada Life and Health Insurance Guaranty Association (Association). The purpose of the Association is to assure that policyholders will be protected, within limits, in the unlikely event that a member insurer becomes financially unable to meet its obligations. If this should happen, the Association assesses its other member insurance companies for the money to pay the claims of the insured persons who live in this state and, in some cases, to keep coverage in force. The valuable extra protection provided by these insurers through the Association is not unlimited, however, and, as noted in the box below, this protection is not a substitute for consumers' care in selecting companies that are well-managed and financially stable.

The Nevada Life and Health Insurance Guaranty Association may not provide coverage for a policy. If coverage is provided, it will be subject to substantial limitations and exclusions, and require continued residency in Nevada. A person should not rely on coverage by the Association when selecting an insurance company or when selecting an insurance policy.
Coverage is NOT provided for a policy or any portion of it that is not guaranteed by the Insurer or for which the policyholder has assumed the risk, such as a variable contract sold by prospectus.
Insurance companies are required by law to deliver this notice to you. **However, insurance companies and their agents are prohibited by law from using the existence of the Association for sales, solicitation or to induce the purchase of any kind of insurance policy.**
The state law that provides for this safety-net coverage is called the Nevada Life and Health Insurance Guaranty Association. Below is a brief summary of this law's coverages, exclusions and limits. The summary does not cover all provisions of the law, nor does it in any way change anyone's rights or obligations under the act or the rights or obligations of the Association. **Anyone may obtain additional information from the Association or file a complaint with the Commissioner of Insurance, at the applicable address listed below, to allege a violation of any provision of the Nevada Life and Health Insurance Guaranty Association Act.**

The Nevada Life and Health Insurance Guaranty Association
4600 Kietzke Lane, Suite O-269
Reno, Nevada 89502
(Business and Mailing address)
Commissioner of Insurance, State of Nevada
Department of Business and Industry, Division of Insurance
1818 E. College Parkway, Suite 103
Carson City, Nevada 89706

COVERAGE

Generally, individuals will be protected by the Association if they live in this state and **hold a life or health insurance contract, or an annuity, or if they are insured under a group insurance contract issued by a member insurer.** The beneficiaries, payees or assignees of the insured persons are protected as well even if they live in another state.

EXCLUSIONS FROM COVERAGE

However, persons holding such policies are **NOT** protected by this Association if:

- They are eligible for protection under the law of another state (this may occur when the insolvent insurer was incorporated in another state whose guaranty association protects insured's who live outside the state);
- the insurer was not authorized to do business in this state;
- their policy was insured by a nonprofit hospital or medical service organization, a health maintenance organization (HMO), a fraternal benefit society, a mandatory state pooling plan, a mutual assessment company or similar plan in which the policyholder is subject to future assessments, or by an insurance exchange.

The Association also does **NOT** provide coverage for:

- any policy or portion of a policy which is not guaranteed by the insurer or for which the individual has assumed the risk, such as a variable contract sold by prospectus;
- interest rate yields that exceed an average rate;
- dividends;
- credits given in connection with the administration of a policy by a group contract holder;
- employers' plans to the extent they are self-funded (that is, not insured by an insurance company, even if an insurance company administers them) and
- unallocated annuity contracts (which give rights to group contract holders, not individuals) other than an annuity owned by a governmental retirement plan established under section 401, 403(b) or 457 of the Internal Revenue Code 26 U.S.C. && 401, 403(b) and 457, respectively, or trustees of such a plan, and
- Medicare or Medicare Advantage contracts

LIMITS ON AMOUNT OF COVERAGE

The act also limits the amount the Association is obligated to pay. The Association cannot pay more than what the insurance company would owe under a policy or contract.

With respect to life insurance policies and annuities, on any one insured life, the Association will pay a maximum of $300,000, regardless of how many policies and contracts there are with the same company, and even if they provide different types of coverage. Within this overall $300,000 limit, the Association will not pay more than $100,000 in cash surrender values, $100,000 in present values of an annuity, or $300,000 in life insurance death benefits. Again, no matter how many policies and contracts there were with the same company, and no matter how many different types of coverage.

With respect to health insurance for any one natural person, the Association will not pay more than: 1) $100,000 for coverage other than disability insurance, basic hospital, medical and surgical insurance or major medical insurance, including any net cash for surrender or withdrawal; 2) $300,000 for disability insurance; 3) $500,000 for basic hospital, medical and surgical insurance or major medical insurance; or 4) $300,000 for Long Term Care insurance.

With respect to each payee of a structured settlement annuity, or beneficiary or beneficiaries of the payee if deceased, the Association will not pay more than $250,000 in present values of benefits from the annuity in the aggregate, including any net cash for surrender or withdrawal. A maximum for all other annuities is $250,000.

With respect to any one life or person, in no event will the Association be obligated to cover more than: 1) an aggregate of $300,000 in benefits, excluding benefits for basic hospital, medical and surgical insurance or major medical insurance; or 2) an aggregate of $500,000 in benefits, including benefit for basic hospital, medical or surgical insurance or major medical insurance.

With respect to one owner of several non-group policies of life insurance, whether the owner is a natural person or an organization and whether the persons insured are officers, managers, employees or other persons, the Association will not pay more than $5,000,000 in benefits, regardless of the number of policies and contracts held by the owner.

With respect to each participant in a governmental retirement plan covered by an unallocated annuity contract as described in NRS 686C, the maximum coverage allowed
is an aggregate of $250,000 regardless of the number of contracts issued by anyone member company.

FOR MORE INFORMATION AND ANSWERS TO MOST ASKED QUESTIONS, PLEASE VISIT THE ASSOCIATION'S WEB SITE:

www.nvlifega.org

HEALTH PLAN OF NEVADA
A UnitedHealthcare Company

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

PREVENTIVE HEALTHCARE GUIDELINES

INTRODUCTION

Health Plan of Nevada and Sierra Health and Life suggest that health plan members get certain screening tests, exams and shots to stay healthy. This document gives our health plan members and doctors in the health plan's network guidelines about when and how often to get preventive care. This advice is not designed to take the place of your doctor's judgment about your own health care needs.

Please talk with your doctor about any questions or concerns. Your doctor may make changes to these guidelines based on your own needs. Please refer to your health plan's Evidence of Coverage and plan documents for details about the coverage and costs to you for these preventive services.

These guidelines are based on the recommendations by the United States Preventive Services Task Force (USPSTF), the Centers for Disease Control and Prevention (CDC), the American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics/Bright Futures.

SECTION 1: GENERAL PREVENTIVE SCREENING TESTS AND EXAMS CHILDREN, TEENS AND ADULTS

Item	Gender		Adults	Newborns, Children and/or Teens	Comments about screening test, Counseling, exam or shot
	Male	Female			
Abdominal Aortic Aneurysm Screening Test	X	Does not apply	X	This screening test is only for adults	This screening test (ultrasound) is a one time test for men between the ages of 65 to 75 years old who have ever smoked.
Alcohol Misuse: Screening and Behavioral Counseling Intervention in Primary Care to Reduce Alcohol Misuse.	X	X	X	These interventions are only for adults	These are screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.
Breast Cancer Screening: Screening Mammography	Does not apply	X	X	This screening test is only for adults	The mammography screening test with or without clinical breast examination is recommended every 1 to 2 years for women aged 40 and older. *Nevada Revised Statutes, NRS 695C.1735 (b) (c) state a baseline mammogram for women between the ages of 35 and 40; and an annual mammogram for women 40 years of age or older.*
Breast Cancer Screening: Genetic Counseling and Evaluation for BRCA testing.	Does not apply	X	X	This counseling is only for adults	This counseling is for women who have family members with breast, ovarian, tubal, or peritoneal cancer.
Breastfeeding: Primary Care Interventions to Promote Breastfeeding	Does not apply	X	X	X	Interventions included in primary care or OB visits during pregnancy and after birth to promote and support breastfeeding.
Chemoprevention for Breast Cancer (Counseling)	Does not apply	X	X	This screening test is only for adults	This discussion by a provider focuses on the topic of medications to reduce risk with women at high risk for breast cancer and at low risk for harmful events of these medications. The discussion should inform the patients of the potential benefits and harms of chemoprevention.
Cervical Cancer Screening or Pap Smear	Does not apply	X	X	X	A screening for cervical cancer in women ages 21 to 65 years (pap smear) every 3 years or, for women ages 30 to 65 years who want to lengthen the screening interval, screening with a combination of pap smear and human papillomavirus (HPV) testing every 5 years.

Item	Gender		Adults	Newborns, Children and/or Teens	Comments about screening test, Counseling, exam or shot
	Male	Female			
Chlamydia Infection Screening	Does not apply	X	X	X	This screening test is for all sexually active non-pregnant women aged 24 and younger and older non-pregnant women at increased risk. This screening is for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.
Cholesterol Screening (Lipid Disorders Screening)	X	X	X	This screening test is only for adults	This screening test is for men aged 20-35 and women over age 20 that are at increased risk for coronary heart disease, and for all men aged 35 and older.
Colorectal Cancer Screening (Fecal Occult Blood Test, Sigmoidoscopy or Colonoscopy	X	X	X	This screening test is only for adults	The screening test is for all adults aged 50-75 years. Screening can be done by an annual high-sensitivity fecal occult blood testing (FOBT) or, a sigmoidoscopy every 5 years with high-sensitivity FOBT every 3 years or, a screening colonoscopy every 10 years.
Contraceptive Methods (including sterilizations)	Does not apply	X	X		For women, all FDA approved contraceptive methods, sterilization procedures and, patient education and counseling (as prescribed).
Depression: Screening for Depression in Adults	X	X	X	This screening test is only for adults	This screening is for adults when staff-assisted depression care supports are in place to assure accurate diagnosis, effective treatment, and follow-up.
Depression: Major Depressive Disorder in Children and Adolescents (Screening)	X	X	Does not apply	X	This screening for major depressive disorder (MDD) is for adolescents between the ages of 12 to 18 years old when systems are in place to ensure accurate diagnosis, psychotherapy and follow-up.
Diabetes Mellitus Screening (Type 2 Diabetes)	X	X	X	This screening test is only for adults	This screening test is for adults who do not have symptoms and have a sustained blood pressure (either treated or untreated) greater than 135/80 mm Hg.
Gonorrhea Screening	Does not apply	X	X	X	This screening test is for all sexually active women, including pregnant women, if they are at increased risk for infection.
Healthy Diet: Behavioral Counseling in Primary Care to Promote a Healthy Diet	X	X	X	This service is only for adults	This intensive behavioral dietary counseling is for adults with hyperlipidemia and other known risk factors for heart and diet-related chronic disease. This counseling can be delivered by primary care providers or by referral to other specialists, such as nutritionists or dietitians.

Item	Gender		Adults	Newborns, Children and/or Teens	Comments about screening test, Counseling, exam or shot
	Male	Female			
Hearing Screening (newborn)	X	X	Does not apply	Newborns only	This screening is for all newborn infants from birth to 90 days old.
Hepatitis B Virus Infection Screening	X	X	X	X	This screening test is for all persons at high risk for infection.
Hepatitis C Virus Infection Screening	X	X	X	X	This screening test is for all persons at high risk for infection. For persons born between 1945 and 1965, a one-time screening test should be offered.
High Blood Pressure: Screening for High Blood Pressure	X	X	X	This screening test is only for adults	This screening test is for adults 18 years of age and older and is included in a preventive care wellness examination.
HIV: Human Immunodeficiency Virus – Screening for Adolescents and Adults.	X	X	X	X	This screening is for all adults and adolescents at risk for human immunodeficiency virus (HIV) and for all pregnant women.
Human Papillomavirus DNA Testing	Does not apply	X	Does not apply	This screening test is only for adult women	This screening test is performed every 3 years for women who are 30 years or older and have normal pap smear results.
Hypothyroidism Screening (newborn)	X	X	Does not apply	Newborns only	This screening test is for all newborn infants from birth to 90 days old.
Intimate Partner Violence: Screening	Does not apply	X	X	X	This is to screen women of childbearing age for intimate partner violence, such as domestic violence, and provide or refer women who screen positive to intervention services.
Lung Cancer: Screening for Lung Cancer with Low-Dose Computer Tomography	X	X	X	This screening test is only for adults	This CT scan is an annual screening test for adults aged 55-80 years who have a 30 pack year smoking history and currently smoke or have quit within the past 15 years.
Metabolic Screening Panel (newborn)	X	X	Does not apply	Newborns only	This screening test is for all newborn infants from birth to 90 days old.
Obesity: Screening for Obesity in Adults	X	X	X	This screening test is only for adults	This screening is for all adults. Patients with a body mass index (BMI) of 30 kg/m^2 or higher should be offered or referred to intensive counseling and behavioral interventions.

Item	Gender		Adults	Newborns, Children and/or Teens	Comments about screening test, Counseling, exam or shot
	Male	Female			
Obesity: Screening for Obesity in Children and Adolescents	X	X	Does not apply	X	This screening is for children 6 years of age and older. Providers should offer or refer patients for intensive counseling and behavioral interventions.
Osteoporosis Screening	Does not apply	X	X	This screening test is only for adults	This screening test is for all women age 65 years of age and older, and in younger women whose risk is greater than or equal to that of a 65 year old white woman who has no additional risk factors.
Phenylketonuria (PKU) Screening	X	X	Does not apply	Newborns only	This screening test is for all newborn infants from birth to 90 days old.
Prevention of Falls in Community-Dwelling Older Adults	X	X	X	This screening is only for adults	Community dwelling adults aged 65 and older at increased risk for falls should have exercise, physical therapy, and/or Vitamin D supplementation provided.
Prostate Cancer Screening (digital rectal exam or prostate specific antigen test)	X	Does not apply	X	This screening test is only for adults	UnitedHealthcare covers prostate cancer screening as a preventive service for males aged 40 and over.
Rubella Screening By History of Vaccination or by Serology.	Does not apply.	X	X	X	This screening test is for all women of childbearing age at their first clinical encounter.
Sexually Transmitted Infections: Behavioral Counseling to Prevent Sexually Transmitted Infections	X	X	X	X	High–intensity behavioral counseling to prevent sexually transmitted infections (STIs) for all sexually active adolescents and for adults at increased risk for STIs.
Sickle Cell Disease Screening (newborn)	X	X	Does not apply	Newborns only	This screening test is for all newborn infants from birth to 90 days old.
Skin Cancer Prevention (counseling)	X	X	X	X	Provide counseling to children, adolescents, and young adults with fair skin, aged 10 to 24 years about reducing exposure to ultraviolet radiation to prevent skin cancer.
Syphilis Screening	X	X	X	X	All persons at increased risk for syphilis infection and all pregnant women should be screened.

Item	Gender		Adults	Newborns, Children and/or Teens	Comments about screening test, Counseling, exam or shot
	Male	Female			
Tobacco Use: Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women	X	X	X	This is only for adults	All adults should be asked about tobacco use and tobacco cessation interventions should be provided to those who use tobacco products. For pregnant women who smoke, counseling should be increased and pregnancy-tailored.
Tobacco Use: Primary Care Interventions to Prevent Tobacco Use in Children and Adolescents	X	X	Does not apply	X	Primary care providers should provide interventions, including education or brief counseling, to prevent initiation of tobacco use among school-aged children and adolescents.
Screening for Visual Impairment in Children	X	X	Does not apply	X	This screening is done at least once between the ages of 3 and 5 years, to detect the presence of amblyopia (lazy eye), or its risk factors.
Wellness Examinations (well baby, well child and well adult)	X	X	X	X	Wellness exams include an initial preventive medicine evaluation and management of an individual. This exam includes an age and gender appropriate history, exam, counseling, anticipatory guidance, risk factor reduction strategies, and the ordering of laboratory and diagnostic procedures. These include breastfeeding support and counseling, contraceptive methods counseling, domestic violence screening, annual HIV counseling, sexually transmitted infection counseling, and well-woman visits.
Other Tests and Exams for Children From Birth to 21 Years.	X	X	Does not apply	X	Other tests and exams for children and teens from birth to 21 years include hearing tests, developmental/autism screening, lead screening, anemia screening, tuberculosis testing, dyslipidemia screening, and the metabolic screening panel. These tests and exams are covered according to individual benefit plans. Please refer to your health plan documents to determine you and your family's specific coverage.

SECTION 2: PREVENTIVE SCREENING TESTS AND EXAMS

PREGNANT WOMEN

Screening	Comments
Alcohol Misuse: Screening and Behavioral Counseling Interventions in Primary Care to Reduce Alcohol Misuse	These screening and behavioral counseling interventions are to reduce alcohol misuse by pregnant women, in primary care settings.
Anemia, Iron Deficiency Anemia Screening	This screening test is for pregnant women who do not have symptoms of anemia.
Bacteriuria Screening	This screening test is for pregnant women at 12 to 16 weeks gestation or at the first prenatal visit if later.
Breastfeeding Support, Supplies and Counseling	Includes comprehensive lactation support and counseling from a trained provider, during pregnancy and/or in the postpartum period, and costs for renting breastfeeding equipment, in conjunction with each birth.
Chlamydia Screening	This screening test is for all pregnant women 24 years of age and younger and for older pregnant women who are at high risk.
Gestational Diabetes Screening	This screening test is for asymptomatic women after 24 weeks of pregnancy.
Gonorrhea Screening	This screening test is for all pregnant women 24 years of age and younger and for older pregnant women who are at high risk.
Hepatitis B Virus Infection Screening	This screening test is for all pregnant women at their first prenatal visit.
HIV – Human Immunodeficiency Virus Infection Screening	This screening is for all pregnant women.
Rh Incompatibility Screening	This screening test is for all pregnant women during their first prenatal visit. Repeat testing is for all unsensitized Rh (D) negative women at 24 to 48 weeks' gestation, unless the biological father is known to be Rh (D) negative
Rubella Screening By History of Vaccination or by Serology	This screening test is for all women of childbearing age at their first clinical encounter.
Syphilis Screening	This screening test is for all pregnant women.
Tobacco Use: Counseling and Interventions to Prevent Tobacco Use and Tobacco-Caused Disease in Adults and Pregnant Women	This counseling is to screen for tobacco use and provide augmented, pregnancy-tailored counseling for pregnant women who smoke.
Wellness Visits (pre-conception, prenatal & postpartum)	Well woman preventive care visit annually for adult women to obtain the recommended preventive services that are age and developmentally appropriate, including preconception and prenatal care.

SECTION 3: IMMUNIZATIONS/SHOTS ADULTS, CHILDREN AND TEENS

Please refer to the most current immunization (shot) recommendations to find out which immunizations are right for you and your family. These recommendations are revised each year by Centers for Disease Control and Prevention (CDC). For more information, please go to the CDC web site at: www.cdc.gov.

2016 Recommended Immunizations for Children from Birth Through 6 Years Old

	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	19–23 months	2–3 years	4–6 years
HepB	HepB				HepB						
RV			RV	RV	RV						
DTaP			DTaP	DTaP	DTaP		DTaP			DTaP	
Hib			Hib	Hib	Hib		Hib				
PCV			PCV	PCV	PCV		PCV				
IPV			IPV	IPV	IPV		IPV				IPV
Influenza (Yearly)*											
MMR									MMR		MMR
Varicella									Varicella		Varicella
HepA§									HepA§		

Shaded boxes indicate the vaccine can be given during shown age range.

Is your family growing? To protect your new baby and yourself against whooping cough, get a Tdap vaccine in the third trimester of each pregnancy. Talk to your doctor for more details.

NOTE: If your child misses a shot, you don't need to start over, just go back to your child's doctor for the next shot. Talk with your child's doctor if you have questions about vaccines.

FOOTNOTES:

* Two doses given at least four weeks apart are recommended for children aged 6 months through 8 years of age who are getting an influenza (flu) vaccine for the first time and for some other children in this age group.

§ Two doses of HepA vaccine are needed for lasting protection. The first dose of HepA vaccine should be given between 12 months and 23 months of age. The second dose should be given 6 to 18 months later. HepA vaccination may be given to any child 12 months and older to protect against HepA. Children and adolescents who did not receive the HepA vaccine and are at high-risk, should be vaccinated against HepA.

If your child has any medical conditions that put him at risk for infection or is traveling outside the United States, talk to your child's doctor about additional vaccines that he may need.

For more information, call toll free **1-800-CDC-INFO** (1-800-232-4636) or visit **http://www.cdc.gov/vaccines**

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Disease	Vaccine	Disease spread by	Disease symptoms	Disease complications
Chickenpox	Varicella vaccine protects against chickenpox.	Air, direct contact	Rash, tiredness, headache, fever	Infected blisters, bleeding disorders, encephalitis (brain swelling), pneumonia (infection in the lungs)
Diphtheria	DTaP* vaccine protects against diphtheria.	Air, direct contact	Sore throat, mild fever, weakness, swollen glands in neck	Swelling of the heart muscle, heart failure, coma, paralysis, death
Hib	Hib vaccine protects against *Haemophilus influenzae* type b.	Air, direct contact	May be no symptoms unless bacteria enter the blood	Meningitis (infection of the covering around the brain and spinal cord), intellectual disability, epiglottitis (life-threatening infection that can block the windpipe and lead to serious breathing problems), pneumonia (infection in the lungs), death
Hepatitis A	HepA vaccine protects against hepatitis A.	Direct contact, contaminated food or water	May be no symptoms, fever, stomach pain, loss of appetite, fatigue, vomiting, jaundice (yellowing of skin and eyes), dark urine	Liver failure, arthralgia (joint pain), kidney, pancreatic, and blood disorders
Hepatitis B	HepB vaccine protects against hepatitis B.	Contact with blood or body fluids	May be no symptoms, fever, headache, weakness, vomiting, jaundice (yellowing of skin and eyes), joint pain	Chronic liver infection, liver failure, liver cancer
Influenza (Flu)	Flu vaccine protects against influenza.	Air, direct contact	Fever, muscle pain, sore throat, cough, extreme fatigue	Pneumonia (infection in the lungs)
Measles	MMR** vaccine protects against measles.	Air, direct contact	Rash, fever, cough, runny nose, pinkeye	Encephalitis (brain swelling), pneumonia (infection in the lungs), death
Mumps	MMR**vaccine protects against mumps.	Air, direct contact	Swollen salivary glands (under the jaw), fever, headache, tiredness, muscle pain	Meningitis (infection of the covering around the brain and spinal cord) , encephalitis (brain swelling), inflammation of testicles or ovaries, deafness
Pertussis	DTaP* vaccine protects against pertussis (whooping cough).	Air, direct contact	Severe cough, runny nose, apnea (a pause in breathing in infants)	Pneumonia (infection in the lungs), death
Polio	IPV vaccine protects against polio.	Air, direct contact, through the mouth	May be no symptoms, sore throat, fever, nausea, headache	Paralysis, death
Pneumococcal	PCV vaccine protects against pneumococcus.	Air, direct contact	May be no symptoms, pneumonia (infection in the lungs)	Bacteremia (blood infection), meningitis (infection of the covering around the brain and spinal cord), death
Rotavirus	RV vaccine protects against rotavirus.	Through the mouth	Diarrhea, fever, vomiting	Severe diarrhea, dehydration
Rubella	MMR** vaccine protects against rubella.	Air, direct contact	Children infected with rubella virus sometimes have a rash, fever, swollen lymph nodes	Very serious in pregnant women—can lead to miscarriage, stillbirth, premature delivery, birth defects
Tetanus	DTaP* vaccine protects against tetanus.	Exposure through cuts in skin	Stiffness in neck and abdominal muscles, difficulty swallowing, muscle spasms, fever	Broken bones, breathing difficulty, death

* DTaP combines protection against diphtheria, tetanus, and pertussis.
** MMR combines protection against measles, mumps, and rubella.

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INFORMATION FOR PARENTS

2016 Recommended Immunizations for Children 7-18 Years Old

Talk to your child's doctor or nurse about the vaccines recommended for their age.

	Flu *Influenza*	Tdap Tetanus, diphtheria, pertussis	HPV Human papillomavirus	Meningococcal: MenACWY	Meningococcal: MenB	Pneumococcal	Hepatitis B	Hepatitis A	Inactivated Polio	MMR Measles, mumps, rubella	Chickenpox *Varicella*
7-8 Years											
9-10 Years											
11-12 Years											
13-15 Years											
16-18 Years											

More information:

- Flu: Preteens and teens should get a flu vaccine every year.
- Tdap: Preteens and teens should get one shot of Tdap at age 11 or 12 years.
- HPV: Both girls and boys should receive 3 doses of HPV vaccine to protect against HPV-related disease. HPV vaccination can start as early as age 9 years.
- Meningococcal MenACWY: All 11-12 year olds should be vaccinated with a single dose of a quadrivalent meningococcal conjugate vaccine (MenACWY). **A booster shot is recommended at age 16.**
- Meningococcal MenB: Teens, 16-18 years old, **may** be vaccinated with a MenB vaccine.

These shaded boxes indicate when the vaccine is recommended for all children unless your doctor tells you that your child cannot safely receive the vaccine.

These shaded boxes indicate the vaccine is recommended for children with certain health or lifestyle conditions that put them at an increased risk for serious diseases. See vaccine-specific recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html

These shaded boxes indicate the vaccine should be given if a child is catching-up on missed vaccines.

This shaded box indicates the vaccine is recommended for children not at increased risk but who wish to get the vaccine after speaking to a provider.

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Vaccine-Preventable Diseases and the Vaccines that Prevent Them

Diphtheria (Can be prevented by Tdap vaccination)

Diphtheria is a very contagious bacterial disease that affects the respiratory system, including the lungs. Diphtheria bacteria can be passed from person to person by direct contact with droplets from an infected person's cough or sneeze. When people are infected, the diptheria bacteria produce a toxin (poison) in the body that can cause weakness, sore throat, fever, and swollen glands in the neck. Effects from this toxin can also lead to swelling of the heart muscle and, in some cases, heart failure. In serious cases, the illness can cause coma, paralysis, and even death.

Hepatitis A (Can be prevented by HepA vaccination)

Hepatitis A is an infection in the liver caused by hepatitis A virus. The virus is spread primarily person-to-person through the fecal-oral route. In other words, the virus is taken in by mouth from contact with objects, food, or drinks contaminated by the feces (stool) of an infected person. Symptoms can include fever, tiredness, poor appetite, vomiting, stomach pain, and sometimes jaundice (when skin and eyes turn yellow). An infected person may have no symptoms, may have mild illness for a week or two, may have severe illness for several months, or may rarely develop liver failure and die from the infection. In the U.S., about 100 people a year die from hepatitis A.

Hepatitis B (Can be prevented by HepB vaccination)

Hepatitis B causes a flu-like illness with loss of appetite, nausea, vomiting, rashes, joint pain, and jaundice. Symptoms of acute hepatitis B include fever, fatigue, loss of appetite, nausea, vomiting, pain in joints and stomach, dark urine, grey-colored stools, and jaundice (when skin and eyes turn yellow).

Human Papillomavirus (Can be prevented by HPV vaccination)

Human papillomavirus is a common virus. HPV is most common in people in their teens and early 20s. It is the major cause of cervical cancer in women and genital warts in women and men. The strains of HPV that cause cervical cancer and genital warts are spread during sex.

Influenza (Can be prevented by annual flu vaccination)

Influenza is a highly contagious viral infection of the nose, throat, and lungs. The virus spreads easily through droplets when an infected person coughs or sneezes and can cause mild to severe illness. Typical symptoms include a sudden high fever, chills, a dry cough, headache, runny nose, sore throat, and muscle and joint pain. Extreme fatigue can last from several days to weeks. Influenza may lead to hospitalization or even death, even among previously healthy children.

Measles (Can be prevented by MMR vaccination)

Measles is one of the most contagious viral diseases. Measles virus is spread by direct contact with the airborne respiratory droplets of an infected person. Measles is so contagious that just being in the same room after a person who has measles has already left can result in infection. Symptoms usually include a rash, fever, cough, and red, watery eyes. Fever can persist, rash can last for up to a week, and coughing can last about 10 days. Measles can also cause pneumonia, seizures, brain damage, or death.

Meningococcal Disease (Can be prevented by meningococcal vaccination)

Meningococcal disease is caused by bacteria and is a leading cause of bacterial meningitis (infection around the brain and spinal cord) in children. The bacteria are spread through the exchange of nose and throat droplets, such as when coughing, sneezing or kissing. Symptoms include nausea, vomiting, sensitivity to light, confusion and sleepiness. Meningococcal bacteria also cause blood infections. About one of every ten people who get the disease dies from it. Survivors of meningococcal disease may lose their arms or legs, become deaf, have problems with their nervous systems, become developmentally disabled, or suffer seizures or strokes.

Mumps (Can be prevented by MMR vaccination)

Mumps is an infectious disease caused by the mumps virus, which is spread in the air by a cough or sneeze from an infected person. A child can also get infected with mumps by coming in contact with a contaminated object, like a toy. The mumps virus causes swollen salivary glands under the ears or jaw, fever, muscle aches, tiredness, abdominal pain, and loss of appetite. Severe complications for children who get mumps are uncommon, but can include meningitis (infection of the covering of the brain and spinal cord), encephalitis (inflammation of the brain), permanent hearing loss, or swelling of the testes, which rarely results in decreased fertility.

Pertussis (Whooping Cough) (Can be prevented by Tdap vaccination)

Pertussis is caused by bacteria spread through direct contact with respiratory droplets when an infected person coughs or sneezes. In the beginning, symptoms of pertussis are similar to the common cold, including runny nose, sneezing, and cough. After 1-2 weeks, pertussis can cause spells of violent coughing and choking, making it hard to breathe, drink, or eat. This cough can last for weeks. Pertussis is most serious for babies, who can get pneumonia, have seizures, become brain damaged, or even die. About two-thirds of children under 1 year of age who get pertussis must be hospitalized.

Pneumococcal Disease (Can be prevented by pneumococcal vaccination)

Pneumonia is an infection of the lungs that can be caused by the bacteria called pneumococcus. This bacteria can cause other types of infections too, such as ear infections, sinus infections, meningitis (infection of the covering around the brain and spinal cord), bacteremia and sepsis (blood stream infection). Sinus and ear infections are usually mild and are much more common than the more serious forms of pneumococcal disease. However, in some cases pneumococcal disease can be fatal or result in long-term problems, like brain damage, hearing loss and limb loss. Pneumococcal disease spreads when people cough or sneeze. Many people have the bacteria in their nose or throat at one time or another without being ill—this is known as being a carrier.

Polio (Can be prevented by IPV vaccination)

Polio is caused by a virus that lives in an infected person's throat and intestines. It spreads through contact with the stool of an infected person and through droplets from a sneeze or cough. Symptoms typically include sore throat, fever, tiredness, nausea, headache, or stomach pain. In about 1% of cases, polio can cause paralysis. Among those who are paralyzed, About 2 to 10 children out of 100 die because the virus affects the muscles that help them breathe.

Rubella (German Measles) (Can be prevented by MMR vaccination)

Rubella is caused by a virus that is spread through coughing and sneezing. In children rubella usually causes a mild illness with fever, swollen glands, and a rash that lasts about 3 days. Rubella rarely causes serious illness or complications in children, but can be very serious to a baby in the womb. If a pregnant woman is infected, the result to the baby can be devastating, including miscarriage, serious heart defects, mental retardation and loss of hearing and eye sight.

Tetanus (Lockjaw) (Can be prevented by Tdap vaccination)

Tetanus is caused by bacteria found in soil, dust, and manure. The bacteria enters the body through a puncture, cut, or sore on the skin. When people are infected, the bacteria produce a toxin (poison) that causes muscles to become tight, which is very painful. Tetanus mainly affects the neck and belly. This can lead to "locking" of the jaw so a person cannot open his or her mouth, swallow, or breathe. Complete recovery from tetanus can take months. One out of five people who get tetanus die from the disease.

Varicella (Chickenpox) (Can be prevented by varicella vaccination)

Chickenpox is caused by the varicella zoster virus. Chickenpox is very contagious and spreads very easily from infected people. The virus can spread from either a cough, sneeze. It can also spread from the blisters on the skin, either by touching them or by breathing in these viral particles. Typical symptoms of chickenpox include an itchy rash with blisters, tiredness, headache and fever. Chickenpox is usually mild, but it can lead to severe skin infections, pneumonia, encephalitis (brain swelling), or even death.

If you have any questions about your child's vaccines, talk to your healthcare provider.

Last updated on 03/28/2016 • CS264259-A

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

P.O. Box 15645
Las Vegas, Nevada 89114-5645

MySHL Solutions
Agreement of Coverage

This Agreement of Coverage contains a Deductible.

This Agreement of Coverage ("AOC") describes your healthcare plan.

Sierra Health and Life Insurance Company, Inc. ("SHL") and the Subscriber have agreed to all of the terms of this AOC. It is part of the contract between SHL and the Subscriber. This plan is guaranteed renewable. It may be terminated by SHL or the Subscriber with written notice.

This AOC and your attached Benefit Schedule tell you about your benefits, rights and duties as an SHL Insured. They also tell you about SHL's duties to you.

Your application form, Attachment A Benefit Schedule, this AOC and any amendments, Riders and endorsements to it are all part of your SHL membership package. Please read them carefully and keep them in a safe place.

Please carefully review your AOC and your Attachment B, Services Requiring Prior Authorization, to determine which services require Prior Authorization under the Plan. Failure of the Insured to comply with the requirements of SHL's Managed Care Program and the Prior Authorization process will result in a reduction of benefits.

Words that are capitalized are defined in Section 13. - Glossary.

NOTICE: If upon examination of this Agreement of Coverage you are not satisfied, for any reason, you may return it within ten (10) days of its delivery, and request a full refund of the premium paid.

Table of Contents

The Department of Business and Industry

State of Nevada

NEVADA DIVISION OF INSURANCE

Telephone Numbers for Consumers of Healthcare

The Division of Insurance ("Division") has established a telephone service to receive inquiries and complaints from consumers of healthcare in Nevada concerning healthcare plans.

Hours of operation for the Division:

Monday through Friday from 8 a.m. until 5 p.m., Pacific Standard Time (PST)
The Division is closed during state holidays.

Contact information for the Division:

Carson City Office:
Phone: (775) 687-0700
Fax: (775) 687-0787
1818 East College Pkwy., Suite 103
Carson City, NV 89706

Las Vegas Office:
Phone: (702) 486-4009
Fax: (702) 486-4007
2501 East Sahara Ave., Suite 302
Las Vegas, NV 89104

The Division also provides a toll-free number for consumers residing outside of the above areas:

1-800-992-0900 Please listen to the greeting and select the appropriate prompt.

If you have any questions regarding your health care coverage, please contact SHL's Member Services Department at the following:

Address:

Sierra Health and Life Insurance Company, Inc.
Attn: Member Services Department
P.O. Box 15645
Las Vegas, NV 89114-5645

Phone:

1-800-888-2264

(Monday – Friday from 8:00 a.m. until 5:00 p.m., Pacific Standard Time):

SECTION 1. Eligibility, Enrollment and Effective Date

Subscribers and Eligible Family Members who meet the following criteria are eligible for healthcare coverage under this Plan.

1.1 Who Is Eligible

Subscriber. To be eligible to enroll as a Subscriber, an Individual must:

- Meet the guidelines established in the SHL Individual PPO Enrollment Application.
- Complete and submit to SHL such applications, or forms that SHL may reasonably request.
- Live in Nevada.

Dependent. To be eligible to enroll as a Dependent, an individual must be one of the following:

- A Subscriber's legal spouse or a legal spouse for whom a court has ordered coverage.
- A registered Domestic Partner.
- A child by birth. Adopted child. Stepchild. Minor child for whom a court has ordered coverage. Child being Placed for Adoption with the Subscriber. A child for whom a court has appointed the Subscriber or the Subscriber's spouse the legal guardian.

The definition of Dependent is subject to the following conditions and limitations:

- A Dependent includes any child listed above under the limiting age of 26.
- A Dependent does not include anyone who is also enrolled as a Subscriber. No one can be a Dependent of more than one Subscriber.
- A Dependent includes a Dependent child who is incapable of self-sustaining employment due to mental or physical handicap, chiefly dependent upon the Subscriber for economic support and maintenance, and who has satisfied all of the requirements of (a) or (b) below:

  a. The child must be covered as a Dependent under this Plan before reaching the limiting age, and proof of incapacity and dependency must be given to SHL by the Subscriber within thirty-one (31) days of the child reaching the limiting age; or

  b. The handicap started before the child reached the limiting age, but the Subscriber was covered by another health insurance carrier that covered the child as a handicapped Dependent prior to the Subscriber applying for coverage with SHL.

SHL may require proof of continuing incapacity and dependency, but not more often than once a year after the first two (2) years beyond the date when the child reaches the limiting age.

Evidence of any Court Order needed to prove eligibility must be given to SHL.

1.2 Who Is Not Eligible

The following individual's are not eligible for coverage:

- An individual who is eligible and/or enrolled for coverage under Medicare Part A and/or B at the time of application.
- A foster child of the applicant or Subscriber.
- A child placed in the applicant's or Subscriber's home other than for adoption.
- A grandchild of the applicant or Subscriber.
- Any other individual not defined in Section 1.1.

1.3 Changes In Eligibility Status

It is the Subscriber's responsibility to give SHL written notice within thirty-one (31) days of changes which affect his Dependents' eligibility under this Plan. Changes include:

- Reaching the limiting age.
- Death.
- Divorce.
- The Eligible Person and/or Dependent loses eligibility under Medicaid or Children's Health Insurance Program (CHIP). Coverage will begin only if SHL receives the completed enrollment form and any required Premium within 60 days of the date coverage ended.

If the Subscriber fails to give notice which would have resulted in termination of coverage, SHL shall have the right to terminate coverage.

A Dependent's coverage terminates on the same day as the Subscriber.

Continuation of Coverage Due to Specific Change in Eligibility Status

An Insured that becomes ineligible for coverage under this Plan due to specific changes in eligibility status may qualify for the same coverage under their current SHL benefit Plan and rates in the following circumstances:

- Death of the Subscriber;
- Divorce between Subscriber and spouse;
- Termination of a domestic partnership; or
- When a child involuntarily fails to meet the eligibility rules outlined in Section 1.1.

In order to qualify for continuation of coverage under the above circumstances, the affected Insured must contact SHL within thirty-one (31) days of the date of loss of eligibility to request continued coverage. Any and all waiting periods satisfied under the current Plan will be credited to the Insured under the continued Plan coverage.

1.4 Application

Eligible Individuals and Eligible Family Members must make application to SHL in order to have coverage under this Plan.

1. **Newly Eligible Family Members.** Any individual becoming a newly Eligible Family Member may apply for coverage under SHL by submitting to SHL the Application Form (or Membership Change Form) within thirty-one (31) days of the date on which the individual becomes eligible. An individual may become a newly Eligible Family Member as the result of:
   - A change in the Subscriber's marital or domestic partnership status.
   - A birth or adoption of a child by the Subscriber.
   - Loss of eligibility under other healthcare coverage.

2. **Right to Deny Application.** SHL can deny membership to any person who:
   - At application, does not meet eligibility guidelines.
   - Fails to make a premium payment.

3. **Right to Deny Application for Renewal.** As a condition of renewal under this Plan, SHL may terminate a Subscriber and/or Dependent(s) who committed fraud upon SHL or misrepresented a material fact which affected his coverage under this Plan.

4. **Annual Open Enrollment Periods.** An Insured is eligible to enroll during the Federally Required Open Enrollment Period.

1.5 Effective Date of Coverage

Before coverage can become effective, SHL must receive and accept premium payments and an SHL Individual PPO Application Form for the person applying to be an Insured.

1. When the Enrollment Application Form is received, approved and applicable premium payments have been accepted by SHL the Effective Date is as follows:

1. **Open Enrollment (2016) -**The annual open enrollment period is November 1, 2015 through January 31, 2016.
   - Applications received between November 1, 2015 and December 31, 2015 will be effective January 1, 2016.
   - Applications received between January 1, 2016 and January 31, 2016 will be effective February 1, 2016.
   - **Subsequent Open Enrollments (2015 and beyond)** – Applications received during the Federally Required Open Enrollment will be reviewed for an effective date of the 1st of the month following the date the application is received.
   - **Outside of Open Enrollment or of a Qualifying Event** – A waiting period of 90 (ninety) days is applied from the date the Application is received by SHL. The Effective Date will be the first of the month immediately following the month in which the waiting period expires.

2. A Subscriber's newborn natural child is covered for the first thirty-one (31) days following birth. Coverage continues after thirty-one (31) days only if the Subscriber makes application for the child as a Dependent and pays any premium within thirty-one (31) days of the date of birth.

3. An adopted child is covered for the first thirty-one (31) days from birth only if the adoption has been legally completed before the child's birth, unless the adopted child is placed with the Subscriber during the first thirty-one (31) days of the child's life. A child Placed for Adoption is covered for the first thirty-one (31) days after the Placement for Adoption.

   Coverage continues after the applicable thirty-one (31) day period only if the Subscriber makes application for the child as a Dependent and pays any premium within thirty-one (31) days after the placement of the child in the Subscriber's home or the child's birth. The coverage of a child Placed for Adoption ends on the date the adoption proceedings are terminated.

4. If a court has ordered Subscriber to cover his or her legal spouse or unmarried minor child, that person will be covered for the first thirty-one (31) days following the date of the court order. Coverage continues after thirty-one (31) days if the Subscriber makes application for the Dependent and pays any required premium. A copy of the court order must be given to SHL.

Subscriber must give SHL a copy of the certified birth certificate, decree of adoption, or certificate of placement for adoption for coverage to continue after thirty-one (31) days for newborn and adopted children.

Subscriber must give SHL a copy of the certified marriage certificate or any other required documents before coverage can be effective for other Eligible Family Members.

SECTION 2. Termination

SHL may terminate coverage under this Plan at the times shown for any one (1) or more of the following reasons:

2.1 Termination by SHL

- If a Subscriber fails to make premium payments within thirty-one (31) days of the premium due date, coverage will be terminated on the first (1st) day of the month for which a premium was due and not received by SHL.
- With thirty (30) days written notice, if the Insured allows his or any other Insured's SHL Identification (ID) card to be used by any other person, or uses another person's card. The Insured will be liable to SHL for all costs incurred as a result of the misuse of the Insured's SHL ID card.
- Failure to maintain eligibility requirements as set forth in Section 1.
- If the Insured performs an act or practice that constitutes fraud, or makes any intentional misrepresentation of material fact, as prohibited by the terms of coverage, SHL has the right to rescind coverage and declare coverage under the Plan null and void as of the original Effective Date of Coverage and refund any applicable premium.

Thirty (30) days written notice shall be provided to the Insured prior to any rescission of coverage. The Insured has the right to appeal any such rescission.

- Except as specifically provided in Section 1.3, on the last day of the calendar month in which an Insured no longer meets the requirements of Section 1
- If the Insured fails to give written notice within thirty-one (31) days of the loss of eligibility, SHL will terminate coverage retroactively and refund any corresponding premium.
- When information provided to SHL in the application form is determined to be untrue, inaccurate, or incomplete, in lieu of termination of coverage. SHL shall have the right to retroactively increase past premium payments to the maximum rate allowed that would have been billed if such untrue, inaccurate, or incomplete information had not been provided. If the revised premium rate is not received by SHL within thirty (30) days of the letter of notification, coverage will be terminated as of the paid-to date.

2.2 Termination by the Subscriber

Subscriber has the right to terminate his coverage under the Plan by written notice to SHL. Such termination is effective on the last day of the month in which the notice is received by SHL unless coverage is terminated prior to such date by SHL.

2.3 Reinstatement

Any Individual PPO Plan, which has been terminated in any manner, may be reinstated by SHL at its sole discretion.

2.4 Effect of Termination

No benefits will be paid under this Plan by SHL for services provided after termination of an Insured's coverage under this Plan. You will be responsible for payment of medical services and supplies incurred after the Effective Date of the termination of this Plan.

SECTION 3. Managed Care

This section tells you about SHL's Managed Care Program and which Covered Services require Prior Authorization.

3.1 Managed Care Program

SHL's Managed Care Program, using the services of professional medical peer review committees, Utilization Review Committees, and/or the Medical Director, determines whether services and supplies are Medically Necessary. The Managed Care Program helps direct care to the most appropriate setting to provide healthcare in a cost-effective manner. Benefits payable for expenses incurred in connection with Covered Services, which are not Prior Authorized by the Managed Care Program, will be reduced as shown in the Attachment A Benefit Schedule.

3.2 Managed Care Program Requirements

SHL's Managed Care Program requires the Insured, Plan Providers and SHL to work together.

- All Plan Providers have agreed to participate in SHL's Managed Care Program. Plan Providers have agreed to accept SHL's Reimbursement Schedule amount as payment in full for Covered Services, less the Insured's payment of any applicable Copayment, Deductible or Coinsurance amount, whereas Non-Plan Providers have not. In no event will SHL pay more than the maximum payment allowance established in the SHL Reimbursement Schedule.
- It is the Insured's responsibility to verify Prior Authorization has been obtained for any Covered Services requiring Prior Authorization and to comply with all other rules of SHL's Managed Care Program.

3.3 Managed Care Process

The Medical Director and/or SHL's Utilization Review Committee will review proposed services and supplies to be received by an Insured to determine:

- If the services are Medically Necessary and/or appropriate.
- The appropriateness of the proposed setting.
- The required duration of treatment or admission.

Following review, SHL will complete the Prior Authorization form and send a copy to the Provider and the Insured. This form will specify approved services and supplies. **Prior Authorization is not a guarantee of payment for Covered Services.**

The final decision as to whether any care should be received is between the Insured and the Provider. If SHL denies a request by an Insured and/or Provider for Prior Authorization of a service, the Insured or his Authorized Representative may appeal the denial to the Grievance Review Committee (see the Appeals Procedures Section).

3.4 Services Requiring Prior Authorization

Please refer to Attachment B, Services Requiring Prior Authorization. The list represents services that are commonly reviewed and may require additional clinical information in order for a determination of Prior Authorization to be made.

SHL recommends that the Insured or the Insured's Physician or practitioner making a specific request for services verify benefits under this Plan and the Prior Authorization requirements prior to providing services. The Attachment B, Services Requiring Prior Authorization list is subject to change periodically and may be modified at any time without notification

3.5 Emergency Admission Notification

The Insured must report all emergency admissions to the Member Services Department within twenty-four (24) hours of admission or as soon as reasonably possible to authorized continued care by contacting the Member Services Department at 1-800-888-2264.

All Emergency Services admissions are reviewed Retrospectively to determine if the treatment received was Medically Necessary and appropriate and was for Emergency Services as defined in this AOC. If such Emergency Services are provided by Non-Plan Providers, all Medically Necessary professional, Inpatient or outpatient Emergency Services will be Covered Services.

3.6 Failure to Comply

Failure of the Insured to comply with the requirements of SHL's Managed Care Program will result in a reduction of benefits. Benefits payable for Covered Services which are not Prior Authorized by SHL's Managed Care Program will be reduced to 50% of what the Insured would have received with Prior Authorization.

3.7 Independent Medical Review; Appeals Rights

SHL may require an Insured to have an Independent Medical Review prior to issuing Prior Authorization for any medical benefits. In that case, only a Physician or chiropractor who is certified to practice in the same field of practice as the primary treating Physician or chiropractor or who is formally educated in that field will conduct the review.

The Independent Medical Review may include a physical exam of the Insured, unless he is deceased, and a personal review of all x-rays and reports made by the primary treating Physician or chiropractor. A certified copy of all reports of findings will be sent to the primary treating Physician or chiropractor and the Insured within ten (10) working days after the Independent Medical Review.

If the Insured disagrees with the findings of the Independent Medical Review, he may submit an appeal for binding arbitration to SHL within thirty (30) days after he receives the report. Please refer to the Appeals Procedures section in this AOC for more information.

3.8 Appeals Rights

All decisions of SHL's Managed Care Program may be appealed by the Insured or his Authorized Representative through the Appeals Procedures. If an imminent and serious threat to the health of the Insured exists, the appeal will be directed to SHL's Medical Director.

SECTION 4. Obtaining Covered Services

This section tells you under what conditions services are available under this Plan and your obligations as an Insured. You should also carefully review the Exclusions and Limitations Sections prior to obtaining any healthcare services.

4.1 Availability of Covered Services

Insureds are entitled to receive benefits for the expenses incurred in connection with the Covered Services shown in Section 5 and the Attachment A Benefit Schedule subject to all terms and conditions of this AOC, and payment of required premium. These Covered Services are available only if and to the extent that they are:

- Provided or Prescribed by a duly licensed Provider; and
- Specifically authorized through SHL's Managed Care Program as applicable; and
- Medically Necessary as defined in this AOC.

To obtain maximum benefits, Prior Authorization must be received from SHL's Managed Care Program in order for full benefits to be payable for certain Covered Services. Please read this AOC and the Attachment B, Services Requiring Prior Authorization, carefully to determine which services require Prior Authorization. This section does not apply to Emergency Services or Urgently Needed Services as defined in this AOC.

4.2 Designated Facilities and Other Providers:

If an Insured has a medical condition that SHL determines to need special services, SHL may direct the Insured to a Designated Facility and/or a Designated Provider selected by SHL. If the Insured requires certain complex Covered Health Services for which expertise is limited, SHL may direct the Insured to a Network facility or provider that is outside the Insured's local geographic area. If the Insured is required to travel to obtain such Covered Health Services from a Designated Facility or Designated Provider, SHL may reimburse certain travel expenses at its discretion.

In both cases, Network Benefits will only be paid if the Insured's Covered Health Services for that condition are provided by or arranged by the Designated Facility, Designated Provider or other provider chosen by SHL.

It is the responsibility of the Insured or of the Network Provider to notify SHL of special service needs (such as transplants or cancer treatment) that might warrant referral to a Designated Facility or Designated Provider. If the Insured does not notify SHL in advance, and if the Insured receives services from a non-Network facility (regardless of whether it is a Designated Facility) or other non-Network provider, Network benefits will not be paid. Non-Network Benefits may be available if the special needs services the Insured received are Covered Health Services for which Benefits are provided under the Policy.

Benefits payable for expenses incurred in connection with Covered Services which are not certified by SHL's Managed Care Program will be reduced to 50% of what the Insured would have received if the services had been certified.

4.3 Provider Selection

Subject to all conditions, exclusions, and limitations, if the Insured uses the services of a Provider who is a licensed Practitioner in the state in which he is practicing and who is operating within the scope of his license, then such services shall be treated as though they had been performed by a Physician.

4.4 Continuity of Care from Plan Providers

Termination of a Plan Provider's contract will not release the Provider from treating an Insured, except for reasons of medical incompetence or professional misconduct as determined by SHL.

Coverage provided under this section is available until the latest of the following dates:

- The 120th day following the date the contract was terminated between the Provider and SHL; or
- If the medical condition is Complication of Pregnancy, the 45th day after the date of delivery or if the pregnancy does not end in delivery the date of the end of the pregnancy.

The Insured or Plan Provider may submit a request for continuity of care to the address shown below. If the Plan agrees to the continued treatment, the Plan will pay for Covered Services at the Plan Provider level of benefits for a limited time, as outlined above. The Plan Provider may not seek payment from the Insured for any amounts for which the Insured would not be responsible if the Provider were still a Plan Provider.

Sierra Health and Life Insurance Co., Inc.
Attn: Provider Services Department
PO Box 15645
Las Vegas, NV 89114-5645
Phone: 1-800-888-2264

SECTION 5. Covered Services

This section tells you what services are covered under this Plan. Only Medically Necessary services are considered to be Covered Services. The Attachment A Benefit Schedule shows the applicable Deductible amount as well as Copayments and/or Coinsurance amounts and benefit limitations for Plan and Non-Plan Provider Covered Services.

5.1 Health Care Facility Services

Covered Services include the following accommodations, services and supplies when received during an admission to a Hospital, Ambulatory Surgical Facility, Skilled Nursing Facility or Hospice Care Facility.

Accommodations:

- Semiprivate (or multibed unit) room, including bed, board and general nursing care.
- Private room including bed, board, and general nursing care, but only when treatment of the Insured's condition requires a private room. The semiprivate room rate will be allowed toward the private room rate when an Insured receives private room accommodations for any reason other than Medical Necessity.
- Intensive care unit (including Cardiac Care Unit), including bed, board, general and special nursing care and ICU equipment.
- Observation unit, including bed, board, and general nursing care not to exceed twenty-three (23) hours.
- Nursery charges for routine care of newborn children regardless of whether or not an Injury or Illness exists.

Services and Supplies. Covered Services and supplies provided by a Hospital, Ambulatory Surgical Facility, Skilled Nursing Facility, or Hospice Care Facility include:

- operating, recovery, and treatment rooms and equipment (Hospital and Ambulatory Surgical Facility only);
- anesthesia materials and anesthesia administration by Hospital staff (Hospital and Ambulatory Surgical Facility only);
- clinical pathology and laboratory services and supplies;
- services and supplies for diagnostic tests required to diagnose Insured's Illness, Injury or other conditions but only when charges for the services and/or supplies are made by the facility (Hospital, Skilled Nursing Facility and Ambulatory Surgical Facility only);
- drugs consumed at the time and place dispensed which have been approved for general marketing in the United States by the Food and Drug Administration (FDA);
- dressings, splints, casts and other supplies for medical treatment provided by the Hospital from a central sterile supply department;
- oxygen and its administration;
- non-replaced blood, blood plasma, blood derivatives and their administration and processing;
- intravenous injections and solutions;
- private duty nursing;
- supportive services for a Hospice patient's family, including care for the patient which provides a respite from the stresses and responsibilities that result from the daily care of the patient and bereavement services provided to the family after the death of the patient (Hospice Care Facility only); and
- sterilization procedures.

5.2 Medical - Physician Services

Covered Services include services which are generally recognized and accepted non-surgical procedures for diagnosing or treating an Illness or Injury, performed by a Physician in his office, the patient's home, or a licensed healthcare facility. Medical Services include:

- direct physical examination of the patient;
- examination of some aspect of the patient by means of pathology laboratory or electronic monitoring procedure which is a generally recognized and accepted procedure for diagnostic or therapeutic purposes in the treatment of an Illness or Injury;
- procedures for prescribing or administering medical treatment;
- Treatment of the temporomandibular joint including Medically Necessary dental procedures, such as dental splints, subject to the maximum benefit limitation;
- Anesthesia services;
- Manual Manipulation (except for reductions of fractures or dislocations); and
- Family planning services including sterilization procedures; and
- Limited diagnostic and therapeutic infertility services determined to be Medically Necessary and Prior Authorized by SHL's Managed Care Program. Covered Services do not include those services specifically excluded herein, but do include limited:
  - Laboratory studies;
  - Diagnostic procedures; and
  - Artificial insemination services, up to six (6) cycles per Insured per lifetime.

5.3 Specialty Services, Second and Third Opinions and Consultations

Covered Services include Medical Services rendered by a Specialist or other duly licensed Provider whose opinion or advice is requested by an Insured's treating Physician or SHL's Medical Director for further evaluation of an Illness or Injury on an Inpatient or outpatient basis.

Subject to all terms and conditions of this Plan, Covered Services shall include:

- **Second Opinions.** When, as a result of an Illness or Injury, a procedure is recommended by a Physician, SHL or the Insured may request a Second Opinion from a Physician qualified to diagnose and treat the specific Illness or Injury.

- **Third Opinions.** In the event a First and Second Opinion for a Covered Service are in conflict, SHL or Insured may request a Third Opinion from a Physician qualified to diagnose and treat the specific Illness or Injury.

- Payment will be made whether or not the Elective Surgery or Inpatient care is performed. Payment will be subject to all terms of the AOC, except as otherwise provided in this Section.

- **Limitations.** No payment will be made for expenses incurred for Second or Third Opinions and Consultations in connection with:

    1. Any services not covered under the Plan, including cosmetic and dental procedures;
    2. Minor surgical procedures that are routinely performed in a Physician's office, such as incision and drainage for abscess or excision of benign lesions; or
    3. Diagnostic tests ordered in connection with Second and Third Opinions/Consultations, unless Prior Authorized by the Managed Care Program.

5.4 Preventive Healthcare Services

Covered Preventive Healthcare Services will be paid at 100% of Eligible Medical Expenses, without application of any Copayment, and/or Calendar Year Deductible and Coinsurance when such services are provided by a Plan Provider**.**

For a complete list of Preventive Services, including all FDA approved contraceptives, go to http://doi.nv.gov/Healthcare-Reform/Individuals-Families/Preventive-Care/.

5.5 Laboratory Services

Covered Services include prescribed diagnostic clinical and anatomic pathological laboratory services and materials when authorized by an Insured's Physician and SHL's Managed Care Program.

5.6 Routine Radiological and Non-Radiological Diagnostic Imaging Services

Covered Services include prescribed routine diagnostic radiological and non-radiological diagnostic imaging services and materials, including general radiography, fluoroscopy, mammography, and sonography, when prescribed by an Insured's Physician and authorized by SHL's Managed Care Program, but only when no charges are made for the same services and/or supplies by a Hospital, Skilled Nursing Facility or an Ambulatory Surgery Center.

5.7 Emergency or Urgently Needed Services

Emergency Services obtained from Non-Plan providers will be payable at the same benefit level as would be applied to care received from Plan Providers.

Benefits are limited to Eligible Medical Expenses for Non-Plan Provider Emergency Services as defined under "SHL Reimbursement Schedule". You are responsible for any Non-Plan Provider Emergency Service charges that exceed payments made by SHL.

Benefits for Emergency Services are subject to any limit shown in the Attachment A Benefit Schedule.

If Emergency Services are required during an emergency as defined in this AOC, all Covered Services which are Medically Necessary and appropriate will be paid for within the limit, if any, established in the Attachment A Benefit Schedule.

IMPORTANT NOTE: If treatment is received by an Insured in a Hospital emergency room or other emergency facility for a condition which is Medically Necessary but which does not require Emergency Services, a reduced benefit will be allowed toward the Covered Services included in such treatment.

Examples of conditions which require Medically Necessary treatment, but **not emergency** treatment, include:

- Sore throats.
- Flu or fever.
- Earaches.
- Sore or stiff muscles.
- Sprains, strains or minor cuts.
- Suture removal.
- Routine dental services.
- Medication refills.

If the treatment received is not a Covered Service or if treatment is received for a condition which is not Medically Necessary, no benefit is payable.

Telephone Advice Nurse. If you are feeling ill and are not sure about where you should go to obtain care or do not know whom to call, you may call the Telephone Advice Nurse for help. A nurse is available twenty-four (24) hours a day, seven (7) days a week at (702) 242-7330, or for the hearing-impaired through Relay Nevada's TDD/TYY at 1-800-326-6888. You may call toll free for assistance at 1-800-288-2264.

5.8 Ambulance Services

Covered Services include Ambulance Services to the nearest appropriate Hospital. SHL will make direct payment to a provider of Ambulance Services if the provider does not receive payment from any other source. Ambulance Services will be reviewed on a Retrospective basis to determine Medical Necessity. The Insured will be fully liable for the cost of Ambulance Services that are not Medically Necessary.

5.9 Physician Surgical Services - Inpatient and Outpatient

Covered Services include surgical services that are generally recognized and accepted procedures for diagnosing or treating an Illness or Injury.

5.10 Assistant Surgical Services

Covered Services include services performed by an assistant surgeon in connection with a covered surgical procedure but only to the extent surgical assistance is necessary due to the complexity of the procedure involved.

5.11 Gastric Restrictive Surgical Services

Covered Services include Prior Authorized Medically Necessary Gastric Restrictive Surgical Services for extreme obesity under the following circumstances:

- Have a body mass index (BMI) of greater than 40kg/m^2; or
- Have a BMI greater than 35kg/m^2 with significant co-morbidities; and
- Can provide documented evidence that dietary attempts at weight control are ineffective; and
- Must be at least 18 years old.

Documentation supporting the reasonableness and necessity of a Gastric Restrictive Surgical Service is required, including compliant attendance at a medically supervised weight loss program (within the last twenty-four (24) months) for at least three (3) months with documented failure of weight loss. Significant clinical evidence that weight is affecting overall health and is a threat to life will also be required.

SHL requires that an initial psychological/ psychiatric evaluation resulting in a recommendation for Gastric Restrictive Surgical Services is performed prior to review consideration by SHL's Managed Care Program. SHL may also require participation in a post-operative group therapy program.

Treatment for complications resulting from Gastric Restrictive Surgical Services will be covered the same as any other illness.

5.12 Mastectomy Reconstructive Surgery

Covered Services for reconstructive procedures for Subscribers and their enrolled Dependents include breast reconstruction following a mastectomy, and reconstruction of the non-affected breast to achieve symmetry including augmentation, mammoplasty, reduction mammoplasty, and mastopexy. Other services required by the *Women's Health and Cancer Rights Act of 1998*, including breast prostheses and treatment of complications, are provided in the same manner and at the same level as those for any other Covered Health Service.

5.13 Oral Physician Surgical Services

Although dental services are not Covered Services, except as otherwise provide in the Attachment A Benefit Schedule, the following Oral Surgical Services are Covered Services:

- Treatment for tumors and cysts requiring pathological examination of the jaws, cheeks, lips, tongue, roof and floor of the mouth. Removal of teeth which is necessary in order to perform radiation therapy.
- Treatment required to stabilize sound natural teeth, the jawbones, or surrounding tissues after an Injury (not to include injuries caused by chewing) when the treatment starts within the first ten (10) days after the Injury and ends within sixty (60) days. Examples of Covered Services, in such instances, include:
    a) Root canal therapy, post and build up.
    b) Temporary crowns.
    c) Temporary partial bridges.
    d) Temporary and permanent fillings.
    e) Pulpotomy.
    f) Extraction's of broken teeth.
    g) Incision and drainage.
    h) Tooth stabilization through splinting.

No benefits are provided for removable dental prosthetics, dentures (partial or complete) or subsequent restoration of teeth, including permanent crowns.

5.14 Organ and Tissue Transplant Surgical Services

All Covered Transplant Procedures are subject to the provisions of SHL's Managed Care Program and all other terms and provisions of the Plan.

Covered Services include services provided by on an Inpatient basis to an Insured who is the recipient of an organ or tissue transplant only in the following situations:

1. SHL will determine if the Insured satisfies SHL's Medically Necessary criteria before receiving benefits for transplant services.
2. SHL will provide a written Referral for care to a Transplant Facility.
3. If, after Referral, either SHL or the medical staff of the Transplant Facility determines that the Insured does not satisfy the Medically Necessary criteria for the service involved, benefits will be limited to Covered Services provided up to such determination.

Covered Transplant Procedures include the following services for human-to-human organ or tissue transplants received during a Transplant Benefit Period on an Inpatient basis due to an Injury or Illness as follows:

- Hospital room and board and medical supplies.
- Diagnosis, treatment, surgery and other Covered Services provided by a Physician.

- Organ and tissue retrieval which includes removing and preserving the donated part.
- Rental of wheel chairs, Hospital-type beds and mechanical equipment required to treat respiratory impairment.
- Ambulance services.
- Medication, x-rays and other diagnostic services.
- Laboratory tests.
- Oxygen.
- Surgical dressings and supplies.
- Immunosuppressive drugs.
- Private nursing care by a Registered Nurse (R.N.) or a Licensed Practical Nurse (L.P.N.).
- Transportation of the Insured and a companion to and from the site of the transplant. If the Insured is a minor, transportation of two (2) persons who travel with the minor is included. Reasonable and necessary lodging and meal costs incurred by such companions are included. Itemized receipts for these expenses are required. Daily lodging and meal costs will be paid up to the limit shown in the Attachment A Benefit Schedule. Benefits for all transportation, lodging and meal costs shall not exceed the maximum shown in the Attachment A Benefit Schedule for transportation, lodging and meals.

SHL makes no representation or warranty as to the medical competence or ability of any Transplant Facility or its respective staff or Physicians. SHL shall have no liability or responsibility, either direct, indirect, vicarious or otherwise, for any actions or inaction, whether negligent or otherwise, on the part of any Transplant Facility or its respective staff or Physicians.

SHL shall have no liability or responsibility, either direct, indirect, vicarious or otherwise, in the event a transplant patient is injured or dies, by whatever cause, while enroute to a Transplant Facility.

If a Covered Transplant Procedure is not performed as scheduled due to a change in the Insured's medical condition or death, benefits will be paid for Prior Authorized EME incurred during the Transplant Benefit Period.

5.15 Home Health Care Services

Covered Services include services given to an Insured in his home by a licensed Home Health Care Provider or an approved Hospital program for Home Health Care. Benefits are payable for such services when an Insured is homebound for medical reasons, physically not able to obtain Medically Necessary care on an outpatient basis, under the care of a Physician and such care is given in place of Inpatient Hospital or Skilled Nursing Facility care.

Covered Services and supplies provided by a Home Health Care agency include:

- Professional services of a registered nurse, licensed practical nurse or a licensed vocational nurse on an intermittent basis.
- Physical therapy, speech therapy and occupational therapy by a licensed therapist.
- Medical and surgical supplies that are customarily furnished by the Home Health Care agency or program for its patients.
- Prescribed drugs furnished and charged for by the Home Health Care Provider or program. Prescribed Drugs under this provision do not include Specialty Prescription Drugs. Please refer to the SHL Individual PPO Prescription Drug Benefit Rider, if applicable to your Plan, for information on benefits available for Specialty covered drugs.
- One (1) medical social service consultation per course of treatment.
- One (1) nutrition consultation by a certified registered dietitian.
- Health aide services furnished to Insured only when receiving nursing services or therapy.

5.16 Short-Term Rehabilitation Services

Short-Term Rehabilitation therapy Covered Services include:

- Speech therapy.
- Occupational therapy.
- Physical therapy on an Inpatient or outpatient basis when ordered by the Insured's Physician and authorized by SHL's Managed Care Program.

Benefits for rehabilitation therapy are limited to services given for acute or recently acquired conditions that, in the judgment of the Insured's Physician and SHL's Managed Care Program, are subject to significant improvement through Short-Term therapy.

Covered Services do not include cardiac rehabilitation services provided on a non-monitored basis nor do they include treatment for mental retardation.

5.17 Genetic Disease Testing Services

Covered Services include Prior Authorized Medically Necessary Genetic Disease Testing when:

- Such testing is prescribed following the Insured's history, physical examination and pedigree analysis, genetic counseling, and completion of conventional diagnostic studies, and a definitive diagnosis remains uncertain and a genetic disease diagnosis is suspected, and;
- The Insured displays clinical features, or is at direct risk of inheriting the mutation in question (presymptomatic); and
- The result of the test will directly impact the treatment being delivered to the Insured.

5.18 Other Diagnostic and Therapeutic Services

Diagnostic and Therapeutic Covered Services when prescribed by an Insured's Physician and authorized by the Managed Care Program include the following:

- Anti-cancer drug therapy, non-cancer related intravenous injection therapy or other Medically Necessary intravenous therapeutic services as approved by SHL;
- Hemodialysis and peritoneal renal dialysis;
- Therapeutic radiology services;
- Complex allergy diagnostic services including RAST and allergoimmuno therapy;
- Otologic evaluations only for the purpose of obtaining information necessary for evaluation of the need for or appropriate type of medical or surgical treatment for a hearing deficit or a related medical problem;

- Complex diagnostic imaging services including nuclear medicine, computerized axial tomography (CT scan), cardiac ultrasonography, magnetic resonance imaging (MRI) and arthrography;
- Complex vascular diagnostic and therapeutic services including Holter monitoring, treadmill or stress testing and impedance venous plethysmography;
- Complex neurological diagnostic services including electroencephalograms (EEG), electromyogram (EMG) and evoked potential;
- Complex psychological diagnostic testing;
- Complex pulmonary diagnostic services including pulmonary function testing and apnea monitoring;
- Treatment of temporomandibular joint disorder; and
- Positron Emission Tomography (PET) Scans.

Different Coinsurance amounts may apply to these Covered Services. Please refer to your Attachment A Benefit Schedule.

5.19 Prosthetic and Orthotic Devices

Benefits payable for expenses for the following devices when received in connection with an Illness or Injury for which benefits are payable and authorized by SHL's Managed Care Program:

- Cardiac pacemakers;
- Breast prostheses for post-mastectomy patients;
- Terminal devices (example: hand or hook) and artificial eyes;
- Braces (only rigid and semi-rigid devices used for supporting a weak or deformed body member or restricting or eliminating motion in a diseased or injured part of the body);
- Adjustment of an initial Prosthetic Device required by wear or by change in the patient's condition when ordered by a Physician.

5.20 Self-Management and Treatment of Diabetes

Coverage includes medication, equipment, supplies and appliances that are for the treatment of diabetes. Diabetes includes Type I, II, and gestational diabetes. Covered Services include:

- Supplies, training and education provided to an Insured for the care and management of diabetes, after he is initially diagnosed with diabetes, to include counseling in nutrition and the proper use of equipment and supplies for the treatment of diabetes;
- Supplies, training and education which is necessary as a result of a subsequent diagnosis that indicates a significant change in the symptoms or condition of the Insured and which requires modification of his program of self-management of diabetes; and
- Supplies, training and education which is necessary because of the development of new techniques and treatment of diabetes.

5.21 Special Food Product/Enteral Formulas

Covered Services include enteral formulas and special food products when prescribed by a Physician and authorized by the Managed Care Program for treatment of an inherited metabolic disease.

- "Inherited Metabolic Disease" means a disease caused by an inherited abnormality of the body chemistry of a person characterized by congenital defects or defects arising shortly after birth resulting in deficient metabolism or malabsorption of amino acid, organic acid, carbohydrate or fat.
- "Special Food Product" means a food product specially formulated to have less than one (1) gram of protein per serving intended to be consumed under the direction of a Physician. The term does not include food that is naturally low in protein.

5.22 Durable Medical Equipment

All benefits for Durable Medical Equipment ("DME") includes administration, maintenance and operating costs of such equipment, if the equipment is Medically Necessary or Prior Authorized. DME includes, but is not limited to:

- Braces;
- Canes;
- Crutches;
- Intermittent positive pressure breathing machine;
- Hospital beds;
- Standard outpatient oxygen delivery systems;
- Traction equipment;
- Walkers;
- Wheelchairs; or
- Any other items that are determined to be Medically Necessary by SHL's Managed Care Program.

Replacements, repairs and adjustments to DME are limited to normal wear and tear or because of significant change in the Insured's physical condition.

SHL will not be responsible for the following:

- Non-Medically Necessary optional attachments and modifications to DME for the comfort or convenience of the Insured;
- Accessories for portability or travel;
- A second piece of equipment with or without additional accessories that is for the same or similar medical purpose as existing equipment;
- Home and car remodeling; and
- Replacement of lost or stolen equipment.

5.23 Mental Health Services and Severe Mental Illness Services

All benefits for Severe Mental Illness and Mental Health Services are subject to SHL's Managed Care Program through Behavioral Healthcare Options.

Mental Health Services. When authorized by Behavioral Healthcare Options, Covered Services include evaluation, crisis intervention or psychotherapy only.

- **Inpatient:** Covered Services for the diagnosis and treatment of a Mental Illness.

- **Outpatient:** Outpatient evaluation and treatment of Mental Illness including individual and group psychotherapy sessions.

Severe Mental Illness Services. When authorized SHL, Covered Services include Inpatient and outpatient treatment for Severe Mental Illness as defined in this AOC.

For the purpose of determining benefits:

- Outpatient visits for the purpose of medication management will not reduce the maximum number of visits for which benefits for outpatient services are payable.
- Two (2) visits for partial or respite care, or a combination thereof, may be substituted for each one (1) day of hospitalization not used by the Insured.

No benefits are available for psychosocial rehabilitation or care received as a custodial Inpatient.

5.24 Substance Abuse Services

All benefits for Inpatient Substance Abuse Services are subject to SHL's Managed Care Program through Behavioral Healthcare Options.

- **Inpatient:** When there has been a history of multiple outpatient treatment failures or when outpatient treatment is not feasible, services for diagnosis and medical treatment for Substance Abuse as defined herein.

- **Outpatient:** Services for the diagnosis, medical treatment and rehabilitation, including individual, group, and family counseling, and outpatient detoxification services for recovery from the effects of Substance Abuse.

- **Detoxification:** Treatment for withdrawal from the physiological effects of Substance Abuse. Inpatient detoxification is considered appropriate treatment only for life-threatening withdrawal syndromes associated with Substance Abuse.

All admissions for Emergency Services are reviewed Retrospectively to determine if the treatment received was Medically Necessary and appropriate. If the Insured receives services other than Emergency Services in a Mental Health Facility without obtaining Prior Authorization from SHL, benefits will be reduced to 50% of what the Insured would have received if the services had been Prior Authorized, provided however, that the benefits paid will not be less than 50% of the Eligible Medical Expenses. If the treatment received is not a Covered Service or if treatment is received for a condition which is not Medically Necessary, no benefit is payable.

5.25 Dental Anesthesia Services

Benefits are payable to the same extent as any other Illness or Injury. Covered Services include general anesthesia, when rendered in a Hospital, Outpatient Surgical Facility, or other duly licensed facility for an enrolled Dependent child, when such child, in the treating dentist's opinion and as Prior Authorized by SHL's Managed Care Program, satisfies one or more of the following criteria:

- Has a physical, mental or medically compromising condition;
- Has dental needs for which local anesthesia is ineffective because of an acute infection, an anatomic anomaly or an allergy;
- Is extremely uncooperative, unmanageable or anxious; or
- Has sustained extensive orofacial and dental trauma to a degree that would require unconscious sedation.

Coverage for dental anesthesia pursuant to this section is limited to that provided by an anesthesia Provider only during procedures performed by an educationally qualified Specialist in pediatric dentistry, or other dentist educationally qualified in a recognized dental specialty for which Hospital privileges are granted, or who is certified by virtue of completion of an accredited program of post-graduate Hospital training to be granted Hospital privileges.

5.26 Clinical Trial or Study

Covered Services include coverage for Prior Authorized medical treatment received as part of a clinical trial or study if the following provisions apply:

- The clinical trial or study is conducted in the state of Nevada and the medical treatment is provided:
  1. In a Phase I, Phase II, Phase III or Phase IV clinical trial or study for the treatment of cancer or other life-threatening disease or condition;
  2. In a Phase II, Phase III or Phase IV clinical trial or study for the treatment of chronic fatigue syndrome;
  3. For cardiovascular disease (cardiac/stroke) which is not life-threatening, for which, as SHL determines, a clinical trial meets the qualifying clinical trial criteria stated below.
  4. For surgical musculoskeletal disorders of the spine, hip and knees, which are not life-threatening, for which, as SHL determines, a clinical trial meets the qualifying clinical trial criteria stated below.
  5. Other diseases or disorders which are not life-threatening not life-threatening, for which, as SHL determines, a clinical trial meets the qualifying clinical trial criteria stated below
- The clinical trial or study is approved by one of the following entities:
  1. An agency of the National Institutes of Health (NIH) as set forth in 42 U.S.C. § 281 (b);
  2. The Centers for Disease Control and Prevention (CDC);
  3. The Agency for Healthcare Research and Quality (AHRO);
  4. Centers for Medicare and Medicaid Services (CMS);
  5. A cooperative group;
  6. A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants;
  7. The Department of Veterans Affairs, the Department of Defense or the Department of Energy as long as the study or investigation has been reviewed and approved through a system of peer review that is determined by the Secretary of Health and Human Services to meet the both of following criteria:
     - Comparable to the system of peer review of studies and investigations used by the National Institutes of Health.

  - Ensures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.
- The study or investigation is conducted under an investigational new drug application reviewed by the U.S. Food and Drug Administration;
- The study or investigation is a drug trial that is exempt from having such an investigational new drug application;
- The clinical trial must have a written protocol that describes a scientifically sound study and have been approved by all relevant institutional review boards (IRBs) before participants are enrolled in the trial. SHL may, at any time, request documentation about the trial;
- The medical treatment is provided by a duly licensed Provider of healthcare and the facility and personnel have the experience and training to provide the medical treatment in a capable manner;
- There is no medical treatment available which is considered a more appropriate alternative than the medical treatment provided in the clinical trial or study;
- There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment; and
- The Insured has signed a statement of consent before his participation in the clinical trial or study indicating that he has been informed of:
    1. The procedure to be undertaken;
    2. Alternative methods of treatment; and
    3. The risks associated with participation in the clinical trial or study.

Benefit coverage for medical treatment received during a clinical trial or study is limited to the following Covered Services:
- The initial consultation to determine whether the Insured is eligible to participate in the clinical trial or study;
- Any drug or device that is approved for sale by the FDA without regard to whether the approved drug or device has been approved for use in the medical treatment of the Insured, if the drug or device is not paid for by the manufacturer, distributor, or Provider:
- Services normally covered under this Plan that are required as a result of the medical treatment or related complications provided in the clinical trial or study when not provided by the sponsor of the clinical trial or study;
- Services required for the clinically appropriate monitoring of the Insured during the clinical trial or study when not provided by the sponsor of the clinical trial or study.

Benefits for Covered Services in connection with a clinical trial or study are payable under this Plan to the same extent as any other Illness or Injury.
Services must be provided by an SHL Plan Provider. In the event an SHL Plan Provider does not offer a clinical trial with the same protocol as the one the Insured's Plan Provider recommended, the Insured may select a Non-Plan Provider performing a clinical trial with that protocol within the State of Nevada. If there is no Provider offering the clinical trial with the same protocol as the one the Insured's Plan Provider recommended in Nevada, the Insured may select a clinical trial outside the State of Nevada but within the United States of America. In no event will SHL pay more than the maximum payment allowance established in the SHL Reimbursement Schedule.

SHL will require a copy of the clinical trial or study certification approval, the Insured's signed statement of consent, and any other materials related to the scope of the clinical trial or study relevant to the coverage of medical treatment.

5.27 Medical Supplies

Medical Supplies are routine supplies that are customarily used during the course of treatment for an Illness or Injury. Medical Supplies include, but are not limited to the following:
- Catheter and catheter supplies – Foley catheters, drainage bags, irrigation trays;
- Colostomy bags (and other ostomy supplies);
- Dressing/wound care-sterile dressings, ace bandages, sterile gauze and toppers, Kling and Kerlix rolls, Telfa pads, eye pads, incontinent pads, lambs wool pads, sterile solutions, ointments, sterile applicators, sterile gloves;
- Elastic stockings;
- Enemas and douches;
- IV supplies;
- Sheets and bags;
- Splints and slings;
- Surgical face masks; and
- Syringes and needles.

5.28 Post-Cataract Surgical Services

Covered Services include Medically Necessary services provided for the initial prescription for corrective lenses (eyeglasses or contact lenses) and frames or intra-ocular lens implants for Post-Cataract Surgical Services.

Contact lenses will be covered if an Insured's visual acuity cannot be corrected to 20/70 in the better eye except for the use of contact lenses.

5.29 Hearing Aids

Hearing aids required for the correction of a hearing impairment (a reduction in the ability to perceive sound which may range from slight to complete deafness). Hearing aids are electronic amplifying devices designed to bring sound more effectively into the ear. A hearing aid consists of a microphone, amplifier and receiver.

Benefits are available for a hearing aid that is purchased as a result of a written recommendation by a Physician. Benefits are provided for the hearing aid and for charges for associated fitting and testing.

Benefits under this section do not include bone anchored hearing aids. Bone anchored hearing aids are a Covered Service for which benefits are available under the applicable medical/surgical Covered Services categories in the SHL AOC, only for Insureds who have either of the following:
- Craniofacial anomalies whose abnormal or absent ear canals preclude the use of a wearable hearing aid; or

- Hearing loss of sufficient severity that it would not be adequately remedied by a wearable hearing aid.

5.30 Autism Spectrum Disorders

Covered Services include Medically Necessary services that are generally recognized and accepted procedures for screening, diagnosing and treating Autism Spectrum Disorders for Insureds under the age of 18 or, if enrolled in high school, until such Insured reaches the age of 22. Covered Services must be provided by a duly licensed physician, psychologist or Behavior Analyst (including an Assistant Behavior Analyst and/or Autism Behavior Interventionist) or other provider that is supervised by the licensed physician, psychologist or behavior analyst and are subject to SHL's Managed Care Program. With the exception of the specific limitation on benefits for Applied Behavior Analysis ("ABA") as outlined in Attachment A Benefit Schedule, benefits for all Covered Services for the treatment of Autism Spectrum Disorders are payable to the same extent as other Covered Services and Covered Drugs under the Plan.

Covered Services for the treatment of Autism Spectrum Disorder do not include services provided by:

- an early intervention agency or school for services delivered through early intervention, or
- school services.

5.31 Pediatric Dental and Vision Services

Covered Services are available to enrolled children up to age (19) when authorized by SHL's Managed Care Program.

Pediatric Vision coverage includes services for:

- Vision Examination;
- Lenses Frames;
- Contact Lenses;
- Low Vision Exam; and
- Optional Lenses and Treatments.

Pediatric Dental coverage includes:

- Diagnostic and Preventive Services;
- Restorative Services;
- Endodontic Services;
- Periodontic Services;
- Prosthodontic Services;
- Orthodontic Services; and
- Oral Surgery Services.

(For a complete listing of Pediatric Dental Services and the associated limitations, please refer to the Nevada Division of Insurance website located at http://doi.nv.gov/Healthcare-Reform/Individuals-Families/Essential-Health-Benefits/.)

Please refer to the SHL Attachment A Benefit Schedule for the associated Insured cost share for Pediatric Dental and Vision Covered Services.

5.32 Habilitative Services

Covered Services are provided for Habilitative Services provided on an outpatient basis for Insureds with a congenital, genetic, or early acquired disorder when both of the following conditions are met:

- The treatment is administered by a licensed speech-language pathologist, licensed audiologist, licensed occupational therapist, licensed physical therapist, Physician, licensed nutritionist, licensed social worker or licensed psychologist and
- the initial or continued treatment must be proven and not experimental, investigational or unproven.

SHL will cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings.

Coverage for Habilitative Services does not apply to those services that are solely educational in nature or otherwise paid under state or federal law for purely educational services. Custodial Care, respite care, day care, therapeutic recreation, vocational training and residential treatment are not Habilitative Services. A service that does not help the Insured to meet functional goals in a treatment plan within a prescribed time frame is not a habilitative service. When the Insured reaches his maximum level of improvement or does not demonstrate continued progress under a treatment plan, a service that was previously habilitative is no longer habilitative.

SHL may require that a treatment plan be provided, request medical records, clinical notes, or other necessary data to allow us to substantiate that initial or continued medical treatment is needed and that the Insured's condition is clinically improving as a result of the habilitative service. When the treating provider anticipates that
continued treatment is or will be required to permit the Insured to achieve demonstrable progress, SHL may request a treatment plan consisting of diagnosis, proposed treatment by type, frequency, anticipated duration of treatment, the anticipated goals of treatment, and how frequently the treatment plan will be updated.

SECTION 6. Exclusions

This section tells you what services or supplies are excluded from coverage under this Plan. The following services and any resulting complications are excluded from coverage.

6.1 Services for which coverage is not specifically provided in this AOC, complications resulting from non-Covered Services, or services which are not Medically Necessary, whether or not recommended or provided by a Provider.

6.2 Any charges for non-Emergency Services provided outside the United States.

6.3 Personal comfort, hygiene or convenience items such as a Hospital television, telephone, or private room when not Medically Necessary. Services and supplies that are included in the basic hospital charges for room, board and nursing services. Housekeeping or meal services as part of Home Health Care. Modifications to a place of residence, including equipment to accommodate physical handicaps or disabilities.

6.4 Services for a private room in excess of the average semi-private room and board rate.

6.5 Except as otherwise provided in the SHL Attachment A Benefit Schedule, dental or orthodontic splints or dental prostheses, or any treatment on or to teeth, gums, or jaws and other services customarily provided by a dentist. Charges for dental services in connection with temporomandibular joint dysfunction are also not covered unless they are determined to be Medically Necessary. Such dental-related services are subject to the limitations shown in the Attachment A Benefit Schedule.

6.6 Except for reconstructive surgery following a mastectomy, cosmetic procedures to improve appearance without restoring a physical bodily function.

6.7 Third-party physical exams for employment, licensing, insurance, school, camp or adoption purposes. Immunizations related to foreign travel unless otherwise provided as a required preventive immunization identified by the USPSTF. Expenses for medical reports, including presentation and preparation. Exams or treatment ordered by a court, or in connection with legal proceedings are not covered.

6.8 The following infertility services and supplies are excluded, in addition to any other infertility services or supplies determined by SHL not to be Medically Necessary or Prior Authorized by SHL's Managed Care Program:

- Advanced reproductive techniques such as embryo transplants, in vitro fertilization, GIFT AND ZIFT procedures, assisted hatching, intracytoplasmic sperm injection, egg retrieval via laparoscope or needle aspiration, sperm preparation, specialized sperm retrieval techniques, sperm washing except prior to artificial insemination if required;
- Home pregnancy or ovulation tests;
- Sonohysterography;
- Monitoring of ovarian response to stimulants;
- CT or MRI of sella turcica unless elevated prolactin level;
- Evaluation for sterilization reversal;
- Laparoscopy;
- Ovarian wedge resection;
- Removal of fibroids, uterine septae and polyps;
- Open or laparoscopic resection, fulguration, or removal of endometrial implants;
- Surgical lysis of adhesions;
- Surgical tube reconstruction.

6.9 Services for the treatment of sexual dysfunction or inadequacies, including, but not limited to, impotence and implantation of a penile prosthesis.

6.10 Reversal of surgically performed sterilization or subsequent resterilizations.

6.11 Elective abortions.

6.12 Except as provided in the Covered Services Gastric Restrictive Surgical section, weight reduction procedures are excluded. Also excluded are any weight loss programs, whether or not recommended, provided or prescribed by a Physician or other medical Practitioner.

6.13 Except as provided in the Covered Services Organ and Tissue Transplant Surgical Services section, any human or animal transplant (organ, tissue, skin, blood, blood transfusions of bone marrow), whether human-to-human or involving a non-human device, artificial organs, or prostheses.

- Any and all services or supplies treatments, laboratory tests or x-rays received by the donor in connection with the transplant (including donor search, donor transportation, testing, registry and retrieval/harvesting costs) and costs related to cadaver or animal retrieval or maintenance of a donor for such retrieval.
- Any and all Hospital, Physician, laboratory or x-ray services in any way related to any excluded transplant service, procedure or treatment.

6.14 Treatment of:

- Marital or family problems;
- Occupational, religious, or other social maladjustments;
- Codependency;
- Impulse control disorders;
- Organic disorders;
- Learning disabilities or mental retardation or any Severe Mental Illness as defined in this AOC and otherwise covered under the Severe Mental Illness Covered Services section.

For purposes of this Exclusion,

- Counseling and other forms of cognitive and behavioral therapy is excluded in connection with the treatment of Attention Deficit Hyperactivity Disorder (ADHD) or Attention Deficit Disorder (ADD). This section is not meant to exclude an evaluation for a diagnosis of ADD or ADHD, or to exclude any corresponding outpatient prescription drugs (if otherwise available under the outpatient Prescription Drug Benefit Rider if applicable to your Plan) when prescribed by a treating Plan Provider, nor is this meant to exclude an evaluation for the diagnosis of any other co-morbid issues.

6.15 Institutional care which is determined to be for the primary purpose of controlling an Insured's environment and Custodial Care, domiciliary care, convalescent care (other than Skilled Nursing Care) or rest cures.

6.16 Except as otherwise provided in the SHL Attachment A Benefit Schedule, Vision exams to determine refractive errors of vision and eye glasses or contacts. Coverage is provided for vision exams only when required to diagnose an Illness or Injury.

6.17 Any prescription corrective lenses (eyeglasses or contact lenses) or frames following Post-Cataract Surgical Service which include, but are not limited to the following:

- Coated lenses;
- Cosmetic contact lenses;
- Costs for lenses and frames in excess of the Plan allowance;
- No-line bifocal or trifocal lenses;
- Oversize lenses;
- Plastic multi-focal lenses;
- Tinted or photochromic lenses;
- Two (2) pairs of lenses and frames in lieu of bifocal lenses and frames; or
- All prescription sunglasses.

6.18 Hearing exams to determine the need for or the appropriate type of hearing aid or similar devices, other than is specifically covered in this Plan. Coverage is provided for hearing exams only when required to diagnose an Illness or Injury.

6.19 Ecological or environmental medicine. Use of chelation, orthomolecular substances; use of substances of animal, vegetable, chemical or mineral origin not specifically approved by the FDA as effective for treatment; electrodiagnosis; Hahnemannian dilution and succussion; magnetically energized geometric patterns; replacement of metal dental fillings; laetrile or gerovital.

6.20 Pain management invasive procedures as defined by SHL's protocols for chronic, intractable pain unless Prior Authorized by SHL and provided by a Plan Provider who is a pain management Specialist. Any Prior Authorized pain management procedures will be subject to the applicable facility and professional Copayments and/or Coinsurance amount as set forth in Attachment A, Benefit Schedule.

6.21 Acupuncture or hypnosis.

6.22 Treatment of an Illness or Injury caused by or arising out of a riot, declared or undeclared war or act of war, insurrection, rebellion, armed invasion or aggression.

6.23 Treatment of an occupational Illness or Injury which is any Illness or Injury arising out of or in the course of employment for pay or profit.

6.24 Outpatient Prescription Drugs, nutritional supplements, vitamins, herbal medicines, appetite suppressants, Specialty drugs, and other over-the-counter drugs, except as specifically covered in the outpatient Prescription Drug Benefit Rider, if applicable to your Plan. This includes drugs and supplies for a patient's use after discharge from a Hospital. Drugs and medicines approved by the FDA for experimental, investigational or unproven use or any drug that has been approved by the FDA for less than one (1) year unless Prior Authorized by SHL.

6.25 Travel and accommodations, whether or not recommended or prescribed by a Provider.

6.26 Vitamins, herbal medicines, appetite suppressants, and other over-the-counter drugs. Drugs and medicines approved by the FDA for experimental, investigational or unproven use except when prescribed for the treatment of cancer or chronic fatigue syndrome under a clinical trial or study approved by the Plan.

6.27 Any services provided before the Effective Date or after the termination of coverage. This includes admission to an Inpatient facility when the admission began before the Effective Date or extended beyond the termination date of the Plan.

6.28 Care for conditions that federal, state or local law requires to be treated in a public facility for which a charge is not normally made.

6.29 Any equipment or supplies that condition the air, arch supports, support stockings, special shoe accessories or corrective shoes unless they are an integral part of a lower-body brace, heating pads, hot water bottles, wigs and their care and other primarily non-medical equipment.

6.30 Any service or supply in connection with routine foot care, including the removal of warts, corns, or calluses, the cutting and trimming of toenails, or foot care for flat feet, fallen arches and chronic foot strain, in the absence of severe systemic disease.

6.31 Special formulas, food supplements other than as specifically covered or special diets on an outpatient basis. (Except for the treatment of inherited metabolic disease.)

6.32 Services, supplies or accommodations provided without cost to the Insured or for which the Insured is not legally required to pay.

6.33 Milieu therapy, biofeedback, behavior modification, sensitivity training, hypnosis, hydrotherapy, electrohypnosis, electrosleep therapy, electronarcosis, narcosynthesis, rolffing, residential treatment, vocational rehabilitation and wilderness programs.

6.34 Experimental, investigational or unproven treatment or devices as determined by SHL.

6.35 Sports medicine treatment plans intended to primarily improve athletic ability.

6.36 Radial keratotomy or any surgical procedure for the improvement of vision when vision can be made adequate through the use of glasses or contact lenses.

6.37 Any services given by a Provider to himself or to members of his family.

6.38 Ambulance Services when an Insured could be safely transported by other means. Air Ambulance Services when an Insured could be safely transported by ground Ambulance or other means.

6.39 Late discharge billing and charges resulting from a canceled appointment or procedure.

6.40 Telemetry readings, EKG interpretations when billed separately from the EKG procedure. Arterial blood gas interpretations when billed separately from the procedure.

6.41 Services of more than one (1) assistant surgeon at one (1) operative session, unless approved in advance by SHL or its Medical Director. Service of an assistant surgeon when the Hospital provides or makes available qualified staff personnel (including Physicians in training status) as surgical assistants. Services of an assistant surgeon provided solely to meet a Hospital's institutional requirements when the complexity of the surgery does not warrant an assistant surgeon.

6.42 Autologous blood donations.

6.43 Covered Services received in connection with a clinical trial or study which includes the following:

- Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry;
- Healthcare services that are specifically excluded from coverage under this Plan regardless of whether such services are provided under the clinical trial or study;
- Healthcare services that are customarily provided by the sponsors of the clinical trial or study free of charge to the Insured in the clinical trial or study;
- Extraneous expenses related to participation in the clinical trial or study including, but not limited to, travel, housing and other expenses that an Insured may incur;
- Any expenses incurred by a person who accompanies the Insured during the clinical trial or study;
- Any item or service that is provided solely to satisfy a need or desire for data collection or analysis that is not directly related to the clinical management of the Insured; and
- Any cost for the management of research relating to the clinical trial or study.

6.44 If you are eligible for Medicare, any services covered by Medicare under Parts A and B are excluded to the extent actually paid for by Medicare.

6.45 Any services or supplies rendered in connection with the Insured acting as or utilizing the services of a surrogate mother.

6.46 Charges for services by a vision Plan Provider to his or her Dependents.

6.47 Visual therapy.

6.48 Replacement of lost or stolen eyewear.

6.49 Two pairs of eyeglasses in lieu of bifocals.

6.50 Coverage is provided for hearing exams only when required to diagnose an Illness or Injury.

6.51 Bone anchored hearing aids are excluded except when either of the following applies:

- For Insured's with craniofacial anomalies whose abnormal or absent ear canals preclude the use of a wearable hearing aid; or
- For Insured's with hearing loss of sufficient severity that it would not be adequately remedied by a wearable hearing aid.

Also excluded is more than one bone anchored hearing aid per Insured who meets the above coverage criteria during the entire period of time the Insured is enrolled under the Plan, as well as repairs and/or replacements for a bone anchored hearing aid for Insured's who meet the above coverage criteria, other than for malfunctions.

6.52 Any services and supplies not provided for in the Agreement of Coverage, not Medically Necessary as defined by the Agreement of Coverage or not required in accordance with the accepted standards of dental practice of the community, including:

- Services provided by non-participating dentists.
- Charges for services by a dental Plan Provider to his or her Dependents.
- Restorations using gold foil and any precious metal restoration when the tooth can be restored using other filling materials**.**
- Bonding for cosmetic purposes.
- Routine extractions for asymptomatic third (3^{rd}) molar teeth.
- Routine extraction of loose deciduous teeth.
- Telephone consultations.

SECTION 7. Limitations

This section tells you what services are limited under this Plan.

7.1 Calendar Year and Lifetime Maximum Benefit Limitations

Please see the Attachment A Benefit Schedule for Calendar Year maximums or lifetime maximums applicable to certain benefits.

7.2 Emergency Services

If treatment is received by an Insured in a Hospital emergency room or other emergency facility for a condition which may be

Medically Necessary but which does not require Emergency Services as defined in this AOC, a reduced benefit will be allowed toward expenses incurred in connection with Covered Services included in such treatment. Examples of treatment occurring in a Hospital emergency room or other emergency facility which may be Medically Necessary, but not of an emergency nature, include treatment for sore throats, flu/fever, earaches, sore or stiff muscles, sprains, strains, or convenience. If the treatment received was not for a Covered Service or if treatment was received which was not Medically Necessary, no benefit will be paid.

SECTION 8. Coordination of Benefits (COB)

This section tells you how other health insurance you may have affects your coverage under this Plan.

8.1 The Purpose of COB

Coordination of Benefits (COB) is intended to help contain the cost of providing healthcare coverage. When an individual person has dual coverage through SHL and another healthcare plan, the COB guidelines outlined in this section apply. The COB guidelines explain how, in a dual healthcare coverage situation, benefits are coordinated or shared by each plan.

8.2 Benefits Subject to COB

All of the healthcare benefits provided under this AOC are subject to this section. The Insured agrees to permit SHL to coordinate its obligations under this AOC with payment under any other Health Benefit Plan that covers the Insured.

8.3 Definitions

Some words in this section have a special meaning to meet the needs of this section. These words and their meaning when used are:

(a) "**Plan**" will mean an entity providing healthcare benefits or services by any of the following methods:
   1. Insurance or any other arrangement for coverage for individuals whether on an insured or uninsured basis, including the following:
      a. Hospital indemnity benefits with regard to the amount in excess of $30 per day.
      b. Hospital reimbursement type plans which permit the insured person to elect indemnity benefits at the time of claim.
   2. Service plan contracts, group practice, individual practice and other prepayment coverage.
   3. Any coverage for students that is sponsored by, or provided through, school or other educational institutions, other than accident coverage for grammar school or high school students that the parent pays the entire premium.
   4. Any coverage under labor management trusteed plans, union welfare plans, employer organization plans, employee benefit plans, or employee benefit organization plans.
   5. Coverage under a governmental program, including Medicare and workers' compensation plans.

   The term "Plan" will be construed separately with respect to each policy, contract or other arrangement for benefits or services and separately with respect to that portion of any such policy, contract or other arrangement which reserves the right to take the benefits or services of other Plans into consideration in determining its benefits and that portion which does not.

(b) "**Allowable Expense**" means the Eligible Medical Expense for Medically Necessary Covered Services. When a Plan provides benefits in the form of services rather than cash payments, the reasonable cash value of each service rendered shall be an Allowable Expense and a benefit paid.

(c) "**Claim Determination Period**" means the Calendar Year.

(d) "**Primary Plan**" means a Plan that, in accordance with the rules regarding the order of benefits determination, provides benefits or benefit payments without considering any other Plan.

(e) "**Secondary Plan**" means a Plan that in accordance with the rules regarding the order of benefit determination, may reduce its benefits or benefit payments and/or recover from the Primary Plan benefit payments.

8.4 When COB Applies

COB applies when an Insured covered under this Plan is also entitled to receive payment for or provision of some or all of the same Covered Services from another Plan.

8.5 Determination Rules

The rules establishing the order of benefit determination are:

(a) **Non-Dependent or Dependent**. A Plan that covers the person as a Subscriber is primary to a Plan that covers the person as a Dependent.

(b) **Dependent Child of Parents Not Separated or Divorced**. Except as stated in 10.5(c) below, when this Plan and another Plan cover the same child as a Dependent of different parents:
   1. The Plan of the parent whose birthday falls earlier in the Calendar Year is primary to the Plan of the parent whose birthday falls later in the year.
   2. If both parents have the same birthday, the Plan that has covered a parent for a longer period of time is primary.
   3. If the other Plan does not have the rule described in (1) immediately above, but instead has a rule based on the gender of the parent, and if, as a result, the Plans do not agree on the order of benefits, the rule in the other Plan will determine the order of benefits.

(c) **Dependent Child of Separated or Divorced Parents.** If two (2) or more Plans cover a person as a Dependent child of divorced or separated parents, benefits for the child are determined in this order:
   1. If there is a court decree that would establish financial responsibility for the medical, dental or other healthcare expenses with respect to the child, the benefits of a Plan that covers the child as a Dependent of the parent with such financial responsibility shall be determined before the benefits of any other Plan that covers the child as a Dependent child;
   2. Second, the Plan of the parent with custody of the child;

3. Third, the Plan of the spouse (stepparent) of the parent with custody of the child;
4. Finally, the Plan of the parent not having custody of the child.

(d) **Active/Inactive Subscriber**. A Plan that covers a person as a Subscriber who is neither laid-off nor retired (or that Subscriber's Dependents) is primary to a Plan that covers that person as a laid-off or retired Subscriber (or that Subscriber's Dependents). If the other Plan does not have this rule, and if as a result, the Plans do not agree on the order of benefits, this rule (d) is ignored.

(e) **Longer/Shorter Length of Coverage**. If none of the above rules determines the order of benefits, the Plan that covered the person for a longer period of time is primary to the Plan which covered that person for the shorter time period.

Two consecutive Plans shall be treated as one Plan if:

1. That person was eligible under the second Plan within 24 hours after the termination of the first Plan; and
2. There was a change in the amount or scope of a Plan's benefits or there was a change in the entity paying, providing or administering Plan benefits; or
3. There was a change from one type of Plan to another (e.g., single employer to multiple employer Plan).

(f) **If No COB Provision**. If another Plan does not contain a provision coordinating its benefits with those of this Plan, the benefits of such other Plan will be considered primary.

8.6 How COB Works

Plans use COB to decide which healthcare coverage programs should be the Primary Plan for the Covered Service. If the Primary Plan payment is less than the charge for the Covered Service, then the Secondary Plan will apply its Allowable Expense to the unpaid balance. Benefits payable under another Plan include the benefits that would have been payable if the Insured had filed a claim for them.

8.7 Right to Receive and Release Information

In order to decide if this COB Section (or any other Plan's COB Section) applies to a claim, SHL (without the consent of or notice to any person) has the right to the following:

(a) Release to any person, insurance company or organization, the necessary claim information.
(b) Receive from any person, insurance company or organization, the necessary claim information.
(c) Require any person claiming benefits under this Plan to give SHL any information needed by SHL to coordinate those benefits.

8.8 Facility of Payment

If another Plan makes a payment that should have been made by SHL, then SHL has the right to pay the other Plan any amount necessary to satisfy SHL's obligation. Any amount paid shall be deemed to be benefits paid under this Plan, and to the extent of such payments, SHL shall be fully discharged from liability under this Plan.

8.9 Right to Recover Payment

If the amount of benefit payment exceeds the amount needed to satisfy SHL's obligation under this section, SHL has the right to recover the excess amount from one or more of the following:
(a) Any persons to or for whom such payments were made.
(b) Any insurance companies or service plans.
(c) Any other organizations.

8.10 Failure to Cooperate

If an Insured fails to cooperate with SHL's administration of this section, the Insured may be responsible for the expenses for the services rendered and if legal action is taken, a court could make the Insured responsible for any legal expense incurred by SHL to enforce its rights under this section.

Insured cooperation includes the completion of the necessary paperwork that would enable SHL to collect payment from the Primary Plan for services. Any benefits paid to the Insured in excess of actual expenses must be refunded to SHL.

SECTION 9. Premium Payments, Grace Period and Changes in Premium Rates

This section tells you when premium payments are due, what happens when payments are not received and when premium rates can change.

9.1 Monthly Payments

The Premium Due Date is the first (1st) day of the calendar month. On or before the Premium Due Date, the Subscriber will remit to SHL, on behalf of the Subscriber and his covered Dependents the premium amount specified by SHL.

9.2 Grace Period

Only Insureds for whom premium payment is actually received by SHL shall be entitled to Covered Services hereunder and then only for the period for which such payment is received. SHL shall not be liable for any healthcare services incurred by any Insured beyond the period for which the premium payment has been paid. SHL shall be entitled to receive reimbursement from the Subscriber for any claims paid by SHL for services provided after the date of termination.

9.3 Changes in Premium Payments

SHL reserves the right to establish a revised schedule of premium payments provided it gives the Subscriber thirty (30) day notice prior to the Annual Open Enrollment as established by Federal guidelines.

SECTION 10. General Provisions

10.1 Relationship of Parties

The relationship between SHL and Plan Providers is an independent contractor relationship. Plan Providers are not

agents or employees of SHL, nor is SHL, or any employee of SHL, an employee or agent of a Provider. SHL shall not be liable for any claims or demands on account of damages arising out of, or in any manner connected with, any injury suffered by an Insured while receiving care from any Plan Provider. SHL is not bound by statements or promises made by its Plan Providers.

10.2 Authority to Change the Form or Content of this AOC

No agent or employee of SHL is authorized to change the form or content of this AOC or waive any of its provisions. Such changes can be made only through an amendment authorized and signed by an officer of SHL.

10.3 Identification Card

Cards issued by SHL to Insureds pursuant to this Plan are for identification only. Possession of an SHL identification card confers no right to services or other benefits under this Plan. To be entitled to such services or benefits the holder of the card must, in fact, be an Insured on whose behalf all applicable premiums under this Plan have actually been paid. Any person receiving services or other benefits to which he is not then entitled pursuant to the provisions of this AOC will be liable for the actual cost of such services or benefits.

10.4 Notice

Any notice under this Plan may be given by United States mail, first class, postage prepaid, addressed as follows:

Sierra Health and Life Insurance Co., Inc.
P. O. Box 15645
Las Vegas, Nevada 89114-5645

Notice to an Insured will be sent to the last address known to SHL for the Insured.

10.5 Interpretations of the AOC

The laws of the state of issue shall be applied to interpretations of the Plan.

10.6 Modifications

By issuance of the Plan and the Agreement, the coverage available under this Plan becomes available to Insureds who are eligible under Section 1. However, the Plan shall be subject to amendment, modification or termination in accordance with any provision hereof or by mutual agreement between SHL and the Insured. This AOC will automatically be modified to conform with any applicable State and Federal law requirements. SHL reserves the right to establish a revised schedule of premium payments provided it gives the Subscriber thirty (30) day notice prior to the Annual Open Enrollment as established by Federal guidelines. By electing medical and hospital coverage through SHL or accepting any benefits under the Plan, all Insureds legally capable of contracting, and the legal representatives of all Insureds incapable of contracting, agree to all terms, conditions, and provisions hereof.

10.7 Policies and Procedures

SHL may adopt reasonable policies, procedures, rules and interpretations to promote the orderly and efficient administration of this Plan with which Insureds shall comply. These policies and procedures are maintained by SHL at its offices. Such policies and procedures may have bearing on whether a medical service and/or supply is covered.

10.8 Choice of Facility of Provider

Nothing contained in the AOC shall be deemed to restrict an Insured in exercising full freedom of choice in the selection of a Hospital, Skilled Nursing Facility, Physician or Provider for care or treatment of an Illness or Injury.

10.9 Overpayments

SHL has the right to correct payments for healthcare services made in error. Hospitals, Physicians, Providers, and/or Insureds have the responsibility to return any overpayments or incorrect payments to SHL. SHL has the right to offset any such overpayment against any future payments.

10.10 Cost Containment Features

The AOC contains a number of cost containment provisions including, but not limited to:
(a) Second and Third Opinions/Consultations;
(b) Preventive healthcare benefits;
(c) Plan Provider benefit incentives as described in Attachment A Benefit schedule; and
(d) SHL's Managed Care Program.

10.11 Entire Agreement

This AOC, including Attachment A Benefit Schedule and any other Attachments, Endorsements, Riders or Amendments to it, the Insured's Enrollment Form, health statements, Insured Identification Card, and all other applications received by SHL constitutes the entire agreement between the Insured and SHL and as of its Effective Date, replaces all other agreements between the parties. For the duration of time an Insured's coverage is continuously effective under SHL, regardless of the occurrence of any specific Plan or product changes during such time, all benefits paid by SHL under any and all such Plans on behalf of such Insured shall accumulate towards any applicable lifetime or other maximum benefit amounts as stated in the Insured's most current Plan Attachment A Benefit Schedule to the AOC.

This policy, including the endorsements and the attached papers, if any, constitutes the entire contract of insurance. No change in this policy shall be valid until approved by an executive officer of the insurer and unless such approval is endorsed hereon or attached hereto. No agent has authority to change this policy or to waive any of its provisions.

Should SHL decide to discontinue offering and renewing health benefit plans delivered or issued for delivery in this state, SHL

will provide notice of its intention to all persons covered by the discontinued insurance at least 180 days before the nonrenewal of any health benefit plan by the SHL.

10.12 Contestability

No statement made by an Insured for the purpose of effecting any coverage or any increase in coverage under the Plan for such Insured will be used in contesting the validity of the coverage with respect to which such statement was made after such coverage or increase in coverage has been in force prior to the contest for a period of two (2) consecutive years unless the statement is contained in a written instrument signed by the Insured.

10.13 Availability of Providers

SHL does not guarantee the continued availability of any specific Plan Provider or the availability of Plan Providers in all specialty fields.

10.14 Legal Proceedings

No action of law or in equity shall be brought to recover on the Plan prior to the expiration of sixty (60) days after proof of claim has been filed in accordance with the requirements of the AOC. No such action shall be brought at any time unless brought within the time allowed by the laws of the jurisdiction of issue.

If the laws of the jurisdiction of issue do not designate the maximum length of time in which such action may be brought, no action may be brought after three (3) years from the time within which proof of loss is required by the AOC.

10.15 Gender References

Whenever a masculine pronoun is used in this AOC, it also includes the feminine pronoun.

10.16 Authorized Representative

An Insured may elect to designate an "Authorized Representative" to act on their behalf to pursue a Claim for Benefits or the appeal of an Adverse Benefit Determination. The term Insured also includes the Insured's Authorized Representative, where applicable and appropriate. To designate an Authorized Representative, written notice, signed and dated by the Insured, is required. The notice must include the full name of the Authorized Representative and must indicate specifically for which Claim for Benefits or appeal the authorization is valid. The notice should be sent to:

Sierra Health and Life Insurance Co., Inc.
Attn: Customer Response and
Resolution Department
P.O. Box 15645
Las Vegas, Nevada 89114 5645

Any correspondence from SHL regarding the specified Claim for Benefits or appeal will be provided to both the Insured and his Authorized Representative.

In case of an Urgent Care Claim, a healthcare professional with knowledge of the Insured's medical condition shall be permitted to act as an Authorized Representative of the Insured without designation by the Insured.

10.17 Failure to Obtain Prior Authorization

If an Insured fails to follow the Plan's procedures for filing a request for Prior Authorization (Pre-Service Claim), the Insured shall be notified of the failure and the proper procedures to be followed in order to obtain Prior Authorization provided the Insured's request for Prior Authorization is received by an employee or department of the Plan customarily responsible for handling benefit matters and the original request specifically named the Insured, a specific medical condition or symptom, and a specific treatment, service or product for which approval is requested. The Insured notification of correct Prior Authorization procedures from the Plan shall be provided as soon as possible, but not later than five (5) days (twenty-four (24) hours in the case of an Urgent Care Claim) following the Plan's receipt of the Insured's original request. Notification by SHL may be oral unless specifically requested in writing by the Insured.

10.18 Timing of Notification of Benefit Determination

Concurrent Care Decision: If SHL has approved an ongoing course of treatment to be provided over a period of time or number of treatments and reduces or terminates coverage of such course of treatment (other than by Plan amendment or termination) before the end of such period of time or number of treatments, SHL will notify the Insured at a time sufficiently in advance of the reduction or termination to allow the Insured to appeal and obtain a determination before the benefit is reduced or terminated. Subject to the paragraph below, such request may be treated as a new Claim for Benefits and decided within the timeframes applicable to either a Pre-Service Claim or a Post-Service Claim as appropriate. Provided, however, any appeal of such a determination must be made within a reasonable time and may not be afforded the full one-hundred eighty (180) day period as described in the Appeals Procedures section.

Any request by an Insured to extend the course of treatment beyond the period of time or number of treatments for an Urgent Care Claim shall be decided as soon as possible. SHL shall notify the Insured within twenty-four (24) hours after receipt of the Claim for Benefits by the Plan, provided that the request is received at least twenty-four (24) hours prior to the expiration of the authorized period of time or number of treatments. If the request is not made at least twenty-four (24) hours prior to the expiration of the authorized period of time or number of treatments, the request will be treated as an Urgent Care Claim.

10.19 Notification of an Adverse Benefit Determination

If you receive an Adverse Benefit Determination, you will be informed in writing of the following:

- The specific reason or reasons for upholding the Adverse Benefit Determination;
- Reference to the specific Plan provisions on which the determination is based;
- A description of any additional material or information necessary for the Claim for Benefits to be approved, modified or reversed, and an explanation of why such material or information is necessary;
- A description of the review procedures and the time limits applicable to such procedures;
- For Insured's whose coverage is subject to ERISA, a statement of the Insured's right to bring a civil action under ERISA Section 502(a) following an appeal of an Adverse Benefit Determination, if applicable;
- A statement that any internal rule, guideline, protocol or other similar criteria that was relied on in making the determination is available free of charge upon the Insured's request; and
- If the Adverse Benefit Determination is based on Medical Necessity or experimental, investigational or unproventreatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment or a statement that such explanation will be provided free of charge.

SECTION 11. Claims Provisions

This Section tells you how and when to file a claim under the Plan.

11.1 Notice and Proof of Claim

Written notice of each Illness or Injury for which benefits are claimed should be given to SHL within twenty (20) days of the date any healthcare services are received. Failure to furnish notice within twenty (20) days will not invalidate or reduce any claim if it is shown that notice was provided as soon as was reasonably possible.

SHL, upon receipt of such notice, will furnish to the Insured within fifteen (15) days forms for filing the proof of claim. If such forms are not furnished within fifteen (15) days, the Insured shall be deemed to have complied with the requirements of this Plan as to proof of loss upon submitting, within fifteen (15) days, written proof covering the occurrence, the character and the extent of the loss for which the claim is being made.

SHL agrees to:
(a) Provide claim forms to the Insured for submitting claims to SHL;
(b) Receive claims and claims documentation;
(c) Correspond with Insureds and Providers of services if additional information is deemed by SHL to be necessary to complete the processing of claims;
(d) Coordinate benefits payable under the Plan with other benefit plans, if any;
(e) Determine the amount of benefits payable under the Plan; and
(f) Pay the amount of benefits determined to be payable under the Plan.

When seeking reimbursement from SHL for expenses incurred in connection with services received, the Insured must complete a claim form and submit it to the SHL Claims Department with copies of all of the medical records, bills and/or receipts from the Provider. Additional claim forms can be obtained by contacting the Member Services Department at 1-800-888-2264.

If the Insured receives a bill for Covered Services, the Insured may request that SHL pay the Provider directly by sending the bill, with copies of all medical records and a signed completed claim form to the SHL Claims Department.

SHL shall approve or deny a claim within thirty (30) days after receipt of the claim. If the claim is approved, the claim shall be paid within thirty (30) days from the date it was approved.

If the approved claim is not paid within that thirty (30) day period, SHL shall pay interest on the claim at the rate set forth by applicable Nevada law. The interest will be calculated from thirty (30) days after the date on which the claim is approved until the date upon which the claim is paid.

SHL may request additional information to determine whether to approve or deny the claim. SHL shall notify the Provider of its request for additional information within twenty (20) days after receipt of the claim. SHL will notify the Provider of the healthcare services of all the specific reasons for the delay in approving or denying the claim. SHL shall approve or deny the claim within thirty (30) days after receiving the additional information. If the claim is approved, SHL shall pay the claim within thirty (30) days after it receives the additional information. If the approved claim is not paid within that time period, SHL shall pay interest on the claim in the manner set forth above.

If SHL denies the claim, notice to the Insured will include the reasons for the rejection and the Insureds right to file an Informal Appeal as set forth in the Appeals Procedures section of this AOC.

11.2 Timely Filing Requirement

All claims must be submitted to SHL within sixty (60) days from the date expenses were incurred, unless it shall be shown not to have been reasonably possible to give notice within the time limit, and that notice was furnished as soon as was reasonably possible. If the Insured authorizes payment directly to the Provider, a check will be mailed to that Provider. A check will be mailed directly to the Insured if direct payment to the Provider is not authorized. The Insured will receive an explanation of how the payment was determined.

11.3 Late Claims Exclusion

No payment shall be made under the Plan with respect to any claim, including additions or corrections to a claim which has already been submitted, that is not received by SHL within twelve (12) months after the date Covered Services were provided. In no event will SHL pay more than SHL's Eligible Medical Expense for such services.

11.4 Examination

SHL will have the right and opportunity at its own expense to examine the person of any individual whose Illness or Injury is the basis of a claim when and as often as it may reasonably require during the pendency of a claim hereunder and in the case of death, to make an autopsy where not prohibited by law.

SECTION 12. Appeals Procedures

The SHL Appeals Procedures are available to you in the event you are dissatisfied with some aspect of the Plan administration or you wish to appeal an Adverse Benefit Determination. This procedure does not apply to any problem of misunderstanding or misinformation that can be promptly resolved by the Plan supplying the Insured with the appropriate information.

If an Insured's Plan is governed by ERISA, the Insured must exhaust the mandatory level of mandatory appeal before bringing a claim in court for a Claim of Benefits.

Concerns about medical services are best handled at the medical service site level before being brought to SHL. If an Insured contacts SHL regarding an issue related to the medical service site and has not attempted to work with the site staff, the Insured may be directed to that site to try to solve the problem there, if the issue is not a Claim for Benefits.

Please see the Glossary Terms Section herein for a description of the terms used in this section.

The following Appeals Procedures will be followed if the medical service site matter cannot be resolved at the site or if the concern involves the Adverse Benefit Determination of a Claim for Benefits. All Appeals will be adjudicated in a manner designed to ensure independence and impartiality on the part of the persons making the decision.

Formal Appeal: An appeal of an Adverse Benefit Determination filed either orally or in writing which SHL's Customer Response and Resolution Department investigates. If a Formal Appeal is resolved to the satisfaction of the Insured, the appeal is closed. The Formal Appeal is **mandatory** if the Insured is not satisfied with the initial determination and the Insured wishes to appeal such determination.

Member Services Representative: An employee of SHL that is assigned to assist the Insured or the Insured's Authorized Representative in appealing an Adverse Benefit Determination.

12.1 Formal Appeal

A Formal Appeal must be submitted orally or in writing to SHL's Customer Response and Resolution Department within 180 days of an Adverse Benefit Determination. Formal Appeals not filed in a timely manner will be deemed waived with respect to the Adverse Benefit Determination to which they relate.

A Formal Appeal shall contain at least the following information:

- The Insured's name (or name of Insured and Insured's Authorized Representative), address, and telephone number;
- The Insured's SHL Membership number ; and
- A brief statement of the nature of the matter, the reason(s) for the appeal, and why the Insured feels that the Adverse Benefit Determination was wrong.

Additionally, the Insured may submit any supporting medical records, Physician's letters, or other information that explains why SHL should approve the Claim for Benefits. The Insured can request the assistance of a Member Services Representative at any time during this process.

The Formal Appeals should be sent or faxed to the following:

Sierra Health and Life Insurance Co., Inc.
Attn: Customer Response and Resolution Department
PO Box 14865
Las Vegas, NV 89114
Fax: 1-702-266-8813

SHL will investigate the appeal. When the investigation is complete, the Insured will be informed in writing of the resolution within thirty (30) days of receipt of the request for the Formal Appeal. This period may be extended one (1) time by SHL for up to fifteen (15) days, provided that the extension is necessary due to matters beyond the control of SHL and SHL notifies the Insured prior to the expiration of the initial thirty (30) day period of the circumstances requiring the extension and the date by which SHL expects to render a decision. If the extension is necessary due to a failure of the Insured to submit the information necessary to decide the claim, the notice of extension shall specifically describe the required information and the Insured shall be afforded at least forty-five (45) days from receipt of the notice to provide the information.

If the Formal Appeal results in an Adverse Benefit Determination, the Insured will be informed in writing of the following:

- The specific reason or reasons for upholding the Adverse Benefit Determination;
- Reference to the specific Plan provisions on which the determination is based;
- A statement that the Insured is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records, and other information relevant to the Insured's Claim for Benefits;
- A statement that any internal rule, guideline, protocol or other similar criteria that was relied on in making the determination is available free of charge upon the Insured's request; and
- If the Adverse Benefit Determination is based on Medical Necessity or experimental, investigational or unproventreatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment or a statement that such explanation will be provided free of charge as well as information regarding the Insured's right to request an External Review by the State of Nevada's Office for Consumer Health Assistance (OCHA).

Limited extensions may be required if additional information is required in order for SHL to reach a resolution.

12.2 Expedited Appeal

The Insured can ask (either orally or in writing) for an Expedited Appeal of an Adverse Benefit Determination for a Pre-Service Claim that involves an Urgent Care Claim if the Insured or his Physician believe that the health of the Insured could be seriously harmed by waiting for a routine appeal decision. Expedited Appeals are not available for appeals regarding denied claims for benefit payment (Post-Service Claim) or for Pre-Service Claims that are not Urgent Care Claims. Expedited Appeals must be decided no later than seventy-two (72) hours after receipt of the appeal, provided all necessary information has been submitted to SHL. If the initial notification was oral, SHL shall provide a written or electronic explanation to the Insured within three (3) days of the oral notification.

If insufficient information is received, SHL shall notify the Insured as soon as possible, but no later than twenty-four (24) hours after receipt of the claim of the specific information necessary to complete the claim. The Insured will be afforded a reasonable amount of time, taking into account the circumstances, but not less than forty-eight (48) hours, to provide the specified information. SHL shall notify the Insured of the benefit determination as soon as possible, but in no case later than forty-eight (48) hours after the earlier of:

- SHL's receipt of the specified information, or
- The end of the period afforded the Insured to provide the specified information.

If the Insured's Physician requests an Expedited Appeal, or supports an Insured's request for an Expedited Appeal, and indicates that waiting for a routine appeal could seriously harm the health of the Insured or subject the Insured to unmanageable severe pain that cannot be adequately managed without care or treatment that is the subject of the Claim for Benefits, SHL will automatically grant an Expedited Appeal.

If a request for an Expedited Appeal is submitted without support of the Insured's Physician, SHL shall decide whether the Insured's health requires an Expedited Appeal. If an Expedited Appeal is not granted, SHL will provide a decision within thirty (30) days, subject to the routine appeals process for Pre-Service Claims.

12.3 Arbitration of Disputes of an Independent Medical Review

If the Insured is dissatisfied with the findings of an Independent Medical Review, the Insured shall have the right to have the dispute submitted to binding arbitration before an arbiter under the commercial arbitration rules applied by the American Arbitration Association. This review is in place of SHL's Appeals Procedures.

The arbiter will be selected by mutual agreement of SHL and the Insured. The cost and expense of the arbitration shall be paid by SHL. The decision of the arbiter shall be binding upon the Insured and SHL.

12.4 External Review

SHL offers to the Insured or the Insured's Authorized Representative the right to an External Review of an adverse determination. For the purposes of this section, an Insured's Authorized Representative is a person to whom an Insured has given express written consent to represent the Insured in an External Review of an adverse determination; or a person authorized by law to provide substituted consent for an Insured; or a family Insured of an Insured or the Insured's treating provider only when the Insured is unable to provide consent.

Adverse determinations eligible for External Review set forth in this section are only those relating to Medical Necessity, appropriateness of service, healthcare service, healthcare setting, or level of care or effectiveness of a healthcare service. SHL will provide the Insured notice of such an adverse determination which will include the following statement:

> SHL has denied your request for the provision or payment of a requested healthcare service or course of treatment. You may have the right to have our decision reviewed by health care professionals who have no association with us if our decision involved making a judgment as to the Medical Necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested by submitting a request for External Review to the Office for Consumer Health Assistance.

Additionally, as per applicable law and regulations, the notice will provide the Insured the information outlined in Section 10.2 as well as the following:

- The telephone number for the Office for Consumer Health Assistance for the state of jurisdiction of the health carrier and the state in which the Insured resides.
- The right to receive correspondence in a culturally and linguistically appropriate manner.

The notice to the Insured or the Insured's Authorized Representative will also include a HIPAA compliant authorization form by which the Insured or the Insured's Authorized Representative can authorize SHL and the Insured's Physician to disclose protected health information ("PHI"), including medical records, that are pertinent to the External Review, and any other forms as required by Nevada law or regulation.

The Insured or the Insured's Authorized Representative may submit a request directly to OCHA for an External Review of an adverse determination by an Independent Review Organization ("IRO") within four (4) months of the Insured or the Insured's Authorized Representative receiving notice of such determination. The IRO must be certified by the Nevada Division of Insurance. Requests for an External Review must be made in writing and submitted to OCHA at the address below and should include the signed HIPAA authorization form, authorizing the release of your medical records. The entire External Review process and any associated medical records are confidential.

> Office for Consumer Health Assistance
> 555 East Washington Avenue #4800
> Las Vegas NV 89101
> (702) 486-3587

The determination of an IRO concerning an External Review in favor of the Insured of an adverse determination is final, conclusive and binding. Upon receipt of the notice of a decision by the IRO reversing an adverse determination, SHL shall immediately approve coverage of the recommended or requested health care service or treatment that was the subject of the adverse determination. The cost of conducting an External Review of an adverse determination will be paid by SHL.

12.4.a Standard External Review

The Insured may submit a request for an External Review of an adverse determination under this section only after the Insured has exhausted the internal SHL Appeals Procedures provided under this Plan or if SHL fails to issue a written decision to the Insured within thirty (30) days after the date the appeal was filed, and the Insured or Insured's Authorized Representative did not request or agree to a delay or, if SHL agrees to permit the Insured to submit the adverse determination to OCHA without requiring the Insured to exhaust all internal SHL appeals procedures. In such event, the Insured shall be considered to have exhausted the internal SHL appeals process.

Within five (5) days after OCHA receives a request for External Review, OCHA shall notify the Insured, the Insured's Authorized Representative and SHL that such request has been received and filed. As soon as practical, OCHA shall assign an IRO to review the case.

Within five (5) days after receiving notification specifying the assigned IRO from OCHA, SHL shall provide to the selected IRO all documents and materials relating to the adverse determination, including, without limitation:

- Any medical records of the Insured relating to the adverse determination;
- A copy of the provisions of this Plan upon which the adverse determination was based;
- Any documents used and the reason(s) given by SHL's Managed Care Program for the adverse determination; and
- If applicable, a list that specifies each Provider who provided healthcare to the Insured and the corresponding medical records from the Provider relating to the adverse determination.

Within five (5) days after the IRO receives the required documentation from SHL, they shall notify the Insured or the Insured's Authorized Representative, if any additional information is required to conduct the review. If additional information is required, it must be provided to the IRO within five (5) days after receiving the request. The IRO will forward a copy of the additional information to SHL within one (1) business day after receipt.

The IRO shall approve, modify, or reverse the adverse determination within fifteen (15) days after it receives the information required to make such a determination. The IRO shall submit a copy of its determination, including the basis thereof, to the:

- Insured;
- Insured's Physician;
- Insured's Authorized Representative, if any; and
- SHL.

12.4.b Expedited External Review

A request for an Expedited External Review may be submitted to OCHA after it receives proof from the Insured's Provider that the adverse determination concerns:

- An inpatient admission;
- availability of inpatient care;
- continued stay or health care service for Emergency Services while still admitted to an inpatient facility; or
- failure to proceed in an expedited manner may jeopardize the life or health of the Insured.

The OCHA shall approve or deny this request for Expedited External Review with seventy-two (72) hours after receipt of the above required proof. If OCHA approves the request, it shall assign the request to an IRO no later than one (1) business day after approving the request. SHL will supply all relevant medical documents and information used to establish the adverse determination to the IRO within twenty-four (24) hours after receiving notice from the OCHA.

The IRO shall complete its Expedited External Review within forty-eight (48) hours after initially being assigned the case unless the Insured or the Insured's Authorized Representative and SHL agree to a longer time period.

The IRO shall notify the following parties no later than twenty-four (24) hours after completing its Expedited External Review:

- Insured;
- Insured's Physician;
- Insured's Authorized Representative, if any; and
- SHL.

The IRO shall then submit a written copy of its determination within forty-eight (48) hours to the applicable parties listed above.

12.5 Request for an External Review Due to Denial of Experimental, Investigational or Unproven Healthcare Service or Treatment.

A Standard or Expedited External Review of an adverse determination due to a requested or recommended healthcare service or treatment being deemed experimental, investigational or unproven, is available in limited circumstances as outlined in the following sections.

12.5.a Standard External Review

The Insured or Insured's Authorized Representative may within four (4) months after receiving notice of an adverse determination subject to this section, submit a request to the OCHA for an External Review.

OCHA will notify SHL and/or any other interested parties within one (1) business day after the receipt of the request for External Review. Within five (5) business days after SHL receives such notice and, subject to applicable Nevada law and regulation and pursuant to this section, SHL will make a preliminary determination of whether the case is complete and

eligible for External Review according to Nevada law and regulations.

Within one (1) business day of making such a determination, SHL will notify in writing, the Insured or the Insured's Authorized Representative and OCHA, accordingly. If SHL determines that the case is incomplete and/or ineligible, SHL will notify the Insured in writing of such determination. Such notice shall include the required additional information or materials needed to make the request complete and, if applicable, state the reasons for ineligibility and also state that such determination may be appealed to OCHA. Upon appeal, OCHA may overturn SHL's determination that a request for External Review of an adverse determination is ineligible, and submit the request to External Review, subject to all of the terms and provisions of this Plan and applicable Nevada law and regulation.

Within one (1) business day after receiving the confirmation of eligibility for External Review from SHL, OCHA will assign the IRO accordingly and notify in writing the Insured or the Insured's Authorized Representative and SHL that the request is complete and eligible for External Review and provide the name of the assigned IRO. SHL, within five (5) days after receipt of such notice from the OCHA, will supply all relevant medical documents and information used to establish the adverse determination to the assigned IRO who will select and assign one or more clinical reviewers to the External Review.

The IRO shall approve, modify, or reverse the adverse determination pursuant to this section within twenty (20) days after it receives the information required to make such a determination.

The IRO shall submit a copy of its determination, including the basis thereof, to the:

- Insured;
- Insured's Physician;
- Insured's Authorized Representative, if any; and
- SHL.

12.5.b Expedited External Review

The Insured or the Insured's Authorized Representative may request in writing, an internal Expedited appeal by SHL and an Expedited External Review from OCHA simultaneously if the adverse determination of the requested or recommended service or treatment is determined by SHL to be experimental, investigational or unproven, and, if the treating provider certifies, in writing, that such service or treatment would be less effective if not promptly initiated.

An oral request for an Expedited External Review may be submitted directly to the OCHA upon the written submission of proof from the Insured's Provider to OCHA that such service or treatment would be significantly less effective if not promptly initiated. Upon receipt of such request and proof, the OCHA shall immediately notify SHL accordingly.

SHL will immediately determine if the request meets the requirements for Expedited External Review pursuant to this section and notify the Insured or the Insured's Authorized Representative and the OCHA of the determination. If SHL determines the request to be ineligible, the Insured will be notified that the request may be appealed to OCHA.

If OCHA approves the request for Expedited External Review, it shall immediately assign the request to an IRO and notify SHL. The IRO has one (1) business day to select one or more clinical reviewers. SHL must submit the documentation used to support the adverse determination to the IRO within five (5) business days. If SHL fails to provide the information within the specified time, the IRO may terminate the External Review and reverse the adverse determination.

The Insured or Insured's Authorized Representative may, within five (5) business days after receiving notice of the assigned IRO, submit any additional information in writing to the IRO. Any information submitted by the Insured or the Insured's Authorized Representative after five (5) business days to the IRO may be considered as well. Any information received by the Insured or the Insured's Authorized Representative must be submitted to SHL by the IRO within one (1) business day.
The clinical reviewers have no more than five (5) days to provide an opinion to the IRO. The IRO has forty-eight (48) hours to review the opinion of the clinical reviewers and make a determination.

The IRO shall notify the following parties no later than twenty-four (24) hours after completing its External Review:

- Insured;
- Insured's Physician;
- Insured's Authorized Representative, if any; and
- SHL.

The IRO shall then submit a written copy of its determination within forty-eight (48) hours to the applicable parties listed above.

12.6 Office for Consumer Health Assistance

- (702) 486-3587 in Las Vegas area
- 1-888-333-1597 outside of Las Vegas area (toll-free)

SECTION 13. Glossary

13.1 "**Adverse Benefit Determination**" means a rescission of coverage; a decision by SHL to deny, reduce, terminate, fail to provide, or make payment for a benefit, including a denial, reduction termination, or failure to provide, or make a payment for a benefit that is based on: an individual's eligibility; a determination that a benefit is not a Covered Service or other limitation on an otherwise Covered Service; or a determination that a benefit isexperimental, investigational or unproven, or not Medically Necessary or appropriate.

External Review is only available for a Final Adverse Benefit Determination based on Medical Necessity, appropriateness, health care setting, level of care or effectiveness of a Covered Service. An Adverse Benefit Determination is final if the Insured has exhausted all complaint and Appeal Procedures set

forth herein for the review of such Adverse Benefit Determination.

13.2 **"Agreement of Coverage" or "AOC"** means this document including any Attachments or Endorsements thereto, the Insured's Identification Card, health statements and all applications received by SHL.

13.3 "**Ambulance**" means a ground or air vehicle licensed to provide Ambulance services.

13.4 "**Ambulatory Surgical Facility**" means a facility that:

- Is licensed by the state where it is located.
- Is equipped and operated mainly to provide for surgeries or obstetrical deliveries.
- Allows patients to leave the facility the same day the surgery or delivery occurs.

13.5 **"Application Review Period"** means the period of time that must pass before coverage for an individual or Eligible Family Member can become effective. The Application Review Period begins on the date the individual submits a substantially complete application for coverage and ends on the following:

- the date coverage begins if the application results in coverage; or
- the date on which the application is denied by SHL if the application does not result in coverage; or
- the date on which the offer for coverage lapses if the application does not result in coverage.

13.6 **"Applied Behavior Analysis"** or **"ABA"** means the design, implementation and evaluation of environmental modifications using behavioral stimuli and consequences to produce socially significant improvement in human behavior, including, but not limited to, the use of direct observation, measurement and functional analysis of the relations between environment and behavior.

13.7 "**Authorized Representative**" means a person designated by the Insured to act on his behalf in pursuing a Claim for Benefits, to file an appeal of an Adverse Benefit Determination, or in obtaining an External Review of an adverse determination. The designation must be in writing unless the claim or appeal involves an Urgent Care Claim and a healthcare professional with knowledge of the Insured's medical condition is seeking to act on the Insured's behalf as his Authorized Representative.

13.8 **"Autism Behavior Interventionist"** means a person who is certified as an Autism Behavior Interventionist by the Board of Psychological Examiners and who provides Behavior Therapy under the supervision of:

1. A licensed psychologist;
2. A Licensed Behavior Analyst; or
3. A Licensed Assistant Behavior Analyst.

13.9 **"Autism Spectrum Disorders"** means a neurobiological medical condition including, but not limited to, autistic disorder, Asperger's Disorder and Pervasive Developmental Disorder not otherwise specified.

13.10 "**Benefit Schedule**" means the brief summary of benefits, limitations and Copayments given to the Subscriber by SHL. It is Attachment A to this AOC.

13.11 **"Blended Lenses"** means bifocals which do not a visible dividing line.

13.12 "**Calendar Year**" means January 1 through December 31 of the same year.

13.13 **"Calendar Year Out of Pocket Maximum"** means the maximum amount of Out of Pocket expenses an Insured is required to pay for Covered Services in a Calendar Year, as outlined in the Attachment A, Schedule of Benefits. Once the Calendar Year Out of Pocket Maximum is met, no further cost share is required for the remainder of the Calendar Year.

The Out of Pocket Maximum does not include any expenses:

- for reduction in benefits resulting from Insured's failure to comply with SHL's Managed Care Program, including the inappropriate use of an emergency room facility for a condition which does not require Emergency Services;
- in excess of Eligible Medical Expenses;
- for services that are not Covered Services under this Plan; or
- in excess of the Calendar Year, per Illness or any other benefit maximums as set forth in Attachment A Benefit Schedule.

13.14 "**Claim for Benefits**" means a request for a Plan benefit or benefits made by an Insured in accordance with the Plan's Appeals Procedures, including any Pre-Service Claims (requests for Prior Authorization) and Post-Service Claims (requests for benefit payment).

13.15 **"Coated Lenses"** means a substance which is added to a finished lens on one or both surfaces.

13.16 **"Coinsurance"** means the percentage of the charges billed or the percentage of eligible Medical Expenses, whichever is less, that an Insured must pay a Provider for Covered Services. Coinsurance amounts are to be paid by the Insured directly to the Provider who bills for the Covered Services. (See Attachment A Benefit Schedule.)

13.17 **"Complications of Pregnancy"** means:

- conditions with diagnoses which are distinct from pregnancy but adversely affected by pregnancy or caused by pregnancy. Such conditions include: acute nephritis; nephrosis, cardiac decompensation; hyperemesis gravidarum;

puerperal infection; toxemia; eclampsia; and missed abortion;
- a nonelective cesarean section;
- terminated ectopic pregnancy; or
- spontaneous termination of pregnancy which occurs during a period of gestation in which a viable birth is not possible.

Complications of pregnancy does NOT include (1) false or premature labor; (2) occasional spotting; (3) prescribed rest during the period of pregnancy; or (4) similar conditions associated with the management of a difficult or high risk pregnancy not constituting a distinct Complication of Pregnancy.

13.18 "**Copayment" or "Cost-share"** means the amount the Insured pays when a Covered Service is received.

13.19 "**Contact Lenses"** means ophthalmic corrective Lenses, either glass or plastic, ground or molded as prescribed by a Plan Provider to be fitted directly to the patient's eyes.

13.20 **"Convenient Care Facility"** means a facility that provides services for Medically Necessary, non-urgent or non-emergent injuries or illnesses. Examples of such conditions include:
1. diagnostic laboratory services;
2. general health screenings;
3. minor wound treatment and repair;
4. minor illnesses (cold/flu);
5. treatment of burns and sprains;
6. blood pressure checks.

13.21 "**Covered Services**" means the health services, supplies and accommodations for which SHL pays benefits under this Plan.

13.22 "**Covered Transplant Procedure**" means any Medically Necessary, human-to-human, organ or tissue transplants performed upon an Insured who satisfies medical criteria developed by SHL for receiving transplant services.

13.23 "**Custodial Care**" means care that mainly provides room and board (meals) for a physically or mentally disabled person. Such care does not reduce the disability so that the person can live outside a Hospital or nursing home. Examples of Custodial Care include:
- Non-Skilled Nursing Care.
- Training or assistance in personal hygiene.
- Other forms of self-care.
- Supervisory care by a Physician in a custodial facility to meet regulatory requirements.

13.24 **"Date of Onset"** means the day the Insured first had a symptom or condition that a Provider could have used to identify the Illness or Injury or other condition with reasonable accuracy.

13.25 **"Deductible"** means the portion of Eligible Medical Expenses, excluding Copayments, billed by Providers each Calendar Year that an Insured must pay, either in the aggregate or for a particular service, before SHL will make any benefit payments for Covered Services. (See Attachment A Benefit Schedule.)

13.26 **"Dentist"** means anyone qualified and licensed to practice dentistry who has a degree of Doctor or Dental Surgery (D.D.S.) or Doctor of Medical Dentistry (D.M.D.)

13.27 **"Dental Director"** means a Dentist designated by SHL to review the utilization of dental services by Insureds.

13.28 "**Dependent**" means an Eligible Family Member of the Subscriber's family who:
- meets the eligibility requirements of the Plan as set forth in Section 1 of the AOC;
- is enrolled under this Plan; and
- for whom premiums have been received and accepted by SHL.

13.29 **"Designated Facility" means** a facility that has entered into an agreement with us, or with an organization contracting on our behalf, to render Covered Health Services for the treatment of specified diseases or conditions. A Designated Facility may or may not be located within your geographic area. The fact that a Hospital is a Network Hospital does not mean that it is a Designated Facility.

13.30 "**Durable Medical Equipment**" or "**DME**" means medical equipment that:
- can withstand repeated use;
- is used primarily and customarily for a medical purpose rather than convenience or comfort;
- generally is not useful to a person in the absence of an Illness or Injury;
- is appropriate for use in the home; and
- is prescribed by a Physician.

13.31 "**Effective Date**" means the initial date on which Insureds are covered for services under this Agreement of Coverage provided any applicable premiums have been received and accepted by SHL.

13.32 **"Eligible Dental Expenses" ("EDE")** means the maximum amount SHL will pay for a particular Covered Service as determined by SHL in accordance with SHL Reimbursement Schedule. Dental Plan Providers have agreed to accept SHL's reimbursement as payment in full for Covered Services, less any applicable Copayment. Deductible or Coinsurance. In no event will SHL pay more than the maximum payment allowance established in the SHL Reimbursement Schedule.

13.33 "**Eligible Family Member**" means a member of the Subscriber's family that is eligible to enroll for coverage under this Plan as a Dependent.

13.34 "**Eligible Medical Expenses**" or "**EME**" means the maximum amount SHL will pay for a particular Covered Service as determined by SHL in accordance with SHL's Reimbursement Schedule.

13.35 **"Eligible Vision Expenses" (EVE)** means the maximum allowable amount the Company will pay for a particular Covered Service as determined by the Company in accordance with the SHL Reimbursement Schedule. Vision Plan Providers have agreed to accept the SHL Reimbursement Schedule as payment in full for Covered Services, less any applicable Copayment. In no event will SHL pay more than the maximum payment allowance established in the SHL Reimbursement Schedule.

13.36 "**Emergency Services**" means Covered Services provided after the sudden onset of a medical condition with symptoms severe enough to cause a prudent person to believe that lack of immediate medical attention could result in serious:

- jeopardy to his health;
- jeopardy to the health of an unborn child;
- impairment of a bodily function; or
- dysfunction of any bodily organ or part.

13.37 "**Enrollment Date**" means the first day of coverage under this Plan or, if there is a Waiting Period, the first day of the Waiting Period.

13.38 "**ERISA**" means Employee Retirement Income Security Act of 1974, as amended, including regulations implementing the Act.

13.39 **"Essential Benefits"** include the following: ambulatory services; Emergency Services; hospitalization; maternity and newborn care; mental health and substance abuse disorder services (including behavioral health treatment); prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services; including oral and vision care.

Such benefits shall be consistent with those set forth under the Patient Protection and Affordable Care Act of 2010 and any regulations issued pursuant thereto.

13.40 "**Expedited Appeal**" means if an Insured appeals a decision regarding a denied request for Prior Authorization (Pre-Service Claim) for an Urgent Care Claim, the Insured or Insured's Authorized Representative can request an Expedited Appeal, either orally or in writing. Decisions regarding an Expedited Appeal are generally made within seventy-two (72) hours from the Plan's receipt of the request.

13.41 "**External Review**" means an independent review of an Adverse Benefit Determination conducted by an Independent Review Organization.

13.42 **"Final Adverse Benefit Determination"** means the upholding of an Adverse Benefit Determination at the conclusion of the internal appeals process or an Adverse Benefit Determination in which the internal appeals process has been deemed exhausted.

External Review is only available for a Final Adverse Benefit Determination based on Medical Necessity, appropriateness, health care setting, level of care, or effectiveness of a Covered Service.

13.43 **"Frames"** mean standard eyeglass Frames adequate to hold two Lenses.

13.44 **"Free Standing Diagnostic Center"** means a licensed establishment which has permanent facilities that are equipped and operated primarily for the purpose of performing outpatient diagnostic services.

13.45 "**Genetic Disease Testing**" means the analysis of human DNA, chromosomes, proteins or other gene products to determine the presence of disease related genotypes, mutations, phenotypes or karyotypes for clinical purposes. Such purposes include those tests meeting criteria for the medically accepted standard of care for the prediction of disease risks, identification of carriers, monitoring, diagnosis or prognosis, but do not include tests conducted purely for research.

13.46 **"Habilitative Services"** means occupational therapy, physical therapy and speech therapy prescribed by the Insured 's treating Physician pursuant to a treatment plan to develop a function not currently present as a result of a congenital, genetic, or early acquired disorder.

- A "congenital or genetic disorder" includes, but is not limited to, hereditary disorders.
- An "early acquired disorder" refers to a disorder resulting from Sickness, Injury, trauma or some other event or condition suffered by an Insured prior to that Insured developing functional life skills such as, but not limited to, walking, talking, or self-help skills.

13.47 "**Health Benefit Plan**" means a policy, contract, certificate or agreement offered by a carrier or similar agreement offered by an employer or other legal entity, to provide for, arrange for payment of, pay for or reimburse any of the costs of healthcare services. This term includes Short-Term and catastrophic health insurance policies, and a policy that pays on a cost-incurred basis. Health Benefit Plans do not include:

- Coverage for accident only, dental only, vision only, disability income insurance, long-term care only insurance, hospital indemnity coverage or other fixed indemnity coverage, limited benefit coverage, specific disease/Illness coverage, credit-only insurance;
- Coverage issued as a supplement to liability insurance;
- Liability insurance, including general liability insurance and automobile liability insurance;
- Workers' compensation insurance;

- Coverage for medical payments under a policy of automobile insurance;
- Coverage for on-site medical clinics; or
- Medicare supplemental health insurance.

13.48 "**Home Healthcare**" means healthcare services given by a Home Healthcare agency under a Physician's orders in the person's home. It is care given to persons who are homebound for medical reasons and physically not able to obtain necessary medical care on an outpatient basis. A Home Healthcare agency must be licensed by the state where it is located.

13.49 "**Hospice**" means an establishment licensed by the state where it is located that furnishes a centrally administered program of palliative and supportive services. Such services are provided by a team of healthcare Providers and directed by a Physician. Services include physical, psychological, custodial and spiritual care for patients who are terminally ill and their families. For the purposes of this benefit only, "family" includes the immediate family, the person who primarily cared for the patient and other persons with significant personal ties to the patient, whether or not related by blood.

13.50 "**Hospice Care Services**" means acute care provided by a Hospice if the Insured has less than six (6) months to live as certified by the treating Physician, and the Insured is not receiving or intending to receive any curative treatment. Care may be provided in the home, at a residential facility or at a medical facility at any time of the day or night. These services include bereavement care provided to the patient's family after the patient dies.

13.51 "**Hospital**" means a facility that:

- is licensed by the state where it is located and is Medicare-certified;
- provides 24-hour nursing services by registered nurses (RNs) on duty or call; and
- provides services under the supervision of a staff of one or more Physicians to diagnose and treat ill or injured bed patients hospitalized for surgical, medical or psychiatric conditions.

Hospital does not include:

- residential or nonresidential treatment facilities;
- health resorts;
- nursing homes;
- Christian Science sanataria;
- institutions for exceptional children;
- Skilled Nursing Facilities, places that are primarily for the care of convalescents;
- clinics;
- Physician offices;
- private homes; or
- Ambulatory Surgical Facilities.

13.52 "**Illness**" means an abnormal state of health resulting from disease, sickness or malfunction of the body; or a congenital malformation, which causes functional impairment. For purposes of this AOC, Illness also includes sterilization or circumcision. Illness does not include any state of mental health or mental disorder other than Mental Illness as it is defined in this AOC.

13.53 "**Independent Medical Review**" means an independent evaluation of the medical or chiropractic care of an Insured that must include a physical examination of the Insured unless he is deceased, and a personal review of all x-rays and reports by a certified Physician or Chiropractor who is formally educated in the applicable medical field.

13.54 **"Independent Review Organization"** means an entity that:

- conducts an independent External Review of an adverse determination; and
- is certified by the Nevada Commissioner of Insurance

13.55 "**Initial Enrollment Period**" means the period of time during which an eligible person may enroll under this Plan.

13.56 "**Injury**" means physical damage to the body inflicted by a foreign object, force, temperature, or corrosive chemical.

13.57 "**Inpatient**" means being confined in a Hospital or Skilled Nursing Facility as a registered bed patient under a Physician's order.

13.58 "**Insured**" means a person who meets the eligibility requirements of Section 1., who has enrolled under this Plan and for whom premiums have been received and accepted by SHL.

13.59 **"Lenses"** mean ophthalmic corrective Lenses, either glass or plastic, ground or molded as prescribed by a Vision Plan Provider to be fitted into frames.

13.60 **"Licensed Assistant Behavior Analyst"** means a person who holds current certification or meets the standards to be certified as a board certified Assistant Behavior Analyst issued by the Behavior Analyst Certification Board, Inc., or any successor in interest to that organization, who is licensed as an Assistant Behavior Analyst by the Board of Psychological Examiners and who provides Behavioral Therapy under the supervision of a Licensed Behavior Analyst or psychologist.

13.61 **"Licensed Behavior Analyst"** means a person who holds current certification or meets the standards to be certified as a board certified Behavior Analyst or a board certified Assistant Behavior Analyst issued by the Behavior Analyst Certification Board, Inc., or any successor in interest to that organization and whom the Board of Psychological Examiners licenses as a Behavior Analyst.

13.62 **"Low Vision"** means a significant loss of vision but not total blindness.

13.63 "**Managed Care Program**" means the process that determines Medical Necessity and directs care to the most appropriate setting to provide quality care in a cost-effective manner, including Prior Authorization of certain services.

13.64 "**Manual Manipulation**" means the diagnosis, treatment or maintenance by a Practitioner for the treatment of:

- musculoskeletal strain surrounding vertebra, spine, broken neck; or
- subluxation of vertebra.

Manual Manipulation does not include diagnosis or treatment requiring general anesthesia, surgery or Hospital confinement.

13.65 "**Medical Director**" means a Physician named by SHL to review use of health services by Insureds.

13.66 "**Medically Necessary**" means a service or supply needed to improve a specific health condition or to preserve the Insured's health and which, as determined by SHL is:

- consistent with the diagnosis and treatment of the Insured's Illness or Injury;
- the most appropriate level of service which can be safely provided to the Insured; and
- not solely for the convenience of the Insured, the Provider(s) or Hospital.

In determining whether a service or supply is Medically Necessary, SHL may give consideration to any or all of the following:

- the likelihood of a certain service or supply producing a significant positive outcome;
- reports in peer-review literature;
- evidence based reports and guidelines published by nationally recognized professional organizations that include supporting scientific data;
- professional standards of safety and effectiveness that are generally recognized in the United States for diagnosis, care or treatment;
- the opinions of independent expert Physicians in the health specialty involved when such opinions are based on broad professional consensus; or
- other relevant information obtained by SHL.

When applied to Inpatient services, "Medically Necessary" further means that the Insured's condition requires treatment in a Hospital rather than in any other setting. **Services and accommodations will not automatically be considered Medically Necessary simply because they were prescribed by a Physician.**

13.67 "**Medically Necessary for External Review**" means healthcare services or products that a prudent Physician would provide to a patient to prevent, diagnose or treat an Illness, Injury or disease or any symptoms thereof that are necessary and:

- provided in accordance with generally accepted standards of medical practice;
- clinically appropriate with regard to type, frequency, extent, location and duration;
- not primarily provided for the convenience of the patient, Physician or other Provider of healthcare;
- required to improve a specific health condition of an Insured or to preserve his existing state of health; and
- the most clinically appropriate level of healthcare that may be safely provided to the Insured.

13.68 "**Medicare**" means Medicare Part A and Medicare Part B healthcare benefits that an Insured is receiving under Title XVIII of the Social Security Act of 1965 as amended.

13.69 "**Mental Illness**" means a pathological state of mind producing clinically significant psychological or physiological symptoms together with impairment in one or more major areas of functioning where improvement can reasonably be anticipated with therapy. Mental Illness does not include any Severe Mental Illness as defined in the AOC and otherwise covered under the Severe Mental Illness Covered Services section, or any of the following when they represent the primary need for therapy:

- Marital or family problems;
- Social, occupational, or religious maladjustment;
- Behavior disorders;
- Impulse control disorders;
- Learning disabilities;
- Mental retardation;
- Chronic organic brain syndrome;
- Personality disorder; or

13.70 "**Non-Plan Provider**" means a Provider who does not have an independent contractor agreement with SHL.

13.71 "**Occupational Illness or Injury**" means any Illness or Injury arising out of or in the course of employment for pay or profit.

13.72 **"Orthoptics"** means the teaching and training process for the improvement of visual perception and coordination of the two eyes for efficient and comfortable binocular vision.

13.73 "**Orthotic Devices**" means an apparatus used to support, align, prevent or correct deformities or to improve the function of movable parts of the body.

13.74 **"Oversize Lenses"** means larger than standard lens blank, to accommodate prescriptions.

13.75 **"Photochromic Lenses"** means lenses which change color with intensity of sunlight.

13.76 "**Physician**" means anyone qualified and licensed to practice medicine and surgery by the state where the

practice is located who has the degree of Doctor of Medicine (MD) or Doctor of Osteopathy (DO). Physician also means Doctor of Dentistry, a Doctor of Podiatric Medicine or a Chiropractor when they are acting within the scope of their license.

13.77 **"Physician Extender/Physician Assistant"** means a health care provider who is not a physician (MD/DO) but who performs medical activities typically performed by a physician. It is most commonly a nurse practitioner or physician assistant.

13.78 "**Placed (or Placement) for Adoption**" means the assumption and retention of a legal obligation for total or partial support of a child by a person with whom the child has been placed in anticipation of the child's adoption. The child's Placement for Adoption with such person ends upon the termination of such legal obligation.

13.79 "**Plan**" means this Agreement of Coverage (AOC), including the Attachment A Benefit Schedule and any other Attachments, Endorsements, Riders or Amendments to it, the Insured's Enrollment Form, health statements, the Insured Identification Card, and all other applications received by SHL.

13.80 **"Plan Dentist"** means a Dentist who has an independent contractor agreement with SHL to provide Covered Services to Insureds.

13.81 "**Plan Physician**" means a Physician who has an independent contractor agreement with SHL to provide certain Covered Services to Insureds. A Plan Provider's agreement with SHL may terminate, and an Insured will be required to select another Plan Provider.

13.82 "**Plan Provider**" means a Provider who has an independent contractor agreement with SHL to provide certain Covered Services to Insureds. A Plan Provider's agreement with SHL may terminate, and an Insured receiving care from that Provider may be required to select another Plan Provider.

13.83 **"Plano Lenses"** means lenses which have no refractive power.

13.84 "**Post-Service Claim**" means any Claim for Benefits under a Health Benefit Plan regarding payment of benefits that is not considered a Pre-Service Claim or an Urgent Care Claim.

13.85 "**Practitioner**" means any person(s) qualified and licensed to practice the healing arts when they are acting within the scope of their license.

13.86 **"Predetermination"** means a system that requires a Plan Provider to get approval from SHL before providing non-emergent healthcare services to a Insured for those services to be considered Covered Services. Prior Authorization is not an agreement to pay for a service.

13.87 "**Pre-Service Claim**" means any Claim for Benefits under a Health Benefit Plan with respect to which the terms of the Plan condition receipt of the benefit, in whole or in part, on approval of the benefit in advance of obtaining medical care.

13.88 "**Prescription Drug**" means any required by federal law or regulation to be dispensed only by a prescription including finished dosage forms and active ingredients subject to the Federal Food, Drug and Cosmetic Act.

13.89 "**Prior Authorization**" or "**Prior Authorized**" means a system that requires a Provider to get approval from SHL before providing non-emergency healthcare services to an Insured for those services to be considered Covered Services. Prior Authorization is not an agreement to pay for a service.

13.90 "**Procurement**" means obtaining Medically Necessary human organs or tissue for a Covered Transplant Procedure as determined by SHL and includes donor search, testing, removal, preservation and transportation of the donated organ or tissue. Procurement will also apply to medically appropriate donor testing services including, but not limited to, HLA typing, subject to any maximum procurement benefit amount. Procurement does not include maintenance of a donor while the Insured is awaiting the transplant.

13.91 **"Professional Vision Services"** means examination, material selection, fitting of glasses, related adjustments, etc.

13.92 "**Prosthetic Device**" means a non-experimental device that replaces all or part of an internal or external body organ or replaces all or part of the function of a permanently inoperative or malfunctioning internal or external organ.

13.93 **"Provider"** means a:

- Hospital,
- Skilled Nursing Facility,
- Urgent Care Facility,
- Ambulatory Surgical Facility,
- Physician,
- Practitioner,
- dentist,
- podiatrist, or
- other person or organization licensed by the state where his practice is located to provide medical or surgical services, supplies, and accommodations acting within the scope of his license.

13.94 "**Referral**" means a recommendation for an Insured to receive a service or care from another Provider or facility.

13.95 "**Retransplant**" means the retransplantation of a previously transplanted organ or tissue.

13.96 "**Retrospective**" or "**Retrospectively**" means a review of an event after it has taken place.

13.97 "**Rider**" means a provision added to the Plan or the AOC to expand benefits or coverage.

13.98 "**Severe Mental Illness**" means any of the following Mental Illnesses that are biologically based and for which diagnostic criteria are prescribed in the Diagnostic and Statistical Manual of Mental Disorder (DSM), published by the American Psychiatric Association:

- Schizophrenia
- Schizoaffective disorder
- Bipolar disorder
- Major depressive disorders
- Panic disorder
- Obsessive-compulsive disorder.

13.99 "**SHL Reimbursement Schedule**" means the schedule showing the amount SHL will pay for Eligible Medical Expenses (EME) to Providers. EME will be applicable to Non-Plan Providers including Non-Plan Facilities. SHL Reimbursement Schedule is based on:

- the amount most consistently paid to the Provider; or
- the amount paid to other Providers with the same or similar qualifications; or
- the relative value and worth of the service compared to other services which SHL determines to be similar in complexity and nature with reference to other industry and governmental sources, examples of these sources include published rates allowed by the Centers for Medicare and Medicaid Services (CMS) for Medicare for the same or similar services within the geographic market, a gap methodology, or Eligible Medical Expense could be based on a percentage of the provider's billed charge.

For Non-Plan Provider Emergency Services, SHL will pay the greater of:

- the amount we have negotiated with Plan Providers for the Emergency Services received (and if there is more than one amount, the median of the amounts); or
- 100% of the Eligible Medical Expense for Emergency Services provided by a Non-Plan Provider under your Plan; or
- the amount that would be paid for the Emergency Services under Medicare.

13.100 "**Short-Term**" means the time required for treatment of a condition that, in the judgment of the Insured's Physician and SHL, is subject to significant improvement within sixty (60) consecutive calendar days from the first day of treatment.

13.101 "**Short-Term Rehabilitation**" means Inpatient or outpatient rehabilitation services which are provided within the applicable number of visits as set forth in the Plan's Attachment A Benefit Schedule. This includes speech therapy, occupational therapy and physical therapy.

13.102 "**Skilled Nursing Care**" means services requiring the skill, training or supervision of licensed nursing personnel.

13.103 "**Skilled Nursing Facility**" means a facility or distinct part of a facility that is licensed by the state where it is located to provide Skilled Nursing Care instead of Hospitalization and that has an attending medical staff consisting of one or more Physicians.

13.104 "**Specialist Physician**" or "**Specialist**" means a Physician who assumes responsibility for the delivery of specialty medical services to Insureds. These specialty medical services include any Physician services not related to the ongoing primary care of the Insured.

13.105 **"Specialty Drugs"** are high-cost oral, injectable, infused or inhaled Covered Drugs as identified by SHL's P&T Committee that are either self-administered or administered by a healthcare Provider and used or obtained in either an outpatient or home setting.

13.106 "**Subscriber**" means an Individual who meets the eligibility requirements of this AOC and who has enrolled under this Plan, and for whom premiums have been received and accepted by SHL.

13.107 **"Summary of Benefits" ("SBC")** means a concise document detailing, in plain language, simple and consistent information about health plan benefits and coverage. The SBC helps consumers better understand the coverage they have and allow them to easily compare different coverage options. It will summarize the key features of the plan or coverage, such as the covered benefits, cost-sharing provisions and coverage limitations and exceptions. Members will receive the summary when shopping for coverage, enrolling in coverage, at each new plan year and within seven business days of requesting a copy from their insurance issuer or group health plan.

13.108 **"Telemedicine"** means certain Covered Services for diagnosis and treatment of low acuity medical conditions delivered to SHL Insureds through the use of interactive audio, video, or other telecommunications or electronic technology by a contracted SHL Telemedicine Provider listed as such in the SHL Provider Directory at a site other than the site at which the patient is located. Telemedicine is available in all states where SHL contracted Telemedicine Providers offer telemedicine services. Telemedicine does not include the use of standard telephone calls, facsimile transactions or e-mail messaging and is only available through designated providers listed as Telemedicine Providers in the SHL Provider Directory.

13.109 "**Therapeutic Supply**" is the maximum quantity of supplies for which benefits are available for a single

applicable Copayment or Coinsurance amount, if applicable, and may be less than but shall not exceed a thirty (30)-day supply.

13.110 **"Tinted Lenses"** means lenses which have additional substance added to produce constant tint (e.g., pink, green, gray, blue, etc.).

13.111 "**Totally Disabled**" means:

- the continuing inability of a Subscriber to substantially perform duties related to his employment or to work for pay, profit or gain at any job for which he is suited by reason of education, training or experience because of Illness or Injury; or
- the inability of a Dependent to engage in his regular and usual activities.

13.112 "**Transplant Benefit Period**" means the period beginning with the date the Insured receives a written Referral from SHL for care in a Transplant Facility and ending on the first of the following to occur:

(a). the date 365 days after the date of the transplant; or

(b). the date when the Insured is no longer covered under this Plan, whichever is earlier.

13.113 "**Transplant Facility**" means a Hospital that has an independent contractor agreement or other contractual relationship with SHL to provide Covered Services related to a Covered Transplant Procedure as defined in this AOC. Non-Plan Hospitals do not have agreements with SHL to provide such services.

13.114 "**Urgent Care Claim**" means a Claim for Benefits that is treated in an expedited manner because the application of the time periods for making determinations that are not Urgent Care Claims could seriously jeopardize the Insured's life, health or the ability to regain maximum function by waiting for a routine appeal decision. An Urgent Care Claim also means a Claim for Benefits that, in the opinion of a physician with knowledge of the Insured's medical conditions, would subject the Insured to severe pain that cannot be adequately managed without the care or the treatment that is the subject of the claim. If an original request for Prior Authorization of an Urgent Care service was denied, the Insured could request an Expedited Appeal for the Urgent Care Claim.

13.115 "**Urgent Care Facility**" means a facility equipped and operated mainly to give immediate treatment for an acute Illness or Injury.

13.116 "**Urgently Needed Services**" means Covered Services needed to prevent a serious deterioration in an Insured's health. While not as immediate as Emergency Services, these services cannot be delayed until the Insured can see a Plan Provider.

13.117 **"Vision Plan Provider**" means a Provider who has an independent contractor agreement with SHL to provide certain Covered Services to Insureds.

13.118 **"Waiting Period"** means a period of 90 (ninety) days applied from the date the Application is received by SHL. The Effective Date will be the first of the month immediately following the month in which the waiting period expires.

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Attachment A Benefit Schedule

Lifetime Maximum Benefit for all Covered Services: Unlimited.

Calendar year Deductible (CYD): There is no Calendar Year deductible for Plan and Non-Plan Provider Services.

Copayments: This Plan includes some fixed dollar copayment amounts for certain Covered Services. Please reference the following pages for detailed Cost-share information.

Coinsurance: Your Coinsurance for most Plan Provider services is 10% of EME. Your Coinsurance for most Non-Plan Provider services is 50% of EME. Please reference the following pages for specific Coinsurance responsibilities.

Calendar Year Out of Pocket Maximum: Your Calendar Year Out of Pocket expenses are limited to a maximum of $2,000 of EME per Insured per Calendar Year and $4,000 of EME per Family when using Plan Providers and $4,000 of EME per Insured per Calendar Year and $8,000 of EME per Family when using Non-Plan Providers. The Calendar Year Out of Pocket Maximum amounts include the Copayments and Coinsurance.

The Calendar Year Out Of Pocket Maximum does not include; 1) amounts charged for non-Covered Services, 2) amounts exceeding applicable Plan benefit maximums or EME payments to Tier II Non-Plan Providers; or, 3) any penalties for not complying with SHL's Managed Care Program.

An Insured may not contribute any more than the individual Calendar Year Out Of Pocket Maximum amount toward the Family Calendar Year Out of Pocket Maximum amount. Further, the stated Out of Pocket Maximum amounts are separate for each tier of benefits and do not accumulate to one another.

Please read your Agreement of Coverage (AOC) to understand how EME payments to Providers are determined. Plan Providers have agreed to accept SHL's Reimbursement Schedule as payment in full for Covered Services, less any applicable Deductibles, Coinsurance and/or Copayments that are payable by you.

Important Note: When receiving Covered Services from Non-Plan Providers, you are responsible for all amounts exceeding the applicable benefit maximums, EME payments to Tier II Non-Plan Providers and any penalties for not complying with SHL's Managed Care Program. Further, such amounts do not accumulate to the Calendar Year Out of Pocket Maximum.

Please refer to Attachment B to the SHL Agreement, List of Services Requiring Prior Authorization, for the list of services and supplies requiring Prior Authorization.

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Benefit Schedule

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Medical Office Visits and Consultations		
Non-Specialist Services		
• Convenient Care Facility	Insured pays $5 per visit.	Insured pays 50% of EME.
• Physician Extender or Assistant	Insured pays $5 per visit.	Insured pays 50% of EME.
• Physician	Insured pays $10 per visit.	Insured pays 50% of EME.
Specialist Services	Insured pays $20 per visit.	Insured pays 50% of EME.
Preventive Healthcare Services - For a complete list of Preventive Services, including all FDA approved contraceptives, go to http://doi.nv.gov/Healthcare-Reform/Individuals-Families/Preventive-Care/. If you question about whether or not a service is "Preventive", please contact the SHL Member Services Department (1-800-888-2264).	Insured pays $0 per visit.	Insured pays 50% of EME.
Non-preventive Routine Lab and X-ray Services Copayment/Cost-share is in addition to the Physician office visit Copayment/Cost-share and applies to services rendered in a Physician's office or at an independent facility.		
• Lab	Insured pays $5 per visit.	Insured pays 50% of EME.
• X-Ray	Insured pays $15 per visit.	Insured pays 50% of EME.
Telemedicine Services (Available through select contracted Providers)	Insured pays $5 per visit.	Insured pays 50% of EME.
Urgent Care Facility	Insured pays $35 per visit.	Insured pays 50% of EME.
Emergency Services		
• Emergency Room Facility (includes Physician Services)	Insured pays 10% of EME	Insured pays 10% of EME
• Hospital Admission - Emergency Stabilization (includes Physician Services) Applies until patient is stabilized and safe for transfer as determined by the attending Physician.	Insured pays 10% of EME.	Insured pays 10% of EME.
The maximum benefit for Medically Necessary but Non-Emergency Services received in an Emergency Room is 50% of EME. You are responsible for all amounts exceeding any applicable maximum benefit and amounts exceeding the Plan's EME payment to Non-Plan Providers. Such amounts do not accumulate to the Calendar Year Out of Pocket Maximum.		

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Ambulance Services		
• Emergency Transport	Insured pays 10% of EME.	Insured pays 50% of EME.
• Non-Emergency - SHL Arranged Transfers	Insured pays $0.	Insured pays $0.
Inpatient Hospital Facility Services (Elective and Emergency Post-Stabilization Admissions)	Insured pays 10% of EME.	Insured pays 50% of EME.
Outpatient Hospital Facility Services	Insured pays 10% of EME.	Insured pays 50% of EME.
Ambulatory Surgical Facility Services	Insured pays 10% of EME.	Insured pays 50% of EME.
Anesthesia Services	Insured pays 10% of EME.	Insured pays 50% of EME.
Physician Surgical Services - Inpatient and Outpatient		
• Inpatient Hospital Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Outpatient Hospital Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Ambulatory Surgical Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Physician's Office		
Non-Specialist Physician (Includes all physician services related to the surgical procedure)	Insured pays 10% of EME.	Insured pays 50% of EME.
Specialist (Includes all physician services related to the surgical procedure)	Insured pays 10% of EME.	Insured pays 50% of EME.
Gastric Restrictive Surgery Services SHL provides a lifetime benefit maximum of one (1) Medically Necessary surgery per Insured.		
• Physician Surgical Services	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
• Physician's Office Visit	Insured pays $20 per visit.	Insured pays 50% of EME.

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Benefit Schedule

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Organ and Tissue Transplant Surgical Services		
• Inpatient Hospital Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Physician Surgical Services - Inpatient Hospital Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Transportation, Lodging and Meals The maximum benefit per Insured per Transplant Benefit Period for transportation, lodging and meals is $10,000. The maximum daily limit for lodging and meals is $200.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
• Procurement The maximum benefit per Insured per Transplant Benefit Period for Procurement of the organ/tissue is $15,000 of EME.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
• Retransplantation Services Benefits are limited to one (1) Medically Necessary Retransplantation per Insured per type of transplant.	Insured pays 50% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Post-Cataract Surgical Services		
• Frames and Lenses	Insured pays $10 per pair of glasses. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
• Contact Lenses Benefit limited to one (1) pair of Medically Necessary glasses or set of contact lenses as applicable per Insured per surgery for Plan and Non-Plan Provider Services combined.	Insured pays $10 per set of contact lenses. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Home Healthcare Services (does not include Specialty Prescription Drugs) Refer to the Outpatient Prescription Drug Benefit Rider for benefits applicable to Outpatient Covered Drug. Home Healthcare Services are limited to a combined Plan and Non-Plan Provider maximum benefit of sixty (60) visits per Insured per Calendar Year. A period of four (4) hours or less of Home Healthcare services equals one visit.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Hospice Care Services		
• Inpatient Hospice Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Outpatient Hospice Services	Insured pays 10% of EME.	Insured pays 50% of EME.
• Inpatient and Outpatient Respite Services Limited to a combined Plan and Non-Plan Provider maximum benefit of five (5) Inpatient days or five (5) Outpatient visits per Insured per ninety (90) days of Home Hospice Care.		
◦ Inpatient	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
◦ Outpatient	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
• Bereavement Services Limited to a combined Plan and Non-Plan Provider maximum benefit of five (5) group therapy sessions. Treatment must be completed within six (6) months of the date of death of the Hospice patient.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Skilled Nursing Facility Limited to a combined Plan and Non-Plan Provider maximum benefit of one hundred (100) days per Insured per Calendar Year.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Manual Manipulation Applies to Medical-Physician Services and Chiropractic office visit. Limited to a combined Plan and Non-Plan Provider maximum benefit of twenty (20) visits per Insured per Calendar Year.	Insured pays $10 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Short-Term Rehabilitation and Habilitation Services (including but not limited to Physical, Speech and Occupational Therapy)		
• Inpatient Hospital Facility	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
• Outpatient	Insured pays $10 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
All Inpatient and Outpatient Short Term Rehabilitation and Habilitative Services are subject to a to a combined Plan and Non-Plan Provider maximum benefit of one hundred twenty (120) days/visits per Insured per Calendar Year.		

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Benefit Schedule

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Durable Medical Equipment Monthly rental or purchase at SHL's option. Purchases are limited to a single purchase of a type of DME, including repair and replacement, once every three (3) years.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Genetic Disease Testing Services		
• Office Visit	Insured pays 25% of EME.	Insured pays 50% of EME.
• Lab Includes Inpatient, Outpatient and independent Laboratory Services.	Insured pays 25% of EME.	Insured pays 50% of EME.
Infertility Office Visit Evaluation Please refer to applicable surgical procedure Copayment/Cost-share and/or Coinsurance amount herein for any **surgical** infertility procedures performed.	Insured pays $20 per visit.	Insured pays 50% of EME.
Medical Supplies (Obtained outside of a medical office visit)	Insured pays 10% of EME.	Insured pays 50% of EME.
Other Diagnostic and Therapeutic Services Copayment/Cost-share amounts are in addition to the Physician office visit Copayment/Cost-share and applies to services rendered in a Physician's office or at an independent facility.		
• Anti-cancer drug therapy, non-cancer related intravenous injection therapy or other Medically Necessary intravenous therapeutic services.	Insured pays $50 per day.	Insured pays 50% of EME.
• Dialysis	Insured pays $50 per day.	Insured pays 50% of EME.
• Therapeutic Radiology	Insured pays $50 per day.	Insured pays 50% of EME.
• Complex Allergy Diagnostic Services (including RAST) and Serum Injections	Insured pays $50 per visit.	Insured pays 50% of EME.
• Otologic Evaluations	Insured pays $50 per visit.	Insured pays 50% of EME.
• Other complex diagnostic imaging services including: CT Scan and MRI; vascular diagnostic and therapeutic services; pulmonary diagnostic services; and complex neurological or psychiatric testing or therapeutic services.	Insured pays 10% of EME.	Insured pays 50% of EME.
• Positron Emission Tomography (PET) scans	Insured pays 10% of EME.	Insured pays 50% of EME.
Prosthetic Devices Purchases are limited to a single purchase of a type of Prosthetic Device, including repair and replacement, once every three (3) years.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Orthotic Devices Purchases are limited to a single purchase of a type of Orthotic Device, including repair and replacement, once every three (3) years.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Self-Management and Treatment of Diabetes		
• Education and Training	Insured pays $10 per visit.	Insured pays 50% of EME.
• Supplies (except for Insulin Pump Supplies)	Insured pays $5 per therapeutic supply.	Insured pays 50% of EME.
Insulin Pump Supplies	Insured pays $10 per therapeutic supply.	Insured pays 50% of EME.
• Equipment (except for Insulin Pump)	Insured pays $20 per device.	Insured pays 50% of EME.
Insulin Pump	Insured pays $100 per device.	Insured pays 50% of EME.
Refer to the Outpatient Prescription Drug Benefit Rider for the benefits applicable to diabetic supplies and equipment obtained at a retail Plan Pharmacy.		
Special Food Products and Enteral Formulas Special Food Products only are limited to a combined Plan and Non-Plan Provider maximum benefit of a one (1) thirty (30) day therapeutic supply per Insured four (4) times per Calendar Year.	Insured pays $0. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Temporomandibular Joint Treatment	Insured pays 50% of EME.	Insured pays 50% of EME.
Mental Health and Severe Mental Illness Services		
• Inpatient Hospital Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Outpatient Treatment	Insured pays $10 per visit.	Insured pays 50% of EME.
Substance Abuse Services		
• Inpatient Hospital Facility	Insured pays 10% of EME.	Insured pays 50% of EME.
• Outpatient Treatment	Insured pays $10 per visit.	Insured pays 50% of EME.
Hearing Aids Purchases are limited to a single purchase of a type of Hearing Aid, including repair and replacement, once every three (3) years.	Insured pays 10% of EME. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Applied Behavioral Analysis (ABA) for the treatment of Autism for Insureds up to age 22 Limited to a combined Plan and Non-Plan Provider maximum benefit of two hundred fifty (250) visits per Insured not to exceed seven hundred fifty (750) total hours of therapy per Insured per Calendar Year.	Insured pays $10 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Benefit Schedule

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Pediatric Vision Services for Insureds up to age 19		
Vision Examination Limited to a combined Plan and Non-Plan Provider maximum benefit of one (1) vision examination, covered once every Calendar Year, to include a complete analysis of the eyes and related structures to determine the presence of vision problems or other abnormalities.	Insured pays $0 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Lenses Limited to a combined Plan and Non-Plan Provider maximum benefit of one (1) pair of lenses, covered once every Calendar Year, when a prescription change is determined to be Medically Necessary. Lenses include choice of glass or plastic lenses, all lens powers (single vision, bifocal, trifocal and lenticular), fashion and gradient tinting, oversized and glass-grey #3 prescription sunglasses.	Insured pays $0 per visit. Subject to maximum benefit.	Insured pays 50% of EME.
Frames Limited to a combined Plan and Non-Plan Provider maximum benefit of one (1) pair of frames, covered once every Calendar Year, from the approved Formulary frame series. Charges for frames selected outside of the approved Formulary frame series are the responsibility of the Insured. Discounts for non-Formulary frames may be available through the Plan Provider.	Insured pays $0 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Contact Lenses Limited to a combined Plan and Non-Plan Provider maximum benefit. Contact lenses are covered once every Calendar Year in lieu of eye glasses. Charges for contact lenses considered to be cosmetic in purposes shall be the responsibility of the Insured.	Insured pays $0 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Low Vision Exam Limited to a combined Plan and Non-Plan Provider maximum benefit of one (1) comprehensive evaluation every five (5) years.	Insured pays $0 per visit. Subject to maximum benefit.	Insured pays 50% of EME. Subject to maximum benefit.
Optional Lenses and Treatments • Standard Anti-Reflective (AR) Coating • UV Treatment • Tint (Fashion & Gradient & Glass-Grey) • Standard Plastic Scratch Coating • Photocromatic/Transitions Plastic (Other optional lenses and treatment services may be available to the Insured at a discount. Please consult with your Provider.)	Insured pays $0.	Insured pays 50% of EME.

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

Covered Services and Limitations	Plan Provider Benefit*(1)	Non-Plan Provider Benefit* (1)
Pediatric Dental Services for Insureds up to age 19		
Diagnostic and Preventive • Oral exam every six (6) months • Periodic X-rays • Diagnostic procedures • Prophylaxis every six (6) months • Topical fluoride treatment every six (6) months • Sealants once per permanent molar • Space maintenance therapy	Insured pays $0. Subject to maximum benefit.	Insured pays 0% of EME. Subject to maximum benefit.
Restorative • Amalgam or composite fillings as needed • Crowns as needed • Sedative fillings	Insured pays 20% of EME.	Insured pays 20% of EME.
Endodontics • Root canal therapy • Pulpal therapy	Insured pays 50% of EME.	Insured pays 50% of EME.
Periodontics Usually limited to Insureds at least fourteen (14) years of age.	Insured pays 50% of EME.	Insured pays 50% of EME.
Prosthodontics • Partial and complete dentures Limited to one unit once every sixty (60) months.	Insured pays 50% of EME.	Insured pays 50% of EME.
Orthodontics Coverage provided for Medically Necessary Services only.	Insured pays 50% of EME.	Insured pays 50% of EME.
Oral Surgery (includes Anesthesia) • Extractions	Insured pays 50% of EME.	Insured pays 50% of EME.
Emergency Dental Services • Services or procedures necessary to control bleeding, relieve significant pain and/or eliminate acute infection. • Services or procedures required to prevent pulpal death and/or imminent loss of teeth.	Insured pays 50% of EME.	Insured pays 50% of EME.

Please read the SHL Agreement of Coverage to determine the governing contractual provisions, exclusions and limitations.

Please note: For Inpatient and Outpatient admissions, in addition to specified surgical Copayments and/or Coinsurance amounts, Insured is also responsible for all other applicable facility and professional Copayments and/or Coinsurance amounts as outlined in the Attachment A Benefit Schedule.

Insured is responsible for any and all amounts exceeding any stated maximum benefit amounts and/or any/all amounts exceeding the Plan's payment to Non-Plan Providers under this Plan. Further, such amounts do not accumulate to the calculation of the Calendar Year Out of Pocket Maximum.

(1) If Medically Necessary Covered Services, with the exception of certain Outpatient, non-emergency Mental Health, Severe Mental Illness, Substance Abuse Services, are provided without obtaining the required Prior Authorization, benefits are reduced to 50% of what the Insured would have received if Prior Authorization had been obtained.

**Refer to the Limitations Section of the AOC for information regarding EME and benefit maximums.*

ATTACHMENT B
TO THE SHL AGREEMENT OF COVERAGE (AOC)
SERVICES REQUIRING PRIOR AUTHORIZATION

In order to be covered, requested services must be Medically Necessary as determined by the Plan and not otherwise excluded under the AOC.	
TYPE OF SERVICES	**DETAILS**
Non-Plan Providers	
Non-Plan Provider Services	○ All Non Plan Provider Services (including all out of area Physician office visits and consultations)* *Except mental health, serious mental health or substance abuse medication management office visits and consultations.
Plan Providers	
Inpatient Services	○ Elective admissions to an inpatient facility ○ Skilled Nursing Facilities ○ Residential Treatment Centers ○ Habilitative and Short Term Rehabilitation Services ○ Gastric Restrictive Surgery ○ Reconstructive including Organ Transplants ○ Orthognathic surgery, including all TMJ related services ○ Sleep disorder surgeries ○ Sinus and nose surgeries
Outpatient Surgical Services	○ Surgical procedures performed in a hospital or an ambulatory surgery facility
Laboratory and X-Ray Services	○ Complex radiology including but not limited to: Computed Tomography (**CT**), Coronary CT angiography (**CTA**), Magnetic resonance imaging (**MRI**), Magnetic resonance angiogram (**MRA**), Positron emission tomography (**PET**) scans and Nuclear Medicine and, Single-photon emission computed tomography (**SPECT**) scans ○ Intensity Modulated Radiation Therapy ○ Genetic Testing
Anesthesia Services	○ Anesthesia for dental procedures ○ Pain Management Procedures
Home Healthcare Services	○ All Home Health services including IV therapy
Prosthetics/ orthotics/ and Durable Medical Equipment	○ Prosthetics/Orthotics over $750 ○ DME purchases or rentals over $750
Maternity Services	○ Obstetrical Ultrasounds for 2nd and subsequent ultrasounds during a pregnancy ○ Maternity management home care including home uterine monitoring
Habilitative and Rehabilitation Services	○ Therapies (Speech, Occupational, Physical) after 15 visits in a Calendar Year ○ Cardiac Rehabilitation and Pulmonary Rehabilitation
Mental Health, Substance Abuse and Severe Mental Illness Services [(1)] *Contact Behavioral Healthcare Options, Inc. (BHO) at: (702) 364-1484 or 1-800-873-2246 for assistance with making an appointment.*	○ All Inpatient and non-routine Outpatient non-Emergency Mental Health, Severe Mental Illness, and Substance Abuse Services.

In order to be covered, requested services must be Medically Necessary as determined by the Plan and not otherwise excluded under the AOC.	
TYPE OF SERVICES	**DETAILS**
Other Services	○ Varicose vein procedures ○ Vagus Nerve Stimulation Therapy ○ Hyperbaric oxygen treatment ○ Applied behavioral analysis for the treatment of Autism ○ Hearing aids ○ Certain Outpatient Prescription Drugs [2]

Please access the SHL website at www.myshlonline.com for the most current list of services requiring Prior Authorization, or please contact Member Services at 1-800-888-2264 for a copy of the list of if you have questions regarding services requiring Prior Authorization.

Please refer to your Attachment A Benefit Schedule for any other limitations that may apply to these services.

[1] All inpatient and non-routine Outpatient non-emergency Mental Health, Severe Mental Illness or Substance Abuse require Prior Authorization by BHO. Insureds must contact Behavioral Health Care Options (BHO) for assistance in scheduling their first appointment in order to verify that any requested Mental Health, Severe Mental Illness or Substance Abuse services are Covered Services under the Plan, and that such Covered Services will be obtained at the appropriate level of care in order to be eligible for full benefit payment. A BHO coordinator will either assist in scheduling the appointment or will make a referral to the appropriate Plan Provider based on the service requested and the associated level of acuity. If the Insured is unable to contact BHO due to an emergency admission, the Insured must contact BHO as soon as reasonably possible following the emergency admission to obtain Prior Authorization of any needed follow up care.

[2] Please refer to the Prescription Drug List located at www.myshlonline.com.

If Medically Necessary Covered Services requiring Prior Authorization are provided without obtaining the required Prior Authorization, benefits are reduced to 50% of what the Insured would have received if Prior Authorization had been obtained.

If services are considered not to be Medically Necessary or are not covered under the Plan, benefits for such services will be denied.

Prior Authorization is not a guarantee of payment for Covered Services.

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

4-Tier Outpatient Prescription Drug Rider to the SHL Individual Agreement of Coverage

Please refer to the SHL Prescription Drug List (PDL) for the listing of Covered Drugs.

Plan Retail Prescription Drug Benefits

Tier I: Insured pays
$10 Copayment per Designated Plan Pharmacy Therapeutic Supply

Tier II: Insured pays
$25 Copayment per Designated Plan Pharmacy Therapeutic Supply

Tier III: Insured pays
$60 Copayment per Designated Plan Pharmacy Therapeutic Supply

Tier IV: Insured pays
$250 Copayment per Designated Plan Pharmacy Therapeutic Supply

Plan Mail Order Prescription Drug Benefit

Insured pays:
2.5 times the applicable Tier Copayment per Plan Mail Order Pharmacy Therapeutic Supply

Non-Plan Pharmacy:
SHL pays 70% of Eligible Medical Expense ("EME") for Covered Drugs less the Copayment per Therapeutic Supply

This Prescription Drug Benefit Rider is issued in consideration of: (a) your election of coverage under this Rider, (b) your eligibility for the benefits described in this Rider, and (c) payment of any additional premium.

This Prescription Drug Benefit Rider is a supplement to your Agreement of Coverage (AOC) and Attachment A Benefit Schedule issued by Sierra Health and Life Insurance Co., Inc., and amends your coverage to include benefits for Covered Drugs. This coverage is subject to the applicable terms, conditions,

Out of Pocket amounts paid for Covered Drugs accumulate to the Annual Out of Pocket Maximum as set forth in the SHL Attachment A Benefit Schedule.

limitations and exclusions contained in your SHL AOC and herein.

SECTION 1. Obtaining Covered Drugs

Benefits for Covered Drugs are payable under the terms of this Rider subject to the following conditions:

- A **Designated** Plan Pharmacy must dispense the Covered Drug, except as otherwise specifically provided in Section 1.2 herein.
- A Generic Covered Drug will be dispensed when available, subject to the prescribing Provider's "Dispense as written" requirements.
- Benefits for Specialty Covered Drugs as defined herein are payable subject to the applicable Tier I, II, III or IV benefit level. If you require certain Covered Drugs, including, but not limited to, Specialty Drugs, SHL may direct you to a Designated Plan Pharmacy with whom SHL have an arrangement to provide those Covered Drugs.

1.1 Designated Plan Pharmacy Benefit Payments

Benefits for Covered Drugs obtained at a Designated Plan Pharmacy are payable according to the applicable benefit tiers described below, subject to the Insured obtaining any required Prior Authorization or meeting any applicable Step Therapy requirement.

(a). **Tier I –** is the low cost option for Covered Drugs.

(b). **Tier II –** is the midrange cost option for Covered Drugs.

(c). **Tier III –** is the high cost option for Covered Drugs.

(d). **Tier IV –** is the highest cost option for Covered Drugs.

(e). **Mandatory Generic benefit provision applies when:**

- a Brand Name Covered Drug is dispensed and a Generic Covered Drug equivalent is available. The Insured will pay the Covered Copayment or Coinsurance plus the difference between the Eligible Medical Expenses ("EME") of the Generic Covered Drug and the EME of the Brand Name Covered Drug to the Designated Plan Pharmacy for each Therapeutic Supply.

(f). When a Drug is dispensed through the Mail Order Plan Pharmacy, the applicable Tier I, Tier II, Tier III or Tier IV Mail Order Plan Pharmacy benefit tier will apply per Therapeutic Supply.

1.2 Non-Plan Pharmacy Benefit Payments

(a). In order that claims for Covered Drugs obtained at a Non-Plan Pharmacy be eligible for benefit payment, the Insured must complete and submit a Pharmacy Reimbursement Claim Form with the prescription label and register receipt to SHL or its designee.

(b). Benefit payments are subject to the limitations and exclusions set forth in the SHL AOC and this Rider as follows:

1. When any Covered Drug is dispensed, the benefit payment will be subject to SHL's EME and the applicable Tier I, II, III or IV Copayment or Coinsurance amount. The Insured is responsible for any amounts exceeding SHL's benefit payment.

2. The Mandatory Generic benefit provision applies when any Brand Name Covered Drug is dispensed and a Generic Covered Drug equivalent is available. The benefit payment is subject to SHL's EME of the Generic Covered Drug less the applicable tier Copayment or Coinsurance. The Insured is responsible for any amounts exceeding SHL's benefit payment.

3. No benefits are payable if SHL's EME of the Covered Drug is less than the applicable Copayment or Coinsurance.

1.3 Mail Order Plan Pharmacy Benefit Payments

(a). Benefits for Covered Drugs are available when dispensed by an SHL Mail Order Plan Pharmacy subject to the applicable Tier I, Tier II, Tier III or Tier IV Mail Order benefit.

(b). Information on how to obtain Mail Order Drugs is provided in the Mail Order Brochure provided after enrollment with SHL.

SECTION 2. Limitations

2.1 Prior Authorization or Step Therapy may be required for certain Covered Drugs.

2.2 A pharmacy may refuse to fill or refill a prescription order when in the professional judgment of the pharmacist the prescription should not be filled.

2.3 Benefits for prescriptions for Mail Order Drugs submitted following SHL's receipt of notice of individual's termination will be limited to the appropriate Therapeutic Supply from the date such notice of termination is received to the Effective Date of termination of the individual.

2.4 Benefits are not payable if you are directed to a Designated Plan Pharmacy and you choose not to obtain your Covered Drug from that Designated Plan Pharmacy.

2.5 If SHL determines that you may be using Prescription Drugs in a harmful or abusive manner, or with harmful frequency, your selection of Plan Pharmacies may be limited. If this happens, SHL may require you to select a single Plan Pharmacy that will provide and coordinate all future pharmacy services. Benefit coverage will be paid only if you use the assigned single Plan Pharmacy. If you do not make a selection within thirty-one (31) days of the date you are notified, then SHL will select a single Plan Pharmacy for you.

SECTION 3. Exclusions

No benefits are payable for the following drugs, devices and supplies as well as for

any complications resulting from their use except when prescribed in connection with the treatment of Diabetes:

3.1 Prescription Drug furnished by the local, state or federal government. Any Prescription Drug to the extent payment or benefits are provided or available from the local, state or federal government (for example, Medicare) whether or not payment or benefits are received, except as otherwise provided by law.

3.2 Prescription Drugs for any condition, Injury, Illness or Mental Illness arising out of, or in the course of, employment for which benefits are available under any workers' compensation law or other similar laws, whether or not a claim for such benefits is made or payment or benefits are received.

3.3 Devices of any type, including those prescribed by a licensed Provider, except for prescription contraceptive devices.

3.4 Durable Medical Equipment. Prescribed and non-prescribed outpatient supplies, other than the diabetic supplies and inhaler spacers specifically stated as covered.

3.5 Any product dispensed for the purpose of appetite suppression or weight loss.

3.6 Medications used for cosmetic purposes.

3.7 Prescription Drug Products when prescribed to treat infertility

3.8 Any medication that is used for the treatment of erectile dysfunction or sexual dysfunction.

3.9 Hypodermic needles, syringes, or similar devices used for any purpose other than the administration of Specialty Covered Drugs.

3.10 Except as otherwise specifically provided, Prescription Drugs related to medical services which are not covered under the SHL AOC.

3.11 Drugs for which prescriptions are written by a licensed Provider for use by the Provider or by his or her immediate family members.

3.12 Prescription Drugs dispensed prior to the Insured's Effective Date of coverage or after Insured's termination date of coverage under the Plan.

3.13 Drugs available over-the-counter that do not require a prescription order or refill by federal or state law before being dispensed, unless SHL has designated the over-the-counter medication as eligible for coverage as if it were a Prescription Drug and it is obtained with a Prescription Order or Refill from a Physician. Prescription Drugs that are available in over-the-counter form or comprised of components that are available in over-the-counter form or equivalent. Certain Prescription Drugs that SHL has determined are Therapeutically Equivalent to an over-the-counter drug. Such determinations may be made up to six times during a calendar year, and SHL may decide at any time to reinstate benefits for a Prescription Drug that was previously excluded under this provision.

3.14 General vitamins, except the following which require a prescription order or refill; prenatal vitamins, vitamins with fluoride, and single entity vitamins.

3.15 Any product for which the primary use is a source of nutrition, nutritional supplements, or dietary management of disease, even when used for the treatment of Illness or Injury except for Prescription Drug Products that are enteral formulas prescribed for the treatment of inherited metabolic diseases as defined by state law.

3.16 Any Prescription Drug for which the actual charge to the Insured is less than the amount due under this Rider.

3.17 Any refill dispensed more than one (1) year from the date of the latest prescription order or as permitted by applicable law of the jurisdiction in which the drug is dispensed.

3.18 Prescription Drugs as a replacement for a previously dispensed Prescription Drug that was lost, stolen, broken or destroyed.

3.19 Medical supplies unless listed on the PDL or Prior Authorized by SHL.

3.20 Coverage for Prescription Drugs for the amount dispensed (days' supply or quantity limit) which exceeds the supply limit.

3.21 Coverage for Prescription Drugs for the amount dispensed (days' supply or quantity limit) which is less than the minimum supply limit.

3.22 Compounded drugs that do not contain at least one ingredient that has been approved by the U.S. Food and Drug Administration (FDA) and requires a Prescription Order or Refill. Compounded drugs that are available as a similar commercially available Prescription Drug. (Compounded drugs that contain at least one ingredient that requires a Prescription Order or Refill are assigned to Tier III or Tier IV).

3.23 Prescriptions for Covered Drugs for which Prior Authorization is required but not obtained.

3.24 Experimental or investigational or unproven services and medications; medication used for experimental indications and/or dosage regimens determined by the Plan to be experimental, investigational or unproven except when prescribed for the treatment of cancer or other life-threatening diseases or conditions, chronic fatigue syndrome, cardiovascular disease, surgical musculoskeletal disorder of the spine, hip and knees, and other diseases or disorders which are not life threatening or study approved by the Plan;

3.25 A Prescription Drug that contains an active ingredient(s) which is (are) a modified version of and Therapeutically Equivalent to a Covered Drug may be excluded as determined by the Plan.

3.26 Prescription Drugs dispensed outside the United States, except as required for emergency treatment.

3.27 Covered Drugs which are prescribed, dispensed or intended for use during an Inpatient admission.

3.28 Covered Drugs that are not FDA approved for a specific diagnosis.

3.29 Unit dose packaging of Prescription Drugs.

SECTION 4. Glossary

4.1 "Brand Name Drug" is a Prescription Drug which is marketed under or protected by:

- a registered trademark;
- or a registered trade name;
- or a registered patent.

4.2 "Compound" means to form or create a Medically Necessary customized composite product by combining two (2) or more different ingredients according to a Physician's specifications to meet an individual patient's need.

4.3 "Covered Drug" is a Brand Name or Generic Prescription Drug or diabetic supply or equipment which:

- can only be obtained with a prescription;
- has been approved by the Food and Drug Administration ("FDA") for general marketing, subject to 3.16 herein;
- is dispensed by a licensed pharmacist;
- is prescribed by a Plan Provider, except in the case of Emergency Services and Urgently Needed Services;
- is a Prescription Drug that does not have an over-the-counter Therapeutic Equivalent available; and
- is not specifically excluded herein.

4.4 "Copayment" means the amount the Insured pays when a Covered Service is received.

4.5 "Designated Plan Pharmacy" means a pharmacy that has entered into an agreement with SHL to provide specific Covered Drugs and/or supplies to Insureds. The fact that a pharmacy is a Plan Pharmacy does not mean that it is a Designated Plan Pharmacy. For the purposes of the Prescription Drug Benefit Rider, please refer to the SHL PDL on the website or contact Member Services for the specific Designated Plan Pharmacy for your Covered Drug and/or supply/equipment.

4.6 "Dispensing Period" as established by SHL means 1) a predetermined period of time; or 2) a period of time up to a predetermined age attained by the Insured that a specific Covered Drug is recommended by the FDA to be an appropriate course of treatment when prescribed in connection with a particular condition.

4.7 "Eligible Medical Expense (EME)" for purposes of this Rider, means the Plan Pharmacy's contracted cost of the Covered Drug to SHL but not more than the actual charge to the Insured.

4.8 "Generic Drug" is an FDA-approved Prescription Drug which does not meet the definition of a Brand Name Drug as defined herein.

4.9 "Mail Order Plan Pharmacy" is a duly licensed pharmacy that has an independent contractor agreement with SHL to provide certain Tier I, Tier II, Tier III and Tier IV Drugs to Insureds by mail.

4.10 "Non-Plan Pharmacy" is a duly licensed pharmacy that does not have an independent contractor agreement with SHL to provide Covered Drugs to Insureds.

4.11 "Plan Pharmacy" is a duly licensed pharmacy that has an independent contractor agreement with SHL to provide Covered Drugs to Insureds. Unless otherwise specified as Mail Order Plan Pharmacy herein, Plan Pharmacy services are retail services only and do not include Mail Order services.

4.12 "Prescription Drug List (PDL)" means a list of FDA approved Generic and Brand Name Prescription Drugs established, maintained, and recommended for use by SHL.

4.13 "Prescription Drug" is any drug required by federal law or regulation to be dispensed upon written prescription including finished dosage forms and active ingredients subject to the Federal Food, Drug and Cosmetic Act.

4.14 "Specialty Drugs" are high-cost oral, injectable, infused or inhaled Covered Drugs as identified by SHL's P&T Committee that are either self-administered or administered by a healthcare Provider and used or obtained in either an outpatient or home setting.

4.15 "Step Therapy" is a program for Insureds who take Prescription Drugs for an ongoing medical condition, such as arthritis, asthma or high blood pressure, which ensures the Insured receives the most appropriate and cost-effective drug therapy for their condition. The Step Therapy program requires that before benefits are payable for a high cost Covered Drug that may have initially been prescribed, the Insured try a lower cost first-step Covered Drug. If the prescribing Physician has documented with SHL why the Insured's condition cannot be stabilized with the first-step Covered Drug, SHL will review a request for Prior Authorization to move the Insured to a second-step drug, and so on, until it is determined by SHL that the prescribed Covered Drug is Medically Necessary and eligible for benefit payment.

4.16 "Therapeutic Equivalent" means that a Covered Drug can be expected to produce essentially the same therapeutic outcome and toxicity.

4.17 "Therapeutic Supply" is the maximum quantity of a Covered Drug for which benefits are available for the applicable Copayment or the applicable Coinsurance amount and may be less than but shall not exceed a 30-day retail supply or 90- day mail order supply.

Coverage Policies and Guidelines

SHLs Prescription Drug List (PDL) Management Committee is authorized to make tier placement changes on SHL's behalf. The PDL Management Committee makes the final classification of an FDA-approved Prescription Drug to a certain tier by considering a number of factors including but not limited to, clinical and economic factors. Clinical factors may include, but are not limited to, evaluations of the place in therapy, relative safety or relative efficacy of the Prescription Drug, as well as whether certain supply limits or prior authorization requirements should apply. Economic factors may include, but are not limited to, the Prescription Drug's acquisition cost including, but not

limited to, available rebates and assessments of the cost effectiveness of the Prescription Drug.

Some Prescription Drugs are more cost effective for specific indications as compared to others; therefore, a Prescription Drug may be listed on multiple tiers according to the indication for which the Prescription Drug was prescribed, or according to whether it was prescribed by a Specialist Physician.

SHL may periodically change the placement of a Prescription Drug among the tiers. These changes generally will occur quarterly, but no more than six times per calendar year. These changes may occur without prior notice to you.

When considering a Prescription Drug for tier placement, the PDL Management Committee reviews clinical and economic factors regarding Covered Persons as a general population. Whether a particular Prescription Drug is appropriate for an individual Covered Person is a determination that is made by the Covered Person and the prescribing Physician.

NOTE: the tier status of a Prescription Drug may change periodically based on the process described above. As a result of such changes, you may be required to pay more or less for that Prescription Drug.

Questions about SHL's PDL should be directed to the Member Services Department at (702) 242-7300 or 1-800-777-1840 or the PDL and the Pharmacy Reimbursement Claim Form is available at http://www.uhcnevada.com/ which leads to SHL's portal www.myshlonline.com.

Advance Directives

DURABLE POWER OF ATTORNEY

DECLARATION OF LIVING WILL

NOTE: This document is not intended as a substitute for legal advice. You should seek qualified legal guidance to assist you in completing and executing an Advance Directive in accordance with the law.

Introduction

There may come a time when you will be seriously injured or become gravely ill and unable to make healthcare decisions for yourself. You may wish to choose in advance what kinds of treatments are administered and whether or not life support systems should be maintained or withdrawn.

Most states allow a competent adult to execute a document which allows him or her to accept or refuse treatment in the event that he or she has a terminal condition and is not able to make decisions for himself or herself. Many states do not specify the particular form that a directive must follow to be effective, but you should check the laws in your own state to be sure. However, we have included information for you on where you can get forms which may be available.

Glossary

Advance Directive - an instruction, such as a Declaration/Living Will or Durable Power of Attorney for Healthcare Decisions, to withhold or withdraw life-sustaining procedures in the event of a terminal condition.

Attorney In Fact - a person authorized by another to act in his place either for some particular purpose, as to do a particular act, or for the transaction of business in general which is not of a legal nature.

Life-sustaining Treatment - a medical procedure or intervention that uses mechanical or other artificial means to sustain, restore or supplant a vital function. It only artificially postpones the moment of death of a patient in a Terminal Condition whose death is imminent or will result within a relatively short time without the application of the procedure. The term does not include the administration of medication or the performance of a medical procedure considered to be necessary to provide comfort or care, or to alleviate pain.

Terminal Condition - an incurable and irreversible condition caused by injury, disease or illness that would result in death without the application of life-sustaining procedures, according to reasonable medical judgement. The application of life-sustaining procedures serves only to postpone the moment of the patient's death.

Types of Advance Directives

A ***Declaration/Living Will*** is one type of Advance Directive. A Declaration/Living Will directs your attending physician to withdraw treatment that only prolongs a Terminal Condition. To be valid under law, a Declaration/Living Will must be signed by you as the declarant and must also be signed by two witnesses who 1) are not related to you by blood or marriage, 2) are not mentioned in your will and 3) would have no claim on your estate.

In addition the Declaration/Living Will may not be witnesses by your physician or by anyone working for your physician. If you are in a healthcare facility at the time you sign the Declaration/Living Will, you may not use as a witness any other patient, or employee of the facility if they are involved in providing direct patient care to you or are directly involved in the financial affairs of the facility. The signatures of the witnesses do not have to be notarized to make the Declaration/Living Will a valid legal document.

A ***Durable Power of Attorney for Healthcare Decisions*** may also be executed. This document allows you to appoint someone to make a variety of healthcare decisions for you should you become unable to do so. Requirements under the law are very specific for properly executing this

document, and you should seek qualified legal guidance to assist you in completing and executing an Advance directive in accordance with the law.

Advance Directives as Part of your Permanent Medical Record

Once you have executed an Advance Directive of any kind, please notify your physician and provide a copy of it to him or her so that it may be made a part of your permanent medical record.

Upon learning of the existence of an Advance Directive, a physician must make reference to the fact that you have an Advance Directive in your permanent medical record.

Frequently Asked Questions

How long is an Advance Directive valid?

Generally, any Advance Directive is effective until it is revoked. You may want to consider initialing and dating your Advance Directive periodically to show that it still expresses your wishes. You may revoke your Advance Directive at any time and in any manner, without regard to your mental or physical condition. A revocation is effective when your attending physician or other healthcare provider receives notice of the revocation from you or from a witness to the revocation. Pursuant to the law, to the extent that a Durable Power of Attorney for Healthcare or Declaration/Living Will conflicts with a directive or treatment decision executed under the law, the instrument executed later in time controls.

What will happen if I become terminally ill and I am unable to make healthcare decisions by myself, yet I haven't executed an Advance Directive?

In preparation for this possibility, you should, at the very least, make your wishes known to those you love. Laws in your state may give a "surrogate decision maker" the authority to consent to the withholding or withdrawal of life-sustaining treatment for you. (This consent must be in writing and attested by two witnesses.)

A "surrogate decision maker" is, in order of authority;

- your spouse;
- your adult child or, if you have more than one child, a majority of the adult children who are reasonably available to consult;
- your parents;
- your adult sibling or, if you have more than one adult sibling, a majority of the adult siblings who are reasonably available to consult;
- or your nearest other adult relative by blood or adoption who is reasonably available to consult.

If a class of "surrogate decision makers" entitled to consent is not reasonably available to consult and competent to decide, or declines to decide, the next class is authorized to make the decision. An equal division in a class does not authorize the next class to decide.

What if my doctor objects to the withholding or withdrawal of life-sustaining treatment?

Healthcare providers have varying beliefs regarding the implementation of an individual's Advance Directive. An attending physician or other provider of healthcare who is unwilling to honor your Advance Directive must take all reasonable steps as promptly as possible to transfer your care to another physician or healthcare provider.

How will my execution of an Advance Directive affect my health and life insurance policies?

The making of an Advance Directive does not affect the sale, purchase or issuance of a life insurance or annuity policy, nor does it affect the terms of an existing policy. It also cannot be prohibited or required as a condition of being insured for, or receiving, healthcare.

What are our policies on the administration of life-sustaining treatment?

As a company we are committed to the preservation of life and the alleviation of suffering. If, however, you wish to have life-sustaining treatment withheld or withdrawn in the event you become terminally ill, we will make every effort to see that your wishes are honored. If you have already executed an Advance Directive, please give a copy to your doctor(s) to be placed in your medical record.

Where can I obtain a Declaration/Living Will or Durable Power of Attorney for Healthcare Decisions form?

Forms are available from a variety of sources, including some physicians, attorneys, and healthcare facilities.

Once you have completed an Advance Directive, discuss your decisions with your family, next of kin, or other responsible parties, and give your attorney and each one of your doctors a copy to be placed in all of your medical records. It is also advisable to keep a copy with you at all times.

Conclusion

It is difficult for people to make good decisions when they are under pressure or emotional strain, particularly in areas where there are no clear-cut answers about life-sustaining treatment. These issues require a great deal of discussion and careful thought. The information provided here has been presented in the hope that you will discuss it with your doctor and others and come to a decision that is right for you or someone you love.

This is only a summary. If you want more detail about your coverage and costs, you can get the complete terms in the policy or plan document at **www.myshlonline.com** or by calling **(702) 242-7700 or 1-800-888-2264**.

Important Questions	Answers	Why this Matters:
What is the overall deductible?	**$0**	See the chart starting on page 2 for your costs for services this plan covers.
Are there other deductibles for specific services?	No. There are no other specific **deductibles**.	You don't have to meet **deductibles** for specific services, but see the chart starting on page 2 for other costs for services this plan covers.
Is there an out-of-pocket limit on my expenses?	Yes, **$2,000**/Insured and **$4,000**/Family when using **Plan Providers** and **$4,000**/Insured and **$8,000**/Family when using **Non-Plan Providers** per Calendar Year.	The **out-of-pocket limit** is the most you could pay during a coverage period (usually one year) for your share of the cost of covered services. This limit helps you plan for health care expenses.
What is not included in the out-of-pocket limit?	Premium, balance-billed charges, penalties for failure to obtain prior authorization and health care this plan doesn't cover.	Even though you pay these expenses, they don't count toward the **out-of pocket limit**.
Is there an overall annual limit on what the plan pays?	No.	The chart starting on page 2 describes any limits on what the plan will pay for *specific* covered services, such as office visits.
Does this plan use a network of providers?	Yes. For a list of **Plan Providers**, see www.myshlonline.com or call 702-242-7700 or 1-800-888-2264.	If you use an in-network doctor or other health care **provider**, this plan will pay some or all of the costs of covered services. Be aware, your in-network doctor or hospital may use an out-of-network **provider** for some services. Plans use the term in-network, **preferred**, or participating for **providers** in their **network**. See the chart starting on page 2 for how this plan pays different kinds of **providers**.
Do I need a referral to see a specialist?	No.	You can see the **specialist** you choose without permission from this plan.

- **Copayments** are fixed dollar amounts (for example, $15) you pay for covered health care, usually when you receive the service.
- **Coinsurance** is *your* share of the costs of a covered service, calculated as a percent of the **allowed amount** for the service. For example, if the plan's **allowed amount** for an overnight hospital stay is $1,000, your **coinsurance** payment of 20% would be $200. This may change if you haven't met your **deductible**.
- The amount the plan pays for covered services is based on the **allowed amount**. If an out-of-network **provider** charges more than the **allowed amount**, you may have to pay the difference. For example, if an out-of-network hospital charges $1,500 for an overnight stay and the **allowed amount** is $1,000, you may have to pay the $500 difference. (This is called **balance billing**.)
- This plan may encourage you to use **Plan Providers** by charging you lower **deductibles**, **copayments** and **coinsurance** amounts.

Common Medical Event	Services You May Need	Your Cost If You Use a Plan Provider	Your Cost If You Use a Non-Plan Provider	Limitations & Exceptions
If you visit a health care provider's office or clinic	Primary care visit to treat an injury or illness	$10 copay/visit	50% co-ins	None
	Specialist visit	$20 copay/visit	50% co-ins	
	Other practitioner office visit	$10 copay/visit	50% co-ins	No coverage for acupuncture. Manual manipulation (Chiropractic) is limited to 20 visits. Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Preventive care/ screening/ immunization	$0 copay/visit	50% co-ins	None
If you have a test	Diagnostic test (x-ray, blood work)	X-ray: $15 copay/service Lab: $5 copay/service	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Imaging (CT/PET scans, MRIs)	10% co-ins	50% co-ins	
If you need drugs to treat your illness or condition	Tier 1	$10 copay (retail) $25 copay (mail)	50% co-ins	Covers up to a 30-day retail supply or up to a 90-day mail order supply. Insured pays for 50% benefit reduction if prior authorization or step therapy is not obtained.
More information about **prescription drug coverage** is available at www.myshlonline.com.	Tier 2	$25 copay (retail) $62.50 copay (mail)	50% co-ins	Covers up to a 30-day retail supply or up to a 90-day mail order supply. Insured pays for 50% benefit reduction if prior authorization or step therapy is not obtained.
	Tier 3	$60 copay (retail) $150 copay (mail)	50% co-ins	
	Tier 4	$250 copay (retail) $625 copay (mail)	50% co-ins	

Common Medical Event	Services You May Need	Your Cost If You Use a Plan Provider	Your Cost If You Use a Non-Plan Provider	Limitations & Exceptions
If you have outpatient surgery	Facility fee (e.g., ambulatory surgery center)	10% co-ins	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Physician/surgeon fees	10% co-ins	50% co-ins	
If you need immediate medical attention	Emergency room services	10% co-ins	10% co-ins	You may be balance billed from Non-Plan Providers.
	Emergency medical transportation	10% co-ins	50% co-ins	
	Urgent care	$35 copay/visit	50% co-ins	You may be balance billed from Non-Plan Providers.
If you have a hospital stay	Facility fee (e.g., hospital room)	10% co-ins	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Physician/surgeon fee	10% co-ins	50% co-ins	
If you have mental health, behavioral health, or substance abuse needs	Mental/behavioral health outpatient services	$10 copay/visit	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Mental/behavioral health inpatient services	10% co-ins	50% co-ins	
	Substance abuse disorder outpatient services	$10 copay/visit	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Substance abuse disorder inpatient services	10% co-ins	50% co-ins	
If you are pregnant	Prenatal and postnatal care	$0 copay/visit	50% co-ins	Routine prenatal care obtained from a Plan Provider is covered at no charge.
	Delivery and all inpatient services	10% co-ins	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
If you have a recovery or other special health need	Home health care	10% co-ins	50% co-ins	Does not include Specialty Prescription Drugs. Limited to 60 visits. Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Rehabilitation services	$10 copay/visit	50% co-ins	Limited to 120 days/visits. Insured pays for 50% benefit reduction if prior authorization is not obtained after 15 visits.
	Habilitative services	$10 copay/visit	50% co-ins	

Common Medical Event	Services You May Need	Your Cost If You Use a Plan Provider	Your Cost If You Use a Non-Plan Provider	Limitations & Exceptions
If you have a recovery or other special health need	Skilled nursing care	10% co-ins	50% co-ins	Limited to 100 days. Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Durable medical equipment	10% co-ins	50% co-ins	Prior authorization is required for purchases/rentals over $750. Monthly rental or purchase at SHL's option. Coverage is limited to a single purchase of a type of DME, including repair and replacement, once every 3 years. Insured pays for 50% benefit reduction if prior authorization is not obtained.
	Hospice services	10% co-ins	50% co-ins	Insured pays for 50% benefit reduction if prior authorization is not obtained.
If your child needs dental or eye care	Eye exam	$0 copay/visit	50% co-ins	One vision exam, glasses and frames will be covered once every Calendar Year for members up to age 19. Please refer to your Plan documents for more information.
	Glasses	$0 copay/visit	50% co-ins	
	Dental check-up	$0 copay/visit	$0 copay/visit	Routine Periodic exams are limited to 1 every 6 months for members up to age 19 per Calendar Year. Please refer to your Plan documents for more information.

Excluded Services & Other Covered Services:

Services Your Plan Does NOT Cover (This isn't a complete list. Check your policy or plan document for other **excluded services**.)

- Abortion (except for rape, incest, life at risk)
- Acupuncture
- Cosmetic surgery
- Dental care (Adult)
- Long-term care
- Non-emergency care when traveling outside the U.S.
- Routine eye care (Adult)
- Routine foot care
- Weight loss programs

Other Covered Services (This isn't a complete list. Check your policy or plan document for other covered services and your costs for these services.)

- Bariatric surgery
- Chiropractic care
- Hearing aids
- Limited infertility treatment
- Private-duty nursing

Your Rights to Continue Coverage:

Federal and State laws may provide protections that allow you to keep this health insurance coverage as long as you pay your **premium**. There are exceptions, however, such as if:

- You commit fraud
- You move outside the coverage area
- The insurer stops offering services in the State

For more information on your rights to continue coverage, contact the insurer at (702) 242-7700 or 1-800-888-2264. You may also contact your state insurance department at (775) 687-0700 (Carson City), (702) 486-4009 (Las Vegas) or toll-free at 1-800-992-0900.

Your Grievance and Appeals Rights:

If you have a complaint or are dissatisfied with a denial of coverage for claims under your plan, you may be able to **appeal** or file a **grievance**. For questions about your rights, this notice, or assistance, you may contact the Nevada Division of Insurance at 1-800-992-0900 or http://www.doi.state.nv.us. Additionally, a consumer assistance program can help you file your appeal. Contact the Office of Consumer Health Assistance at 1-888-333-1597 or http://dhhs.nv.gov. A list of states with Consumer Assistance Programs is available at http://cciio.cms.gov/programs/consumer/capgrants/index.html.

Does this Coverage Provide Minimum Essential Coverage?

The Affordable Care Act requires most people to have health care coverage that qualifies as minimum essential coverage. **This plan or policy does provide minimum essential coverage.**

Language Access Services:

Spanish (Español): Para obtener asistencia en español, llame al número de teléfono de servicio al cliente que se incluye en este documento.

Tagalog (Tagalog): Para sa tulong sa Tagalog, tawagan ang numero ng serbisyo sa customer na kabilang sa dokumentong ito.

Chinese (中文): 若需要中文协助，请拨打本文件内的客户服务电话。

Navajo (Dine): Dine k'ehji shich'i' hadoodzih ninizingo, koji' hodiilnih dine yikah 'anidaalwoji ei binumber dii naaltsoos bikaa doo.

----------*To see examples of how this plan might cover costs for a sample medical situation, see the next page*----------

About these Coverage Examples:

These examples show how this plan might cover medical care in given situations. Use these examples to see, in general, how much financial protection a sample patient might get if they are covered under different plans.

This is not a cost estimator.

Don't use these examples to estimate your actual costs under this plan. The actual care you receive will be different from these examples, and the cost of that care will also be different.

See the next page for important information about these examples.

Having a baby
(normal delivery)

- **Amount owed to providers:** $7,600
- **Plan pays** $6,700
- **Patient pays** $900

Sample care costs:

Hospital charges (mother)	$2,700
Routine obstetric care	$1,200
Hospital charges (baby)	$900
Anesthesia	$900
Laboratory tests	$500
Prescriptions	$200
Radiology	$200
Vaccines, other preventive	$1,000
Total	**$7,600**

Patient pays:

Deductibles	$0
Copays	$300
Coinsurance	$600
Limits or Exclusions	$0
Total	**$900**

Managing type 2 diabetes
(routine maintenance of a well-controlled condition)

- **Amount owed to providers:** $5,400
- **Plan pays** $4,300
- **Patient pays** $1,100

Sample care costs:

Prescriptions	$2,900
Medical Equipment and Supplies	$1,300
Office Visits and Procedures	$700
Education	$300
Laboratory tests	$100
Vaccines, other preventive	$100
Total	**$5,400**

Patient pays:

Deductibles	$0
Copays	$1,100
Coinsurance	$0
Limits or Exclusions	$0
Total	**$1,100**

Questions and answers about the Coverage Examples:

What are some of the assumptions behind the Coverage Examples?

- Costs don't include **premiums**.
- Sample care costs are based on national averages supplied by the U.S. Department of Health and Human Services, and aren't specific to a particular geographic area or health plan.
- The patient's condition was not an excluded or preexisting condition.
- All services and treatments started and ended in the same coverage period.
- There are no other medical expenses for any member covered under this plan.
- Out-of-pocket expenses are based only on treating the condition in the example.
- The patient received all care from in-network **providers**. If the patient had received care from out-of-network **providers**, costs would have been higher.
- If other than individual coverage, the Patient Pays amount may be more.

What does a Coverage Example show?

For each treatment situation, the Coverage Example helps you see how **deductibles**, **copayments**, and **coinsurance** can add up. It also helps you see what expenses might be left up to you to pay because the service or treatment isn't covered or payment is limited.

Does the Coverage Example predict my own care needs?

× **No.** Treatments shown are just examples. The care you would receive for this condition could be different based on your doctor's advice, your age, how serious your condition is, and many other factors.

Does the Coverage Example predict my future expenses?

× **No.** Coverage Examples are **not** cost estimators. You can't use the examples to estimate costs for an actual condition. They are for comparative purposes only. Your own costs will be different depending on the care you receive, the prices your **providers** charge, and the reimbursement your health plan allows.

Can I use Coverage Examples to compare plans?

✓ **Yes.** When you look at the Summary of Benefits and Coverage for other plans, you'll find the same Coverage Examples. When you compare plans, check the "Patient Pays" box in each example. The smaller that number, the more coverage the plan provides.

Are there other costs I should consider when comparing plans?

✓ **Yes.** An important cost is the **premium** you pay. Generally, the lower your **premium**, the more you'll pay in out-of-pocket costs, such as **copayments**, **deductibles**, and **coinsurance**. You should also consider contributions to accounts such as health savings accounts (HSAs), flexible spending arrangements (FSAs) or health reimbursement accounts (HRAs) that help you pay out-of-pocket expenses.

Questions: Call (702) 242-7700 or 1-800-888-2264 or visit us at www.myshlonline.com.
If you aren't clear about any of the underlined terms used in this form, see the Glossary. You can view the Glossary at cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf or call the phone number above to request a copy.

SHL 002686

JA3008
00004-000100

Sierra Health and Life
P.O. Box 15645
Las Vegas, NV 89114-5645

WILLIAM G ESKEW
5825 EGAN CREST DR
LAS VEGAS NV 89149

For online access to your benefit information, visit our online member center at mySHLonline.com

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company

mySHLonline.com

SHL/UHC
2/5/2016
SAHMAD
(NMEN)

Date: 02/05/2016
Time: 11:59:00
User Id: gguerrero

Case Number: 160340910

Member Name: WILLIAM G ESKEW
Member Num: 150222942-0
Address: 5825 EGAN CREST DR
City,ST,Zip: LAS VEGAS, NV 89149
DOB: 10/03/1951 Age: 65
Phone: 702-885-3019 Ext:
Group: 10003502 - OFF EXCHANGE
SubGroup: 1001 - OFF EXCHANGE
Plan: INDMED03 - Medical
Product: I14PP200 - IND NX PPO 2014 My Solutions Platinum 2
Product Eff Dt: 01/01/2016

Diagnosis Information

Diag	Description
C3411	IDCD Not On File
C7951	IDCD Not On File

****
No UM Services records found meeting the given criteria
****

Note Section

UserId: lhamill5
Date: 2/3/2016 2:18:52 PM

Notes:

SHL SNV
64 M RECEIVED CALL
REQ DR ZHONGXING LIAO CON RAD/ONC
SVC PROTON
THERAPY CTR NON CON RADIATION THERAPY
PX RADIATION THERAPY
DX MALIGNANT
NEOPLASM OF UPPER LOBE RT BRONCHUS OR LUNG, SECONDARY MALIGNANT NEOPLASM
OF
BONE
DOS 02/08/16
DISCLAIMER KNOWN
ROUTED TO RN FORREVIEW
CLINICALS

PATIENT TO HAVE TREATMENT 5 DAYS PER WEEK FOR 30TREATMENTS. THERE IS A
LETTER OF MEDICAL NECESSITY, PATHOLOGY REPORT-07/23/15 TUMOR CELLS ARE
POS FOR
PANCYTOKERATIN(AE1/AE3),P63,CK5/6 ANDGATA3 WHILE NEG FOR TTF-1, CK7 AND
CK20.

BASED ON IMMUNOHYSTO CHEMICAL PROFILE, POSSIBILITIES OF UROTHELIAL CARCINOMA
NEEDS TO BE EXCLUDED.CLOSE CLINICAL AND RADIOLOGICAL CORRELATIONS ARE RECOMMENDED. SIMULATION NOTE 02/01/16 , CONSULTATION NOTE 01/27/16, PET CT SCAN
DONE 01/26/16 AND LAB WORK DONE 01/26/16.
Zhongxing Liao, MD
Specialty:

Radiation Oncology
Group Affiliation:
Physicians Referral
Service
Moreabout this provider

UserId: lamogawi
Date: 2/3/2016 4:47:57 PM

Notes:

UHG CHOICE PLUS NATIONAL PPO (Domiciled)
Req: AUTHORIZATION REQUEST FOR
RADIATION THERAPY: IMRT RADIATION TREATMENT
RADIATION SITE: LUNG
RADIATION
TYPE: IMRT
Number of fractions 30
Energy per Dose: 220/ 200cGy
Total Energy:
6600/ 6000 cGy
DX: LUNG CANCER
SENT TO MED DIRECTOR FOR REVIEW.
LA/RN

UserId: lamogawi
Date: 2/4/2016 3:21:20 PM

Notes:

From: shamoonahmad@yahoo.com [mailto:shamoonahmad@yahoo.com]
Sent: Thursday,
February 04, 2016 3:12 PM
To: Amogawin, Lou Ann
Subject: RE: Secure message
from Lou-Ann.Amogawin@uhc.com---160340910--DENY

Reviewer: Shamoon Ahmad MD,
FACP
Criteria used: ONC006
Effective Date: 11/2014.
NCCN guidelines for
radiation therapy version 2016

CaseSummary: Lung cancer
The requested
procedure does not meets currentHPN policy.
Decision: Proton therapy and all
associated codes are not covered and are denied.

To ADT.

LA/RN

UserId: cpollack
Date: 2/5/2016 8:23:42 AM

Notes:

DENIAL NOTIF
REC'D CALL FROM ADEL @ THE PROTON THERAPY CENTER HOUSTON- RE:
DENIAL REASON
INFORMED HER OF MED/DIR DENIAL/REASON
PHY TO PHY COMMUNICATION
RIGHTS (GOOD FOR 14 DAYS FROM DATE OF DENIAL NOTIFICATION) & APPEAL
RIGHTS
GIVEN. LEFT MY DIRECT LINE FOR ANY QUESTIONS.

UserId: gguerrero
Date: 2/5/2016 11:57:54 AM

Notes:

DENIAL LTRS HAND TYPED FROM TEMPLATE W/THE TEXT BELOW:

Based upon
UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy,
coverage is denied. Your provider asked for a Proton Beam
RadiationTherapy
(therapy that uses a beam of protons that carry a positive charge to
destroy
cancer cells) for you because you have lung cancer. This type of
radiation
therapy is considered unproven and not medically necessary for treating
lung
cancer. Current published evidence does notallow for any definitive
conclusions
about the safety and efficacy ofproton beam therapy to treat your
condition.
Therefore, the request cannot be approved at this time by your health
plan.

UserId: cpollack
Date: 2/5/2016 4:12:28 PM

Notes:

PLACED LINES IN DENIED STATUS
HOLDING LETTERS PER NW/RN-AUDITOR - AWAITING
CLARIF ON MED/DIR DECISION/PROTOCOL

UserId: AUTO
Date: 2/5/2016 4:15:33 PM

Notes:

Decision Logged on 02/05/2016 at: 4:15PM

UserId: lamogawi
Date: 2/5/2016 4:42:27 PM

Notes:

From: 'shamoonahmad@yahoo.com' [mailto:shamoonahmad@yahoo.com]
Sent:Friday,
February 05, 2016 4:42 PM
To: Amogawin, Lou Ann
Subject: RE: Secure message
from Lou-Ann.Amogawin@uhc.com--160340910--DENY

Reviewer: Shamoon Ahmad MD,
FACP
UHC Policy Number: 2015T0132T
Effective Date: December 1, 2015
NCCN
guidelines for radiation therapy version 2016

Case Summary: Mediastinal
tumor
The requested procedure does not meets current HPN/UHC policy.

Decision: Proton therapy and allassociated codes are not covered and are
denied.

To ADT.

LA/RN

Contact Section
------- -------

Contact: VELMA
Phone: 7137925702 Ext:
Fax: 7135638611 Ext:

Guerrero, Gustavo

From: Amogawin, Lou Ann
Sent: Friday, February 05, 2016 4:42 PM
To: Figueroa, Mari; Guerrero, Gustavo; Houghton, Melissa; Santos, June; Pollack, Carol
Subject: FW: Secure message from Lou-Ann.Amogawin@uhc.com--160340910--DENY

Thank You.

Kind Regards,
Lou Ann Amogawin, RN, BSN
Pre Service Review Nurse
United HealthCare Nevada Market
Phone: 702-242-7579
Fax: 702-838-1443
Email: Lou-Ann.Amogawin@uhc.com

--SecureDelivery--

-----Original Message-----
From: 'shamoonahmad@yahoo.com' [mailto:shamoonahmad@yahoo.com]
Sent: Friday, February 05, 2016 4:42 PM
To: Amogawin, Lou Ann
Subject: RE: Secure message from Lou-Ann.Amogawin@uhc.com--160340910--DENY

Reviewer: Shamoon Ahmad MD, FACP
UHC Policy Number: 2015T0132T
Effective Date: December 1, 2015
NCCN guidelines for radiation therapy version 2016

Case Summary: Mediastinal tumor
The requested procedure does not meets current HPN/UHC policy.
Decision: Proton therapy and all associated codes are not covered and are denied.

----------Original Message:

From: "Amogawin, Lou Ann" <Lou-Ann.Amogawin@uhc.com>
To: "'shamoonahmad@yahoo.com'" <shamoonahmad@yahoo.com>
Date: 02/05/2016 10:50:30 PM GMT
Subject: Secure message from Lou-Ann.Amogawin@uhc.com

Hi Dr. Ahmad,

This is the case for proton beam.
Can you please send me an updated denial text with correct protocol.
Attached is the UHC -KL protocol please send me an edited denial note for documentation.

Thank You.

Kind Regards,
Lou Ann Amogawin, RN, BSN
Pre Service Review Nurse
United HealthCare Nevada Market
Phone: 702-242-7579
Fax: 702-838-1443
Email: Lou-Ann.Amogawin@uhc.com

--SecureDelivery--

-----Original Message-----
From: shamoonahmad@yahoo.com [mailto:shamoonahmad@yahoo.com]
Sent: Thursday, February 04, 2016 4:20 PM
To: Amogawin, Lou Ann
Subject: RE: Secure message from
Lou-Ann.Amogawin@uhc.com--160340910--DENY

Reviewer: Shamoon Ahmad MD, FACP
Criteria used: ONC006
Effective Date: 11/2014.
NCCN guidelines for radiation therapy version 2016

Case Summary: Metastatic cancer to lung unknown primary The requested procedure does not meets current HPN policy.
Decision: Proton therapy and all associated codes are not covered and are denied.

----------Original Message:

From: "Amogawin, Lou Ann" <Lou-Ann.Amogawin@uhc.com>
To: "shamoonahmad@yahoo.com" <shamoonahmad@yahoo.com>
Date: 02/04/2016 01:20:13 AM GMT
Subject: Secure message from Lou-Ann.Amogawin@uhc.com

CORRECTION:

Req: AUTHORIZATION REQUEST FOR RADIATION THERAPY: IMRT VS IMPT RADIATION TREATMENT

RADIATION SITE: LUNG
RADIATION TYPE: IMRT VS IMPT
Number of fractions 30
Energy per Dose: 220/ 200cGy
Total Energy: 6600/ 6000 cGy

Thank You.

Kind Regards,
Lou Ann Amogawin, RN, BSN
Pre Service Review Nurse
United HealthCare Nevada Market
Phone: 702-242-7579
Fax: 702-838-1443
Email: Lou-Ann.Amogawin@uhc.com (link: mailto:Lou-Ann.Amogawin@uhc.com)

--SecureDelivery--

From: Amogawin, Lou Ann
Sent: Wednesday, February 03, 2016 4:48 PM
To: shamoonahmad@yahoo.com
Subject: Secure: Pls Review -STAT OOA REQUEST-
Importance: High

Hi Dr. Ebbin,

OOA STAT REQUEST: SHL WITH UHC BENEFIT

Please review: 160340910

Member: WILLIAM ESKEW

64 year old - MALE

REQUESTING MD: : DR ZHONGXING LIAO –RAD ONCO- (UHC CONTR).

SERVICING FACILITY: : MD ANDERSON CANCER CENTER- PROTON THERAPY CTR –OOA-TEXAS (UHC CONTR).

Req: AUTHORIZATION REQUEST FOR RADIATION THERAPY: IMRT RADIATION TREATMENT

RADIATION SITE: LUNG
RADIATION TYPE: IMRT
Number of fractions 30
Energy per Dose: 220/ 200cGy
Total Energy: 6600/ 6000 cGy

Dx: MALIGNANT NEOPLASM OF THE LUNG

Please see attached clinicals

Thank You.

Kind Regards,
Lou Ann Amogawin, RN, BSN
Pre Service Review Nurse
United HealthCare Nevada Market
Phone: 702-242-7579
Fax: 702-838-1443
Email: Lou-Ann.Amogawin@uhc.com (link: mailto:Lou-Ann.Amogawin@uhc.com)

--SecureDelivery--

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recipient or his or her authorized agent, the reader is hereby notified that any dissemination, distribution or copying of this e-mail is prohibited. If you have received this e-mail in error, please notify the sender by replying to this message and delete this e-mail immediately.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Proton Therapy

SECURE FAX 713-563-8611

URGENT PRIOR AUTHORIZATION #160340910

TO:	FROM:
URGENT PRIOR AUTHORIZATION	ZELMA HUGHES
COMPANY:	DATE:
UHC-SIERRA HEALTH	2/3/2016
FAX NUMBER:	TOTAL NO. OF PAGES, INCLUDING COVER:
702-304-7411	
PHONE NUMBER:	SENDER'S CONTACT NUMBER:
	713-792-5702
RE:	POLICY NO#/ DATE OF BIRTH
WILLIAM ESKEW	ID:15022294200 DOB: 10/03/1951

☐ URGENT ☐ FOR REVIEW ☐ PLEASE COMMENT ☐ PLEASE REPLY ☐ PLEASE RECYCLE

NOTES/COMMENTS:
URGENT PRIOR AUTHORIZATION FOR PROTON RADIATION TREATMENT

	NPI#	TAX ID#
DR. ZHONGXING LIAO	**1316048465**	**760273984**
PROTON THERAPY CENTER	**1760462709**	**760679446**

************CONFIDENTAL NOTICE*************

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THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Proton Therapy

February 3, 2016

United Healthcare – Sierra Health
PO Box 15645
Las Vegas, Nevada 89114

RE: William Eskew **DOB : 10/03/1951** **MDACC : 1195025**
GROUP: 1000350210001 **ID# : 15022294200** **ICD : C34.11, C79.51**

CPT Codes: 77263 (1), 77470 (1), 77321 (1), 77290 (2), 77280(6), 77370 (1), 77295 (2), 77293(1), 77300 (8), 77334 (17), 77522 (30) or 77523 (30) or 77525 (30) , G6002 (T-30) and 77387 (P-30), 77427 (6), 77336 (6)

Urgent Letter of Medical Necessity

To Whom It May Concern:

This Letter of Medical Necessity is presented on behalf of your member Mr. William Eskew. We are requesting certification of CT simulation and 30 treatments of proton radiation therapy for over six weeks for a 64-year-old male diagnosed with a diagnosis of stage IV malignant carcinoma with squamoid features, primary site undetermined. He is being considered for concurrent chemoradiation therapy using proton therapy to maximize local control. All relevant clinical information has been reviewed and this patient is meeting eligibility criteria for treatment with proton beam therapy. Please see supporting clinical information attached.

Radiotherapy is an accepted plan of treatment for lung carcinoma. Radiotherapy employing proton beam instead of photons is able to provide the optimum dose to the targeted area without causing potentially serious normal tissue complications, especially to the heart, esophagus, spinal cord, and normal lungs. Additional radiation dose to these structures puts the patient at risk for costly side effects including pericarditis, myocardial infarction, acute respiratory distress syndrome and pneumonitis.

MD Anderson is well recognized as a center of excellence for cancer treatment, patient care and research. Our positive outcomes are based on our years of experience and the treatment of cancer and its associated complications.

Thanking you kindly for an expeditious processing and approval for this medically necessary treatment for Mr. Eskew. Please contact Zelma Hughes, Patient Access Specialist (713-792-5702), or Elizabeth Traje, RN, Patient Access Coordinator (713-792-0417) for additional information.

Please mail all correspondence to:
UT MD Anderson Cancer Center- The Proton Therapy Center
Attention : Patient Access Services Department
1840 Old Spanish Trail Houston, Texas 77054
Tax ID # 760679446

Sincerely,

Zhongxing Liao.MD
Professor
Department of Radiation Oncology
The University of Texas M D Anderson Cancer Center

UT M.D. Anderson Cancer Center
Transcribed Document Print by ETRAJE at 2/3/2016 12:17:25 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

SN 02/01/2016 XRT Simulation Note

02/01/2016

Diagnosis: Malignant neoplasm of upper lobe, unspecified bronchus or lung
Histopathology: Squamous cell carcinoma
Stage: Stage IV

Brief History:
William G. Eskew is a 64-year-old male diagnosed with a right squamous cell carcinoma Malignant neoplasm of upper lobe, unspecified bronchus or lung.

Prior Radiation:
Radiation therapy to abdoman for lymphoma in 2003.

Type of Simulation: Initial

Goal of Treatment: Curative

ECOG Performance Status: 0

Consents: Present in chart

The patient was brought to the AcQsimCT and a timeout was performed to correctly identify the patient using two identifiers. He was placed in the supine position with bilateral arm(s) Above head.

The following was created to optimize day-to-day setup: a(n) upper Vac-Lok.

A wing board was used to position the patient.

Axial CT images were obtained through the volume of interest. Isocenters for treatment planning were placed as per routine. Images were accurately transferred from the CT scanner to the Pinnacle treatment planning workstation.

This patient was simulated using respiratory correlated 4DCT in which a marker was placed on the patient and this was used to reconstruct images that represent the location of the tumor and critical structures throughout the breathing cycle. These images were imported in our treatment planning system and based on these we developed target and avoidance volumes that represent the patient during normal respiration. We then developed a treatment strategy that ensures good target coverage and normal tissue sparing in regions affected by respiratory motion.

The volumes of interest, port selections, and provisional doses anticipated for this patient's IMRT and protons are as follows:

Site	Technique	Modality	FX	D/FX	Dose
RUL tumor and MD node	IMRT vs.IMPT	x06	30	220.00 GTV/200 PTV cGy	6600/6000 cGy

Custom blocking will be used.

The patient tolerated the procedure well.

Dr. Zhongxing Liao was physically present for the simulation.

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1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

SN 02/01/2016 XRT Simulation Note

Dr. Zhongxing Liao reviewed the following: (1) prior radiation history, (2) electronic medical devices, and (3) pregnancy status: N/A.

ZHONGXING LIAO, MD, 10145
Dictated By: ZHONGXING LIAO , MD, 10145

D: 02/01/2016 11:16:31 T: 02/01/2016 11:16:31

Electronically Signed By: ZHONGXING LIAO, MD on 02/01/2016 16:56:57

UT M.D. Anderson Cancer Center
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1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

CO 01/27/2016 Consultation

01/27/2016

REASON FOR CONSULTATION: Stage IV non-small cell lung cancer with a right upper lobe tumor, mediastinal lymphadenopathy, and a single bone metastases involving the humerus, status post 6 cycles of chemotherapy.

HISTORY OF PRESENT ILLNESS:
Mr. Eskew is a 64-year-old gentleman from Las Vegas with a significant past medical history of low-grade non-Hodgkin's lymphoma diagnosed in 2003. He received chemotherapy and radiation therapy to the abdomen since then he has been in remission.

In July 2015, he sustained a right humerus fracture while he was playing golf. He went to the local emergency center will an x-ray of the right humerus was done which showed a distal humerus shaft fracture with displacement of 8 millimeter . An underlying lesion was noted as well.

In July 22, 2015, MRI of the right humerus demonstrated a pathological oblique fracture of the distal shaft of the right humerus with an underlying lesion measure 1.4 by 2.8 centimeter. There is another for 1.5 centimeter triangular-shaped abnormality proximal to the main portion of the lesion.

CT scan of the chest showed a spiculated 2 x 2 by 2 centimeter pulmonary nodule within the posterior aspect of the right upper lobe of the lung. Mildly enlarged right lower lobe paratracheal lymph node, right hilar lymph node as well as a subcarinal lymph node were noted. CT scan of the abdomen showed no evidence of metastasis. Bone scan showed abnormal activity in the right lateral third rib which corresponds to the suspicious lytic lesion demonstrated on the CT scan.

PET/CT scan on August 7, 2015 confirmed a right upper lobe tumor 2.3 by 2.2 centimeters with a maximum SUV of 7.2. Right upper lateral rib lesion is FDG active with SUV of 3.0. Distal radius fracture also was seen on the PET/CT scan.

In July 2015, he underwent ORIF of the right humerus. The outside pathological report demonstrated a right humerus tumor, metastatic carcinoma, immunohistochemical stain was positive for pain carotene, p63, and a CK 5/6. The tumor was negative for CK 7, TTF-1, and a CK 20. Poorly differentiated carcinoma consistent with a squamous cell carcinoma was considered. The outside histological slice has been reviewed by our institution. The review confirmed metastatic carcinoma with a squamous future primary site undetermined.

10/28/2015 to January 2016, patient has received chemotherapy consist of flow couple platelet and paclitaxel for 4 cycles. He also received radiation therapy to the right humerus 14 treatments. However I do not have his outside medical records available to review. I also do not have his outside radiation records for his abdomen no radiation therapy for his lymphoma.

This patient is referred her to us for consideration of local regional treatment. Currently patient has a performs a status of 90. He is asymptomatic from the tumor.

Please refer to Chunyi Yang' APN of Radiation Oncology complete documentation of the complete REVIEW OF SYSTEMS, ALLERGIES, PAST SURGICAL HISTORY, PAST MEDICAL HISTORY, SOCIAL HISTORY, CURRENT MEDICATIONS, FAMILY HISTORY. I have personally reviewed the information as documented.

PHYSICAL EXAMINATION:
General: Mr. Eskew is a very pleasant well-developed, well-nourished male in no apparent

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1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

CO 01/27/2016 Consultation

distress. He is accompanied to my clinic by wife. He is alert and oriented x3 in no acute distress.
Vitals: Height 175 centimeter, weight 86.6 kilograms, temperature 36.7, pulse 83, respiration 18, blood pressure 118/61, KPS 90.
HEENT: Normocephalic, atraumatic, PERRLA, EOMI. Neck is supple, there is no JVD or thyroidomegaly. There were no palpable lymphadenopathy at bilateral cervical, supraclavicular, and his infraclavicular fossa.
Lungs: clear to auscultation without crackle, rales, or wheezing. There is no rubbing.
Heart: Regular rate and rhythm, without murmur S3-S4.
Abdomen: Soft nontender, nondistended, no organomegaly.
Extremities: No edema, clubbing, cyanosis.
Neurological system: Grossly nonfocal. Mood: Patient is quite positive symptoms without significant distress.

LABORATORY/IMAGING DATA:
PET/CT scan January 26, 2016, showed a right upper lobe spiculated hypermetabolic tumor on the outside PET/CT scan the mass measured 1.7 by 2.3 cm in and had a maximum SUV of 7.2 (image 179 of the outside study from 08/07/2015) the mass now measures 2.8 x 3.1 cm and has a maximum SUV of 8.0 (image 77 of today's study).

Lymph Nodes: There are subcarinal nodes which are somewhat more prominent than they were on the prior study. A subcarinal node on the outside study seen on image 161 had a maximum SUV of 2.0 that node is about the same size but the maximum SUV is now 5.7 (image 161 of the outside study and image 97 of the M.D. Anderson cancer Center study).

A right hilar node that is difficult to measure without contrast material employed had a maximum SUV of 2.6 that node now has a maximum SUV of 3.4, a 31% increase in metabolic activity.
Bones: There is a healed fracture of the right 3rd rib. There is a subtle focus of increased metabolism in the left femoral head (image 65). A subtle focus of increased metabolism is noted in the left anterior superior iliac spine (image 199) No suspicious lytic or sclerotic osseous lesions are seen on CT scanning.

Pathological: METASTATIC CARCINOMA WITH SQUAMOID FEATURES, PRIMARY SITE UNDETERMINED.

WORKING DIAGNOSIS: Stage IV non-small cell lung cancers most probably squamous cell carcinoma status post 4 cycles of couple plating and paclitaxel chemotherapy. Patient also had radiation therapy to the right humerus. He also has a possible medical history of radiation therapy to the periaortic lymph node and spleen for his low-grade lymphocytic lymphoma. There was done in 2003.

IMPRESSION/PLAN: This patient has a oligo metastasis to the right humerus which has been treated successfully with radiation therapy and chemotherapy. His primary tumor and mediastinal lymph node has shown some progression. I recommend a course of oral aggressive consolidative chemoradiation therapy consisted of 6 weeks of radiation therapy with concurrent chemotherapy. I have discussed the rationale, benefit, side effect and the technical consideration of his treatment. I have given them ample time to ask questions. I have communicated to my recommendation with a his medical oncology Dr. Ferrarotto. We agreed to proceed with concurrent chemoradiation therapy as aggressive consolidation. Patient is not eligible for ending protocol due to his his stage IV status. He has been consented for radiation therapy and simulation is arranged for tomorrow.

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1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

CO 01/27/2016 Consultation

ZHONGXING LIAO, MD, 10145
Dictated By: ZHONGXING LIAO , MD, 10145

D: 01/27/2016 18:00:50 T: 01/27/2016 18:00:50

Electronically Signed By: ZHONGXING LIAO, MD on 01/27/2016 18:23:48

CC List:
CLARK JEAN MD
COMPREHENSIVE CA CENTERS OF NV
7445 PEAK DR
LAS VEGAS, NV 891289011 US

UT M.D. Anderson Cancer Center
Transcribed Document Print by ETRAJE at 2/3/2016 12:19:28 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

CO 01/27/2016 Consultation

01/27/2016

RADIATION CONSULT NOTE

REFERRING PHYSICIAN:
Dr. Ferrarotto from Thoracic Medical Oncology.

REASON FOR CONSULTATION:
Treatment recommendations regarding patient's newly diagnosed lung cancer.

HEENT: The patient denies any sores or lesions inside the mouth and throat. He denies any eye pain or discharges.
CONSTITUTIONAL: The KPS is 90%.
HEENT: The patient denies any sores or lesions inside the mouth and throat. He denies any eye pain or discharges.
RESPIRATORY: The patient complains of dyspnea, no hemoptysis. O2 saturation on room air is 95%.
CARDIOVASCULAR: The patient denies any chest pain, palpitations, wheezes, or irregular heartbeats.
NEUROLOGIC: The patient denies any severe headache, any visual changes or seizure activity.
PSYCHOLOGICAL: The patient denies any anxiety and depression.
GASTROINTESTINAL: The patient denies any diarrhea, constipation, or abdominal pain.

PAST MEDICAL HISTORY:
Low-grade non-Hodgkin's lymphoma, primary peripheral artery disease, ventricular tachycardia, heart failure in 2013, type 2 diabetes, kidney disease.

PAST SURGICAL HISTORY:
Resection of her right inguinal lymph nodes in 2003, triple bypass in 2004, peripheral artery bypass and 2 stent placement in 2005, surgery toenail was done related to diabetes in the history.

SOCIAL HISTORY:
The patient is accompanied by his wife in the clinic today. The patient is currently disabled, not working. The patient is married and with 1 son and 1 daughter. The patient had 1 brother. The patient smokes approximately 30 years already and 2 packs a day, quit smoking in 2003. The patient denies any alcohol or drug abuse.

FAMILY HISTORY:
The patient's mother died at age 79 for diabetes. The patient's father died from multiple myeloma.

DRUG ALLERGIES:
CLINDAMYCIN.

CURRENT MEDICATION:
Amlodipine, aspirin, carvedilol, Lipitor, Tricor, magnesium, insulin Victoza, glipizide, vitamin D, probiotics.

IMPRESSION AND PLAN:
Please refer to Dr.Liao detailed dictation dated on 01/27/2016.

Transcribed Document Print by ETRAJE at 2/3/2016 12:19:28 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

CO 01/27/2016 Consultation

CHUNYI YANG, APN, 11898
Dictated By: CHUNYI YANG , APN, 11898

D: 01/28/2016 17:47:49 T: 01/29/2016 00:28:59

Electronically Signed By: CHUNYI YANG, APN on 02/01/2016 22:55:55

CC List:
CLARK JEAN MD
COMPREHENSIVE CA CENTERS OF NV
7445 PEAK DR
LAS VEGAS, NV 891289011 US

UT M.D. Anderson Cancer Center
Tamtron Print by ETRAJE at 2/3/2016 12:17:55 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

Accession: S-15-079632
Specimen Date/Time: 07/23/2015

MATERIALS RECEIVED

Accession #	Collected	Received	Slides	Blocks	UnstSlides
MS15-4821	07/23/2015	10/07/2015	12	1	0

DIAGNOSIS

One outside block and twelve outside slides (MS15-4821), designated as:

A. Humerus, right tumor, biopsy:

METASTATIC CARCINOMA WITH SQUAMOID FEATURES, PRIMARY SITE UNDETERMINED, (SEE COMMENT).

COMMENT

Submitted immunohistochemical stains demonstrate that tumor cells are positive for pancytokeratin (AE1/AE3), P63, CK5/6 and GATA 3 while negative for TTF-1, CK7 and CK20. Based on immunohistochemical profile the possibility of urothelial carcinoma needs to be excluded. Close clinical and radiological correlations are recommended.

CAM:PA/elk
DD: 10/7/15
10/8/2015 10:56 AM

BIOMARKER TESTING

Primary
Tumor Block: A2

SNOMED CODES

T-12410, M-80706

"Some tests reported here may have been developed and performance characteristics determined by UT MD Anderson Pathology and Laboratory Medicine. These tests have not been specifically cleared or approved by the U.S. Food and Drug Administration."
Entire report and diagnosis completed by: Cesar Moran MD 10525 Oct 08, 2015

------END OF REPORT------

Division of Pathology and Laboratory Medicine
U.T.M.D. Anderson Cancer Center
1515 Holcombe Boulevard
Houston, Texas 77030

UT M.D. Anderson Cancer Center
Radiology Print by TRAJE,ELIZABETH at 2/3/2016 12:18:03 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

PET/CT NSCLC Restaging 1/26/2016 9:22:00 AM
Accession: 13773188

FULL RESULT:
Examination: FDG PET/CT, 1/26/2016 9:22 AM

Tumor Type: Non-small cell lung cancer
Clinical History: 64-year-old Caucasian male with non-Hodgkin's lymphoma stage I treated in 2003.

In 07/20/2015 exam have a pathologic fracture is right humerus he underwent surgery for that pathology showed metastatic carcinoma with squamoid features with primary site undetermined a PET CT scan August revealed a right upper lobe mass with SUV of 2.3 as well as right hilar and right mediastinal nodes and a fractured rib.. The patient is status post radiation therapy for the humerus 10 doses. He then started 1st line chemotherapy with carboplatin and paclitaxel status post 4 cycles with disease stability.

Indication: Subsequent treatment strategies.

Comparison: Outside PET/CT scan of 08/07/2015

Technique:
Radiopharmaceutical: F-18 fluorodeoxyglucose
Administered activity: 10.4 mCi
Route of administration: Intravenous via the left antecubital vein
Localization time: 60 minutes
Serum blood glucose: 126 mg/dl
Scan range: Upper midbrain to proximal thighs

Findings:
Head and Neck:
Brain: The visualized portions of the brain are normal in appearance on non-contrast CT scanning.
Mucosa: Tracer uptake in the head and neck mucosa is normal and symmetric.
Lymph Nodes: There is no nodal hypermetabolism or adenopathy in the cervical chains.

Chest: There is evidence of a sternotomy. The patient is status post triple bypass surgery 2004.

Lungs: There is a right upper lobe spiculated hypermetabolic tumor on the outside PET/CT scan the mass measured 1.7 by 2.3 cm in and had a maximum SUV of 7.2 (image 179 of the outside study from 08/07/2015) the mass now measures 2.8 x 3.1 cm and has a maximum SUV of 8.0 (image 77 of today's

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

PET/CT NSCLC Restaging1/26/2016 9:22:00 AM
Accession: 13773188

study).

Lymph Nodes: There are subcarinal nodes which are somewhat more prominent than they were on the prior study. A subcarinal node on the outside study seen on image 161 had a maximum SUV of 2.0 that node is about the same size but the maximum SUV is now 5.7 (image 161 of the outside study and image 97 of the M.D. Anderson cancer Center study).

A right hilar node that is difficult to measure without contrast material employed had a maximum SUV of 2.6 that node now has a maximum SUV of 3.4, a 31% increase in metabolic activity.

Esophagus: Normal
Pleural Spaces: Normal.
Heart/Pericardium: Cardiac chamber sizes normal. There is no evidence of pericardial effusion. Multivessel coronary artery calcification is stable.

Abdomen and Pelvis:
Liver: Tracer uptake in the hepatic parenchyma is homogeneous, and no intrahepatic masses are identified on non-contrast CT images. Patient has cholelithiasis without evidence of cholecystitis.

Spleen: The spleen is normal in size and FDG avidity.
Adrenal Glands: Normal
Pancreas: Normal
Kidneys: Normal.
Lymph Nodes: No progressive subdiaphragmatic nodal hypermetabolism or adenopathy.
GI Tract: The stomach, small bowel, and colon are normal in caliber, with physiologic FDG uptake.

Genitourinary: Dystrophic calcification is noted in the prostate gland.
The abdominal aorta and its major branches show focal areas of calcification includes the renal arteries.

Musculoskeletal:
Mild degenerative changes noted throughout the spine.
Bones: There is a healed fracture of the right 3rd rib. There is a subtle focus of increased metabolism in the left femoral head (image 65). A subtle focus of increased metabolism is noted in the left anterior superior iliac spine (image 199) No suspicious lytic or sclerotic osseous lesions are seen on CT scanning.

Soft Tissues: Normal

IMPRESSION:
There appears to be progressive disease involving the primary right upper lobe malignancy and the subcarinal and right hilar nodal metastases as described above.

The subtle findings in the left humeral head and left iliac bone were acquired follow-up.

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

PET/CT NSCLC Restaging1/26/2016 9:22:00 AM
Accession: 13773188

904 - PODOLOFF, DONALD A.
SIGNED BY: 904 - PODOLOFF, DONALD A. 1/26/2016 3:27:00 PM

D: 1/26/2016 3:27:00 PM T: 1/26/2016 3:27:00 PM

UT M.D. Anderson Cancer Center
Laboratory printed by ETRAJE at 2/3/2016 12:18:24 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

Accession: 16-026-03043 01/26/2016 10:26

Complete Blood Count w/ Automated Differential

WBC	7.5	K/uL	(4.0-11.0)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
RBC	4.41 L	M/uL	(4.50-6.00)
Hgb	13.6 L	gm/dL	(14.0-18.0)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Hct	40.5	%	(40.0-54.0)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
MCV	92	fL	(82-98)
MCH	30.8	pg	(27.0-31.0)
MCHC	33.6	gm/dL	(31.0-36.0)
RDW-SD	48.1 H	fL	(35.1-46.3)
RDW-CV	14.3	%	(12.0-15.5)
Platelet	262	K/uL	(140-440)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
MPV	9.7	fL	(4.0-10.4)
INRBC	0.0	%	
The INRBC (instrument NRBC) value reflects the enumeration of nucleated red blood cells contained in a 200uL sample of whole blood analyzed by the instrument. This value may differ from the NRBC value reported in a manual differential, which is based on a 100 cell differential.			
*Method	Auto		

Other tests ordered on the same accession number are available below.

Total Protein	7.7	gm/dL	(6.0-8.2)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Albumin Lvl	4.4	gm/dL	(3.5-4.7)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			

UT M.D. Anderson Cancer Center
Laboratory Printed by ETRAJE at 2/3/2016 12:18:24 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)

Calcium Lvl	9.4	mg/dL	(8.4-10.2)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Phosphorus	4.2	mg/dL	(2.5-4.5)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Glucose Level	174 H	mg/dL	(70-110)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
BUN	17	mg/dL	(8-20)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Creatinine	1.21	mg/dL	(0.70-1.30)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Uric Acid	6.3	mg/dL	(2.6-7.1)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Bili Total	0.5	mg/dL	(0.2-1.3)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Alk Phos	85	IU/L	(38-126)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
LDH	510	IU/L	(313-618)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030			

UT M.D. Anderson Cancer Center
Laboratory Printed by ETRAJE at 2/3/2016 12:18:24 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)
CLIA License: 45D0874047

ALT	29	IU/L	(7-56)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			

Electrolyte Panel

Sodium Lvl	142	mEq/L	(135-147)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Potassium Lvl	4.5	mEq/L	(3.5-5.0)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
Chloride	102	mEq/L	(98-108)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
CO2	26	mEq/L	(23-30)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			

Magnesium	1.9	mg/dL	(1.8-2.9)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			

Prothrombin Time

PT	13.1	second(s)	(12.7-15.0)
Testing Performed at ACB Lab Ambulatory Care Bldg 1220 Holcombe Blvd, Unit #24 Houston,Tx 77030 CLIA License: 45D0874047			
INR	0.98		(0.90-1.20)

PTT	25.2	second(s)	(24.7-35.9)
Testing Performed at ACB Lab Ambulatory Care Bldg			

UT M.D. Anderson Cancer Center
Laboratory Printed by ETRAJE at 2/3/2016 12:18:24 PM

1195025 - ESKEW, WILLIAM G 64yo M 10/03/1951 (175.0cm 86.6kg BSA: 2.05m² 01/27/16)
1220 Holcombe Blvd, Unit #24
Houston,Tx 77030
CLIA License: 45D0874047

Differential

IG Abs	0.02	K/uL	(0.00-0.04)
IGRE %	0.3	%	(0.0-0.4)
IGRE % count includes Metamyelocytes, Myelocytes, and Promyelocytes.			
Neutrophil %	58.3	%	(42.0-66.0)
The Neutrophil count includes Bands.			
Lymphocyte %	22.3 L	%	(24.0-44.0)
Monocyte %	13.8 H	%	(2.0-7.0)
Eosinophil %	4.8 H	%	(1.0-4.0)
Basophil %	0.5	%	(0.0-1.0)
Neutrophil Abs	4.40	K/uL	(1.70-7.30)
Lymphocyte Abs	1.68	K/uL	(1.00-4.80)
Monocyte Abs	1.04 H	K/uL	(0.08-0.70)
Eosinophil Abs	0.36	K/uL	(0.04-0.40)
Basophil Abs	0.04	K/uL	(0.00-0.10)

Glomerular Filtration Rate

eGFR-AA 73 mL/min/1.73 sq. m
These results are estimated for an African American male.
Testing Performed at
ACB Lab Ambulatory Care Bldg
1220 Holcombe Blvd, Unit #24
Houston,Tx 77030
CLIA License: 45D0874047
eGFR-NAA 60 mL/min/1.73 sq. m
These results are estimated for a non-African American male.
According to the National Kidney Foundation's Kidney Disease Outcome Quality Initiative (KDOQI) classification and 2012 Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guildline, the stage of CKD should be categorized based on estimated GFR.

Stage	Description	GFR mL/min/1.73 m2
1	Kidney damage with normal or high GFR	>=90
2	Kidney damage with milde decrease in GFR	60-89
3a	Mild to moderate decrease in GFR	45-59
3b	Moderate to severe decrease in GFR	30-44
4	Severe decrease in GFR	15-29
5	Kidney Failure	<15 (or dialysis)

Other tests ordered on the same date with different accession numbers are available below.

Accession: 16-026-01726 01/26/2016 07:50

GLU SCRN	126 H	mg/dL	(70-110)

Unless otherwise noted, all lab tests performed by:
Division of Pathology and Laboratory Medicine

UnitedHealthcare®

MEDICAL POLICY

PROTON BEAM RADIATION THERAPY

Policy Number: 2015T0132T
Effective Date: December 1, 2015

Table of Contents

Related Policies:
Intensity-Modulated Radiation Therapy

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

This policy applies to persons 19 years of age and older. Proton beam radiation therapy is covered without further review for persons younger than 19 years of age.

Where proton beam therapy is deemed proven, in-network benefits may be available for what is otherwise an out-of-area or out-of-network service. The enrollee-specific benefit document must be consulted to determine what form of coverage exists.

- If an enrollee has benefits for out-of-network services ("Plus"), proton beam therapy would be covered at the out-of-network benefit level. Additional coverage for travel costs would not be allowed in this situation.
- If an enrollee does not have benefits for out-of-network services ("Standard"), no out-of-network benefit would be available for proton beam therapy as long as external beam radiation therapy is available within the network.

Some Certificates of Coverage allow coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The enrollee-specific benefit document must be consulted to make coverage decisions for this service.

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage.

COVERAGE RATIONALE

Proton beam radiation therapy is proven and medically necessary for the following indications:

- Intracranial arteriovenous malformations (AVMs)
- Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid)
- Skull-based tumors (e.g., chordomas, chondrosarcomas or paranasal sinus tumors)

Proton beam radiation therapy is unproven and not medically necessary for treating ALL other indications, including but not limited to:

- Age-related macular degeneration (AMD)
- Bladder cancer
- Brain and spinal cord tumors
- Choroidal hemangioma
- Esophageal cancer
- Gynecologic cancers
- Head and neck cancers
- Hepatocellular carcinoma
- Lung cancer
- Lymphomas
- Pancreatic cancer
- Prostate cancer
- Vestibular tumors (e.g. acoustic neuroma or vestibular schwannoma)

There is limited clinical evidence that directly compares proton beam therapy (PBT) with other types of radiation therapy. Current published evidence does not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat conditions other than those noted above as proven and medically necessary.

Proton beam radiation therapy used in conjunction with intensity-modulated radiation therapy (IMRT) is unproven and not medically necessary.
Clinical evidence is insufficient to support the combined use of these technologies in a single treatment plan. Comparative effectiveness studies including randomized controlled trials are needed to demonstrate the safety and long-term efficacy of combined therapy.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex

CPT® is a registered trademark of the American Medical Association.

HCPCS Code	Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

Proven ICD-9 Codes (Discontinued 10/01/15)
The following list of codes is provided for reference purposes only. Effective October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) implemented ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures), replacing the ICD-9-CM diagnosis and procedure code sets.
ICD-9 codes will not be accepted for services provided on or after October 1, 2015.

ICD-9 Diagnosis Code (Proven) (Discontinued 10/01/15)	Description
170.0	Malignant neoplasm of bones of skull and face, except mandible
190.0	Malignant neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid
190.6	Malignant neoplasm of choroid
191.9	Malignant neoplasm of brain, unspecified site
213.0	Benign neoplasm of bones of skull and face

224.0	Benign neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid
224.6	Benign neoplasm of choroid
234.0	Carcinoma in situ of eye
747.81	Congenital anomaly of cerebrovascular system

ICD-10 Codes
ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures) must be used to report services provided on or after October 1, 2015.
ICD-10 codes will not be accepted for services provided prior to October 1, 2015.

ICD-10 Diagnosis Code	Description
C41.0	Malignant neoplasm of bones of skull and face
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C71.9	Malignant neoplasm of brain, unspecified
D09.20	Carcinoma in situ of unspecified eye
D09.21	Carcinoma in situ of right eye
D09.22	Carcinoma in situ of left eye
D16.4	Benign neoplasm of bones of skull and face
D31.30	Benign neoplasm of unspecified choroid
D31.31	Benign neoplasm of right choroid
D31.32	Benign neoplasm of left choroid
D31.40	Benign neoplasm of unspecified ciliary body
D31.41	Benign neoplasm of right ciliary body
D31.42	Benign neoplasm of left ciliary body
Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

DESCRIPTION OF SERVICES

Unlike other types of radiation therapy that use x-rays or photons to destroy cancer cells, proton beam therapy (PBT) uses a beam of special particles (protons) that carry a positive charge. There is no significant difference in the biological effects of protons versus photons; however, protons can deliver a dose of radiation in a more confined way to the tumor tissue than photons. After they enter the body, protons release most of their energy within the tumor region and, unlike photons, deliver only a minimal dose beyond the tumor boundaries (American College of Radiology website, 2012).

The greatest energy release with conventional radiation (photons) is at the surface of the tissue and decreases exponentially the farther it travels. In contrast, the energy of a proton beam is released at the end of its path, a region called the Bragg peak. Since the energy release of the proton beam is confined to the narrow Bragg peak, collateral damage to the surrounding tissues should be reduced, while an increased dose of radiation can be delivered to the tumor.

Because of these physical properties, PBT may be useful when the target volume is in close proximity to one or more critical structures and sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiation therapy.

CLINICAL EVIDENCE

AHRQ published a report on particle beam therapy for treating a variety of cancers. More than half of the publications the AHRQ identified described treatment of ocular cancers (uveal melanoma in particular), and cancers of the head and neck (brain tumors, and tumors arising from skull base, cervical spine and nearby structures). In order of decreasing number of studies, the following types of malignancies were also described: gastrointestinal (esophageal cancer, hepatocellular carcinomas of the liver, pancreatic cancer), prostate, lung, spine and sacrum, bone and soft tissue, uterine (cervix and corpus), bladder, and miscellaneous (skin cancer or a compilation of a center's experience with a variety of cancers treated there).

According to the AHRQ report, there are many publications on particle (mainly proton) beam therapy for the treatment of cancer. However, they typically do not use a concurrent control, focus on heterogeneous populations and they employ different definitions for outcomes and harms. These studies do not document the circumstances in contemporary treatment strategies in which radiotherapy with charged particles is superior to other modalities. Comparative effectiveness studies including randomized controlled trials are needed to document the theoretical advantages of charged particle radiotherapy to specific clinical situations. At present, there is very limited evidence comparing the safety and effectiveness of PBRT with other types of radiation therapies for cancer. Therefore, it is not possible to draw conclusions about the comparative safety and effectiveness of PBRT at this time (AHRQ, 2009).

In an emerging technology report, ECRI detailed major clinical and operational issues related to proton beam radiation therapy. However, no analysis of the evidence was possible due to the lack of appropriately designed studies comparing the efficacy of proton therapy to other modes of radiation therapy (ECRI, 2010; updated 2013).

Several systematic reviews (Terasawa et al., 2009; Brada et al., 2009; Lodge et al., 2007; Olsen et al., 2007) previously reported the lack of evidence supporting proton beam therapy and the need for well-designed prospective studies comparing proton beam therapy to other forms of radiation therapy.

Professional Societies

American Society for Radiation Oncology (ASTRO)

ASTRO's Emerging Technology Committee concluded that current data do not provide sufficient evidence to recommend proton beam therapy (PBT) outside of clinical trials in lung cancer, head and neck cancer, GI malignancies (with the exception of hepatocellular carcinoma) and pediatric non-central nervous system (CNS) malignancies. In hepatocellular carcinoma and prostate cancer, there is evidence of the efficacy of PBT but no suggestion that it is superior to photon based approaches. In pediatric CNS malignancies, PBT appears superior to photon approaches, but more data is needed. In large ocular melanomas and chordomas, ASTRO states that there is evidence for a benefit of PBT over photon approaches. More robust prospective clinical trials are needed to determine the appropriate clinical setting for PBT (Allen et al., 2012).

Intracranial Arteriovenous Malformations

In a Cochrane review, Ross et al. (2010) assessed the clinical effects of various interventions to treat brain arteriovenous malformations (AVMs) in adults. Interventions include neurosurgical excision, stereotactic radiotherapy/radiosurgery (using gamma knife, linear accelerator, proton beam or CyberKnife), endovascular embolization (using glues, particles, fibres, coils or balloons) and staged combinations of these interventions. The authors concluded that there is no evidence from randomized trials with clear clinical outcomes comparing different interventional treatments for brain AVMs against each other or against usual medical therapy to guide the interventional treatment of brain AVMs in adults.

Hattangadi-Gluth et al. (2014) evaluated the obliteration rate and potential adverse effects of single-fraction proton beam stereotactic radiosurgery (PSRS) in patients with cerebral

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company
P.O. Box 15645, Las Vegas, NV 89114-5645
ADDRESS SERVICE REQUESTED

FILE COPY
February 5, 2016

William G. Eskew
5825 Egan Crest Dr.
Las Vegas, NV 89149

Employee Name: William G. Eskew
Group Name: Off Exchange
Group Number: 10003502
Member Name: William G. Eskew
Service Reference Number: 160340910

Dear William G. Eskew:

We review health care services requested for coverage under the terms of your health benefit plan to determine if they are covered, as defined in your plan document. We received a request to cover the proposed Proton Beam Radiation Therapy for you. Based on the information submitted, we have determined that the requested service(s) is/are not covered.

Here are the details of our determination:

We have determined that Proton Beam Radiation Therapy is/are not covered

- Type of Treatment: Proton Beam Radiation Therapy
- Physician/Health Care Professional: Zhongxing Liao, MD
- Place of Treatment: The Proton Therapy Center Houston
- Date of Service: February 8, 2016
- Diagnosis: Malignant Neoplasm of Upper Lobe, Right Bronchus or Lung with Bone Metastasis
- The reason for our determination is: Based upon UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy, coverage is denied. Your provider asked for a Proton Beam Radiation Therapy (therapy that uses a beam of protons that carry a positive charge to destroy cancer cells) for you because you have lung cancer. This type of radiation therapy is considered unproven and not medically necessary for treating lung cancer. There is limited clinical evidence that directly compares proton beam therapy with other types of radiation therapy. Current published evidence does not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat your condition. Therefore, the request cannot be approved at this time by your health plan.

We reviewed the following information to make our determination:

Based on the information submitted, your health benefit plan and UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy, we determined that the health care services are not covered.

Our clinical staff reviewed the case, and the services are not eligible expenses under your plan.

We will not cover any excluded service, treatment, item or supply even if it is recommended or prescribed by a physician or other health care professional or is the only available treatment for your condition. Please refer to the sections of your plan document on limitations and exclusions.

Compliance by the Member with SHL's Managed Care Program is mandatory. The managed care program is a process that uses evidence-based medicine to determine whether a service/procedure has been proven to be effective.

Please note that the information in this letter is not a treatment decision; it addresses only payment for the service(s) in question. Treatment decisions are made between you and your physician. Coverage for these services is subject to the terms and conditions of your plan including exclusions, limitations, conditions and patient eligibility. You are responsible for deductibles, coinsurance, copayments and items not covered by your plan.

If the treating physician would like to discuss this case with a physician reviewer, he or she may call the Health Plan at (702) 562-8098 or toll free 1-888-693-1006.

The member will be provided (upon request and free of charge) reasonable access to and copies of all documents, records and other information relevant to the request. In addition, the member is entitled to an explanation of the scientific basis or clinical judgment used in making our determination. This includes a copy of any internal rules, guidelines or protocols used in making the non-coverage decision.

If you have any questions regarding this notice, please contact Member Services at 702-242-7700 or 800-888-2264 toll free, TTY 711. Representatives are available Monday through Friday from 8 a.m. through 5 p.m., PST.

若需要中文协助，请拨打本文件内的客户服务电话。

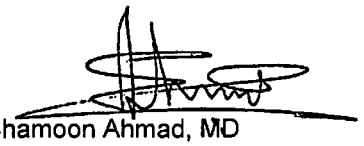
Para obtener asistencia en español, llame al número de teléfono de servicio al cliente que se incluye en este documento.

Dine k'ehji shich'i' hadoodzih ninizingo, koji' hodiilnih dine yikah 'anidaalwoji ei binumber dii naaltsoos bikaa doo.

Para sa tulong sa Tagalog, tawagan ang numero ng serbisyo sa customer na kabilang sa dokumentong ito.

Please contact Member Services at 702-242-7700 or 800-888-2264 toll free, TTY 711 from 8 a.m. to 5 p.m. PST if you need diagnosis and/or treatment code information regarding the services referenced in this communication.

Sincerely,



Shamoon Ahmad, MD
Medical Director
UnitedHealthcare, Nevada

cc: Member
Service Provider
Facility
File

Si necesita esta informaciòn traducida en español, llame el Departamento de Servicios para Miembros al (702) 242-7700 o, (800) 888-2264.

If you have questions regarding this determination, please call your Member Services Representative Monday through Friday from 8:00 a.m. to 5:00 p.m. (PST) at (702) 242-7700 or toll-free at (800)-888-2264 if outside the Las Vegas area. If you have a speech or hearing impairment, please call TTY 711. Oral interpreter services are also available.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Expedited Appeal Rights
An expedited internal appeal may be available if the medical condition is such that the time needed to complete a standard appeal could seriously jeopardize the patient's life, health, or ability to regain maximum function. **You must request an appeal within 24 hours from receipt of this notice.** If we confirm that an expedited appeal is needed, we will complete the review within 72 hours of receiving the appeal request and any additional information. Or, your physician may request an expedited appeal. To request an expedited appeal:

- You may contact the Member Services Department during normal business hours at (702) 242-7300 or toll free at (800) 777-1840 if outside the Las Vegas area; or
- Fax your written request to the Customer Response and Resolution Department (CR&R) at (702) 266-8813; or
- After normal business hours, you can call the Customer Response and Resolution Department (CR&R) at (702) 242-7839 or toll free at (800) 578-6757 if outside the Las Vegas area.

Your expedited appeal request should include the following information:

- an explanation of what you are asking us to reconsider;
- the specific reasons why you feel the service should be considered for coverage; and
- any additional information that supports your position and will help us in the review of your appeal.

Standard Appeal Rights
You must ask for a **1st Level Formal Appeal** within 180 days of receiving this notice either orally or in writing. If you do not comply with this requirement, you may forfeit your right to an appeal. Inquiring about the appeals process does not change the time frame to submit an appeal. The 1st Level Formal Appeal is a mandatory requirement before pursuing further appeal rights. To file your verbal appeal, please contact Member Services during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area. Or, you may fax your request to (702) 266-8813. To file your written appeal, please submit your request to:

Sierra Health & Life Insurance Company, Inc. (SHL)
ATTN: Customer Response and Resolution Department/Appeals
P.O. Box 15645
Las Vegas, Nevada 89114-5645

Your appeal request should include the following:

- an explanation of what you are asking us to reconsider;
- the specific reasons why you feel the service should be considered for coverage; and
- any additional information that supports your position and will help us in the review of your appeal.

We will notify you of the decision within 30 calendar days from receipt of your request. If you disagree with the decision, there are other appeal options available to you.

Members covered under an Individual Plan

- For benefit decisions, you are only eligible for the standard appeals rights. For medical necessity denials, you may have the right to an external review. Please refer to your coverage documents for more information, or call Member Services during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

Further Appeal Rights

2nd Level Formal Appeal

- After exhaustion of 1st Level Formal Appeal, you or your authorized representative may request a 2nd Level Formal Appeal, this is a voluntary level of review at no cost to you. Please refer to your Plan document for more information. **2nd Level Formal Appeal Rights do not apply to Individual Plans.** For more information, please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

Standard External Review

After exhaustion of the mandatory 1st Level Formal Appeal, you may have a right to have our decision reviewed by independent health care professionals who have no association with us if our decision involved making judgment as to the medical necessity, appropriateness, health care setting level of care, or effectiveness of the health care services or treatment. For information regarding the external review process please call Member Services at (702) 242-7700. If you are outside Las Vegas, please call toll free at (800) 888-2264.

Other Member Rights

.If your plan is governed by the Employee Retirement Income and Security Act of 1974 (ERISA), you may have the right to file a civil action under ERISA if all required reviews of your claim have been completed.

- Your employer can tell you if ERISA governs your plan.
- Individual health Plans are not governed by ERISA.
- You may appoint a person to act on your behalf (your Authorized Representative). Your appeal request should include the name of the person, family member, attorney, that you request to appoint to represent you during the appeals process.
- You have the right to submit written comments, documents, records or other information relevant to your appeal. This information should be submitted to the Customer Response and Resolution Department by fax at (702) 266-8813 or at the below address:

Sierra Health & Life Insurance Company, Inc. (SHL)
ATTN: Customer Response and Resolution Department/Appeals
P.O. Box 15645
Las Vegas, Nevada 89114-5645

- You may request that this notification and future correspondence be translated into a non-English language. To request language translation services, please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

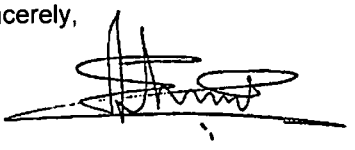
Availability of Consumer Assistance /Ombudsman Services
There may be other resources available to help you understand the appeals process. If your plan is governed by ERISA, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). If your plan is not governed by ERISA, or your state does not have a Consumer Assistance Program, you can contact the Department of Health and Human Services Health Insurance Assistance Team at 1-888-393-2789.

Your state consumer assistance program may also be able to assist you at
Office of the Governor, Consumer Health Assistance
555 East Washington Ave #4800
Las Vegas, NV 89101
Telephone: (702) 486-3587
Toll-free telephone: 1-888-333-1597
Web site: http://www.govcha.state.nv.us
E-mail: cha@govcha.state.nv.us

Please refer to your SHL Certificate of Coverage (EOC) or Agreement of Coverage (AOC) which explains your appeal rights under your plan or to obtain a copy of your coverage documents please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

How to Contact Us
If you have any questions regarding this notice, please contact Member Services at (702) 242-7700, Monday through Friday from 8 a.m. to 5 p.m. If you are outside the Las Vegas area, please call our toll-free number 1-800-888-2264. A Member Services Representative will be happy to assist you.

Sincerely,



Shamoon Ahmad, MD
Medical Director
UnitedHealthcare, Nevada

cc: Member
Service Provider
Facility
File

NOTICE OF APPEAL RIGHTS

You have a right to appeal any decision we make that denies payment on your claim or your request for coverage of a health care service or treatment.

You may request additional explanation when your claim or request for coverage of a health care service or treatment is denied or the health care service or treatment you received was not fully covered. Contact the Member Services Department at (800)888-2264 or (702)242-7700 when you:

- Do not understand the reason for the denial;
- Do not understand why the health care service or treatment was not fully covered;
- Do not understand why a request for coverage of a health care service or treatment was denied;
- Cannot find the applicable provision in your Benefit Plan Document;
- Want a copy (free of charge) of the guideline, criteria or clinical rationale that we used to make our decision; or
- Disagree with the denial or the amount not covered and you want to appeal.

If your claim was denied due to missing or incomplete information, you or your health care provider may resubmit the claim to the Claims Department at P.O. Box 15645, Las Vegas, NV 89114 with the necessary information to complete the claim.

Appeals: All appeals for claim denials (or any decision that does not cover expenses you believe should have been covered) must be sent to Sierra Health and Life Insurance Company, Inc. (SHL), Attention: Customer Response and Resolution Department/Appeals, P.O. Box 15645, Las Vegas, NV 89114-5645, within **180 days** of the date you receive our denial.[1] We will provide a full and fair review of your claim by individuals associated with us, but who were not involved in making the initial denial of your claim. You may provide us with additional information that relates to your claim and you may request copies of information that we have that pertains to your claims. We will notify you of our decision in writing within **30 days** of receiving your appeal. If you do not receive our decision within **30 days** of receiving your appeal, you are entitled to file a request for eternal review.

External Review: If we have denied your request for the provision of or payment for a health care service or course of treatment, you may have a right to have our decision reviewed by independent health care professionals who have no association with us if our decision involved making a judgment as to the medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested by submitting a request for external review within 4 **months** after receipt of this notice to the Office for Consumer Health Assistance at 555 East Washington #4800, Las Vegas, NV 89101, Phone: (702) 486-3587, (888) 333-1597, or Fax 702-486-3586, Web: www.govcha.nv.gov. For standard external review, a decision will be made within **45 days** of receiving your request. If you have a medical condition that would seriously jeopardize your life or health or would jeopardize your ability to regain maximum function if treatment is delayed, you may be entitled to request an **expedited external review** of our denial. If our denial to provide or pay for health care service or course of treatment is based on a determination that the service or treatment is experimental or investigational, you also may be entitled to file a request for external review of our denial. For details, please review your Evidence of Coverage or Certificate of Coverage, contact us, the Office for Consumer Health Assistance or contact the Nevada Division of Insurance.

[1] Unless your plan or any applicable state law allows you additional time.

This **EXTERNAL REVIEW REQUEST FORM** must be filed with Office for Consumer Health Assistance within **FOUR (4) MONTHS** after receipt from your insurer of a denial of payment on a claim or request for coverage of a health care service or treatment.

EXTERNAL REVIEW REQUEST FORM

APPLICANT NAME _____
☐Covered person/Patient ☐ Provider ☐ Authorized Representative

COVERED PERSON/PATIENT INFORMATION

Covered Person Name: _____

Patient Name: _____

Address:

_____

_____

Covered Person Phone #: Home (_____)_____

Work (_____)_____

INSURANCE INFORMATION

Insurer/HMO Name: _____

Covered Person Insurance ID#:

_____

Insurance Claim/Reference #:

_____

Insurer/HMO Mailing Address:

_____

_____

Insurer Telephone #: (_____)_____

EMPLOYER INFORMATION

Employer's Name:

_____

Employer's Phone #: (____)_____

Is the health coverage you have through your employer a self-funded plan? _____. If you are not certain please check with your employer. Some self-funded may voluntarily provide external review, but may have different procedures. You should check with your employer.

HEALTH CARE PROVIDER INFORMATION

Treating Physician/Health Care Provider:

_____

Address:

_____

_____

_____

Contact Person:_____

Phone (____)_____

Medical Record #:_____

REASON FOR HEALTH CARRIER DENIAL (Please check one)

☐ The health care service or treatment is not medically necessary.
☐ The health care service or treatment is experimental or investigational.

SUMMARY OF EXTERNAL REVIEW REQUEST (Enter a brief description of the claim, the request for health care service or treatment that was denied, and/or attach a copy of the denial from your health carrier)*

_____

_____

_____

*You may also describe in your own words the health care service or treatment in dispute and why you are appealing this denial using the attached pages below.

EXPEDITED REVIEW

If you need a fast decision, you may request that your external appeal be handled on an expedited basis. To complete this request, your treating health care provider must fill out the attached form stating that a delay would seriously jeopardize the life or health of the patient or would jeopardize the patient's ability to regain maximum function.

Is this a request for an expedited appeal? **Yes** _____ **No** _____

SIGNATURE AND RELEASE OF MEDICAL RECORDS

To appeal your health carrier's denial, you must sign and date this external review request form and consent to the release of medical records.

I, _____, hereby request an external appeal. I attest that the information provided in this application is true and accurate to the best of my knowledge. I authorize by insurance company and my health care providers to release all relevant medical or treatment records to the independent review organization and the Office for Consumer Health Assistance. I understand that the independent review organization and the Office for Consumer Health Assistance will use this information to make a determination on my external appeal and that the information will be kept confidential and not be released to anyone else. This release is valid for one year.

_____ _____

Signature of Covered Person (or legal representative)* Date

*(Parent, Guardian, Conservator or Other – Please Specify)

APPOINTMENT OF AUTHORIZED REPRESENTATIVE

(Fill out this section only if someone else will be representing you in this appeal.)

You can represent yourself, or you may ask another person, including your treating health care provider, to act as your authorized representative. You may revoke this authorization at any time.

I hereby authorize _____ to pursue my appeal on my behalf.

_____ _____

Signature of Covered Person (or legal representative)* Date

*(Parent, Guardian, Conservator or Other—Please Specify)

Address of Authorized Representative:

_____

_____

Phone #: Daytime (_____)_____

Evening (_____)_____

HEALTH CARE SERVICE OR TREATMENT DECISION IN DISPUTE

DESCRIBE IN YOUR OWN WORDS THE DISAGREEMENT WITH YOUR HEALTH CARRIER. INDICATE CLEARLY THE SERVICE(S) BEING DENIED AND THE SPECIFIC DATE(S) BEING DENIED. EXPLAIN WHY YOU DISAGREE. ATTACH ADDITIONAL PAGES IF NECESSARY AND INCLUDE AVAILABLE PERTINENT MEDICAL RECORDS, ANY INFORMATION YOU RECEIVED FROM YOUR HEALTH CARRIER CONCERNING THE DENIAL, ANY PERTINENT PEER LITERATURE OR CLINICAL STUDIES, AND ANY ADDITIONAL INFORMATION FROM YOUR PHYSICIAN/HEALTH CARE PROVIDER THAT YOU WANT THE INDEPENDENT REVIEW ORGANIZATION REVIEWER TO CONSIDER.

WHAT TO SEND AND WHERE TO SEND IT

PLEASE CHECK BELOW (NOTE: YOUR REQUEST WILL NOT BE ACCEPTED FOR FULL REVIEW UNLESS ALL FOUR (4) ITEMS BELOW ARE INCLUDED*)

1. ☐ **YES**, I have included this completed application form signed and dated.

2. ☐ **YES**, I have included a photocopy of my insurance identification card or other evidence showing that I am insured by the health insurance company named in this application;

3. ☐ **YES****, I have enclosed the letter from my health carrier or utilization review company that states:
   (a) Their decision is final and that I have exhausted all internal review procedures; or
   (b) They have waived the requirement to exhaust all of the health carrier's internal review procedures.

** You may make a request for external review without exhausting all internal review procedures under certain circumstances. You should contact the Office for Consumer Health Assistance, 555 East Washington #4800 Las Vegas NV 89101, Phone: (702) 486-3587, (888) 333-1597, or Fax 702-486-3586, Web: www.govcha.nv.gov.

4. ☐ **YES**, I have included a copy of my certificate of coverage or my insurance policy benefit booklet, which lists the benefits under my health benefit plan.

* Call the Office for Consumer Health Assistance at (702) 486-3587 or (888) 333-1597 if you need help in completing this application or if you do not have one or more of the above items and would like information on alternative ways to complete your request for external review.

If you are requesting a standard external review, send all paperwork to: Office for Consumer Health Assistance, 555 East Washington #4800, Las Vegas, NV 89101.

If you are requesting an expedited external review, call the Office for Consumer Health Assistance at (702) 486-3587 or (888) 333-1597 before sending your paperwork, and you will receive instructions on the quickest way to submit the application and supporting information.

CERTIFICATION OF TREATING HEALTH CARE PROVIDER FOR EXPEDITED CONSIDERATION OF A PATIENT'S EXTERNAL REVIEW APPEAL

NOTE TO THE TREATING HEALTH CARE PROVIDER

Patients can request an external review when a health carrier has denied a health care service or course of treatment on the basis of a utilization review determination that the requested health care service or course of treatment does not meet the health carrier's requirements for medical necessity, appropriateness, health care setting, level of care or effectiveness of the health care service or treatment you requested. The Office for Consumer Health Assistance oversees external appeals. The standard external review process can take up to 45 days from the date the patient's request for external review is received by our department. Expedited external review is available only if the patient's treating health care provider certifies that adherence to the time frame for the standard external review would seriously jeopardize the life or health of the covered person or would jeopardize the covered person's ability to regain maximum function. An expedited external review must be completed at most within 72 hours. This form is for the purpose of providing the certification necessary to trigger expedited review.

GENERAL INFORMATION

Name of Treating Health Care Provider:

_____

Mailing Address:

_____

_____

Phone Number: (____)_____

Fax Number: (_____)_____

Licensure and Area of Clinical Specialty:

_____

_____

Name of Patient:

_____

Patient's Insurer Member ID#:_____

CERTIFICATION

I hereby certify that: I am a treating health care provider for

_____

(hereafter referred to as "the patient"); that adherence to the time frame for conducting a standard external review of the patient's appeal would, in my professional judgment, seriously jeopardize the life or health of the patient or would jeopardize the patient's ability to regain maximum function; and that, for this reason, the patient's appeal of the denial by the patient's health carrier of the requested health care service or course of treatment should be processed on an expedited basis.

_____

Treating Health Care Provider's Name (Please Print)

_____ _____

Signature Date

PHYSICIAN CERTIFICATION
EXPERIMENTAL/INVESTIGATIONAL DENIALS
(To Be Completed by Treating Physician)

I hereby certify that I am the treating physician for _____ (covered person's name) and that I have requested the authorization for a drug, device, procedure or therapy denied for coverage due to the insurance company's determination that the proposed therapy is experimental and/or investigational. I understand that in order for the covered person to obtain the right to an external review of this denial, as treating physician I must certify that the covered person's medical condition meets certain requirements:

In my medical opinion as the Insured's treating physician, I hereby certify to the following:
(Please check all that apply) (NOTE: Requirements #1 - #3 below must all apply for the covered person to qualify for an external review).

☐ 1) The covered person has a terminal medical condition, life threatening condition, or a seriously debilitating condition.

☐ 2) The covered person has a condition that qualifies under one or more of the following: [please indicate which description(s) apply]:

- ☐ Standard health care services or treatments have not been effective in improving the covered person's condition;
- ☐ Standard health care services or treatments are not medically appropriate for the covered person; or
- ☐ There is no available standard health care service or treatment covered by the health carrier that is more beneficial than the requested or recommended health care service or treatment.

☐ 3) The health care service or treatment I have recommended and which has been denied, in my medical opinion, is likely to be more beneficial to the covered person than any available standard health care services or treatments.

☐ 4) The health care service or treatment recommended would be significantly less effective if not promptly initiated.

Explain:

_____

_____

☐ 5) It is my medical opinion based on scientifically valid studies using accepted protocols that the health care service or treatment requested by the covered person and which has been denied is likely to be more beneficial to the covered person than any available standard health care services or treatments.

Explain:

_____

_____

Please provide a description of the recommended or requested health care service or treatment that is the subject of the denial. (Attach additional sheets as necessary)

_____

_____

_____

_____ _____

Physician's Signature Date

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company
P.O. Box 15645, Las Vegas, NV 89114-5645

ADDRESS SERVICE REQUESTED

FILE COPY
February 5, 2016

Zhongxing Liao, MD
1515 Holcombe Blvd.
Houston, TX 77030

Employee Name: William G. Eskew
Group Name: Off Exchange
Group Number: 10003502
Member Name: William G. Eskew
Service Reference Number: 160340910

Dear Zhongxing Liao, MD:

We review health care services requested for coverage under the terms of your health benefit plan to determine if they are covered, as defined in your plan document. We received a request to cover the proposed Proton Beam Radiation Therapy for William G. Eskew. Based on the information submitted, we have determined that the requested service(s) is/are not covered.

Here are the details of our determination:

We have determined that Proton Beam Radiation Therapy is/are not covered

- Type of Treatment: Proton Beam Radiation Therapy
- Physician/Health Care Professional: Zhongxing Liao, MD
- Place of Treatment: The Proton Therapy Center Houston
- Date of Service: February 8, 2016
- Diagnosis: Malignant Neoplasm of Upper Lobe, Right Bronchus or Lung with Bone Metastasis
- The reason for our determination is: Based upon UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy, coverage is denied. Your provider asked for a Proton Beam Radiation Therapy (therapy that uses a beam of protons that carry a positive charge to destroy cancer cells) for you because you have lung cancer. This type of radiation therapy is considered unproven and not medically necessary for treating lung cancer. There is limited clinical evidence that directly compares proton beam therapy with other types of radiation therapy. Current published evidence does not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat your condition. Therefore, the request cannot be approved at this time by your health plan.

We reviewed the following information to make our determination:

Based on the information submitted, your health benefit plan and UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy, we determined that the health care services are not covered.

Our clinical staff reviewed the case, and the services are not eligible expenses under your plan.

We will not cover any excluded service, treatment, item or supply even if it is recommended or prescribed by a physician or other health care professional or is the only available treatment for your condition. Please refer to the sections of your plan document on limitations and exclusions.

Compliance by the Member with SHL's Managed Care Program is mandatory. The managed care program is a process that uses evidence-based medicine to determine whether a service/procedure has been proven to be effective.

Please note that the information in this letter is not a treatment decision; it addresses only payment for the service(s) in question. Treatment decisions are made between you and your physician. Coverage for these services is subject to the terms and conditions of your plan including exclusions, limitations, conditions and patient eligibility. You are responsible for deductibles, coinsurance, copayments and items not covered by your plan.

If the treating physician would like to discuss this case with a physician reviewer, he or she may call the Health Plan at (702) 562-8098 or toll free 1-888-693-1006.

The member will be provided (upon request and free of charge) reasonable access to and copies of all documents, records and other information relevant to the request. In addition, the member is entitled to an explanation of the scientific basis or clinical judgment used in making our determination. This includes a copy of any internal rules, guidelines or protocols used in making the non-coverage decision.

If you have any questions regarding this notice, please contact Member Services at 702-242-7700 or 800-888-2264 toll free, TTY 711. Representatives are available Monday through Friday from 8 a.m. through 5 p.m., PST.

若需要中文协助，请拨打本文件内的客户服务电话。

Para obtener asistencia en español, llame al número de teléfono de servicio al cliente que se incluye en este documento.

Dine k'ehji shich'i' hadoodzih ninizingo, koji' hodiilnih dine yikah 'anidaalwoji ei binumber dii naaltsoos bikaa doo.

Para sa tulong sa Tagalog, tawagan ang numero ng serbisyo sa customer na kabilang sa dokumentong ito.

Please contact Member Services at 702-242-7700 or 800-888-2264 toll free, TTY 711 from 8 a.m. to 5 p.m. PST if you need diagnosis and/or treatment code information regarding the services referenced in this communication.

Sincerely,

Shameon Ahmad, MD
Medical Director
UnitedHealthcare, Nevada

cc: Member
Service Provider
Facility
File

Si necesita esta informaciòn traducida en español, llame el Departamento de Servicios para Miembros al (702) 242-7700 o, (800) 888-2264.

If you have questions regarding this determination, please call your Member Services Representative Monday through Friday from 8:00 a.m. to 5:00 p.m. (PST) at (702) 242-7700 or toll-free at (800)-888-2264 if outside the Las Vegas area. If you have a speech or hearing impairment, please call TTY 711. Oral interpreter services are also available.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Expedited Appeal Rights
An expedited internal appeal may be available if the medical condition is such that the time needed to complete a standard appeal could seriously jeopardize the patient's life, health, or ability to regain maximum function. **You must request an appeal within 24 hours from receipt of this notice.** If we confirm that an expedited appeal is needed, we will complete the review within 72 hours of receiving the appeal request and any additional information. Or, your physician may request an expedited appeal. To request an expedited appeal:

- You may contact the Member Services Department during normal business hours at (702) 242-7300 or toll free at (800) 777-1840 if outside the Las Vegas area; or
- Fax your written request to the Customer Response and Resolution Department (CR&R) at (702) 266-8813; or
- After normal business hours, you can call the Customer Response and Resolution Department (CR&R) at (702) 242-7839 or toll free at (800) 578-6757 if outside the Las Vegas area.

Your expedited appeal request should include the following information:

- an explanation of what you are asking us to reconsider;
- the specific reasons why you feel the service should be considered for coverage; and
- any additional information that supports your position and will help us in the review of your appeal.

Standard Appeal Rights
You must ask for a **1st Level Formal Appeal** within 180 days of receiving this notice either orally or in writing. If you do not comply with this requirement, you may forfeit your right to an appeal. Inquiring about the appeals process does not change the time frame to submit an appeal. The 1st Level Formal Appeal is a mandatory requirement before pursuing further appeal rights. To file your verbal appeal, please contact Member Services during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area. Or, you may fax your request to (702) 266-8813. To file your written appeal, please submit your request to:

Sierra Health & Life Insurance Company, Inc. (SHL)
ATTN: Customer Response and Resolution Department/Appeals
P.O. Box 15645
Las Vegas, Nevada 89114-5645

Your appeal request should include the following:

- an explanation of what you are asking us to reconsider;
- the specific reasons why you feel the service should be considered for coverage; and
- any additional information that supports your position and will help us in the review of your appeal.

We will notify you of the decision within 30 calendar days from receipt of your request. If you disagree with the decision, there are other appeal options available to you.

Members covered under an Individual Plan

- For benefit decisions, you are only eligible for the standard appeals rights. For medical necessity denials, you may have the right to an external review. Please refer to your coverage documents for more information, or call Member Services during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

Further Appeal Rights

2nd Level Formal Appeal

- After exhaustion of 1st Level Formal Appeal, you or your authorized representative may request a 2nd Level Formal Appeal, this is a voluntary level of review at no cost to you. Please refer to your Plan document for more information. **2nd Level Formal Appeal Rights do not apply to Individual Plans.** For more information, please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

Standard External Review

After exhaustion of the mandatory 1st Level Formal Appeal, you may have a right to have our decision reviewed by independent health care professionals who have no association with us if our decision involved making judgment as to the medical necessity, appropriateness, health care setting level of care, or effectiveness of the health care services or treatment. For information regarding the external review process please call Member Services at (702) 242-7700. If you are outside Las Vegas, please call toll free at (800) 888-2264.

Other Member Rights

.If your plan is governed by the Employee Retirement Income and Security Act of 1974 (ERISA), you may have the right to file a civil action under ERISA if all required reviews of your claim have been completed.

- Your employer can tell you if ERISA governs your plan.
- Individual health Plans are not governed by ERISA.
- You may appoint a person to act on your behalf (your Authorized Representative). Your appeal request should include the name of the person, family member, attorney, that you request to appoint to represent you during the appeals process.
- You have the right to submit written comments, documents, records or other information relevant to your appeal. This information should be submitted to the Customer Response and Resolution Department by fax at (702) 266-8813 or at the below address:

Sierra Health & Life Insurance Company, Inc. (SHL)
ATTN: Customer Response and Resolution Department/Appeals
P.O. Box 15645
Las Vegas, Nevada 89114-5645

- You may request that this notification and future correspondence be translated into a non-English language. To request language translation services, please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

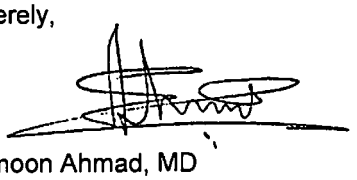
Availability of Consumer Assistance /Ombudsman Services
There may be other resources available to help you understand the appeals process. If your plan is governed by ERISA, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). If your plan is not governed by ERISA, or your state does not have a Consumer Assistance Program, you can contact the Department of Health and Human Services Health Insurance Assistance Team at 1-888-393-2789.

Your state consumer assistance program may also be able to assist you at
Office of the Governor, Consumer Health Assistance
555 East Washington Ave #4800
Las Vegas, NV 89101
Telephone: (702) 486-3587
Toll-free telephone: 1-888-333-1597
Web site: http://www.govcha.state.nv.us
E-mail: cha@govcha.state.nv.us

Please refer to your SHL Certificate of Coverage (EOC) or Agreement of Coverage (AOC) which explains your appeal rights under your plan or to obtain a copy of your coverage documents please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

How to Contact Us
If you have any questions regarding this notice, please contact Member Services at (702) 242-7700, Monday through Friday from 8 a.m. to 5 p.m. If you are outside the Las Vegas area, please call our toll-free number 1-800-888-2264. A Member Services Representative will be happy to assist you.

Sincerely,



Shamoon Ahmad, MD
Medical Director
UnitedHealthcare, Nevada

cc: Member
Service Provider
Facility
File

SIERRA HEALTH AND LIFE
A UnitedHealthcare Company
P.O. Box 15645, Las Vegas, NV 89114-5645
ADDRESS SERVICE REQUESTED

FILE COPY
February 5, 2016

The Proton Therapy Center Houston
1840 Old Spanish Trail
Houston, TX 77054

Employee Name: William G. Eskew
Group Name: Off Exchange
Group Number: 10003502
Member Name: William G. Eskew
Service Reference Number: 160340910

Dear The Proton Therapy Center Houston:

We review health care services requested for coverage under the terms of your health benefit plan to determine if they are covered, as defined in your plan document. We received a request to cover the proposed Proton Beam Radiation Therapy for William G. Eskew. Based on the information submitted, we have determined that the requested service(s) is/are not covered.

Here are the details of our determination:

We have determined that Proton Beam Radiation Therapy is/are not covered

- Type of Treatment: Proton Beam Radiation Therapy
- Physician/Health Care Professional: Zhongxing Liao, MD
- Place of Treatment: The Proton Therapy Center Houston
- Date of Service: February 8, 2016
- Diagnosis: Malignant Neoplasm of Upper Lobe, Right Bronchus or Lung with Bone Metastasis
- The reason for our determination is: Based upon UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy, coverage is denied. Your provider asked for a Proton Beam Radiation Therapy (therapy that uses a beam of protons that carry a positive charge to destroy cancer cells) for you because you have lung cancer. This type of radiation therapy is considered unproven and not medically necessary for treating lung cancer. There is limited clinical evidence that directly compares proton beam therapy with other types of radiation therapy. Current published evidence does not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat your condition. Therefore, the request cannot be approved at this time by your health plan.

We reviewed the following information to make our determination:

Based on the information submitted, your health benefit plan and UnitedHealthcare, Inc. Medical Policy for Proton Beam Radiation Therapy, we determined that the health care services are not covered.

Our clinical staff reviewed the case, and the services are not eligible expenses under your plan.

We will not cover any excluded service, treatment, item or supply even if it is recommended or prescribed by a physician or other health care professional or is the only available treatment for your condition. Please refer to the sections of your plan document on limitations and exclusions.

Compliance by the Member with SHL's Managed Care Program is mandatory. The managed care program is a process that uses evidence-based medicine to determine whether a service/procedure has been proven to be effective.

Please note that the information in this letter is not a treatment decision; it addresses only payment for the service(s) in question. Treatment decisions are made between you and your physician. Coverage for these services is subject to the terms and conditions of your plan including exclusions, limitations, conditions and patient eligibility. You are responsible for deductibles, coinsurance, copayments and items not covered by your plan.

If the treating physician would like to discuss this case with a physician reviewer, he or she may call the Health Plan at (702) 562-8098 or toll free 1-888-693-1006.

The member will be provided (upon request and free of charge) reasonable access to and copies of all documents, records and other information relevant to the request. In addition, the member is entitled to an explanation of the scientific basis or clinical judgment used in making our determination. This includes a copy of any internal rules, guidelines or protocols used in making the non-coverage decision.

If you have any questions regarding this notice, please contact Member Services at 702-242-7700 or 800-888-2264 toll free, TTY 711. Representatives are available Monday through Friday from 8 a.m. through 5 p.m., PST.

若需要中文协助，请拨打本文件内的客户服务电话。

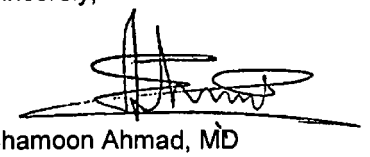
Para obtener asistencia en español, llame al número de teléfono de servicio al cliente que se incluye en este documento.

Dine k'ehji shich'i' hadoodzih ninizingo, koji' hodiilnih dine yikah 'anidaalwoji ei binumber dii naaltsoos bikaa doo.

Para sa tulong sa Tagalog, tawagan ang numero ng serbisyo sa customer na kabilang sa dokumentong ito.

Please contact Member Services at 702-242-7700 or 800-888-2264 toll free, TTY 711 from 8 a.m. to 5 p.m. PST if you need diagnosis and/or treatment code information regarding the services referenced in this communication.

Sincerely,



Shamoon Ahmad, MD
Medical Director
UnitedHealthcare, Nevada

cc: Member
Service Provider
Facility
File

Si necesita esta informaciòn traducida en español, llame el Departamento de Servicios para Miembros al (702) 242-7700 o, (800) 888-2264.

If you have questions regarding this determination, please call your Member Services Representative Monday through Friday from 8:00 a.m. to 5:00 p.m. (PST) at (702) 242-7700 or toll-free at (800)-888-2264 if outside the Las Vegas area. If you have a speech or hearing impairment, please call TTY 711. Oral interpreter services are also available.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Expedited Appeal Rights
An expedited internal appeal may be available if the medical condition is such that the time needed to complete a standard appeal could seriously jeopardize the patient's life, health, or ability to regain maximum function. **You must request an appeal within 24 hours from receipt of this notice.** If we confirm that an expedited appeal is needed, we will complete the review within 72 hours of receiving the appeal request and any additional information. Or, your physician may request an expedited appeal. To request an expedited appeal:

- You may contact the Member Services Department during normal business hours at (702) 242-7300 or toll free at (800) 777-1840 if outside the Las Vegas area; or
- Fax your written request to the Customer Response and Resolution Department (CR&R) at (702) 266-8813; or
- After normal business hours, you can call the Customer Response and Resolution Department (CR&R) at (702) 242-7839 or toll free at (800) 578-6757 if outside the Las Vegas area.

Your expedited appeal request should include the following information:

- an explanation of what you are asking us to reconsider;
- the specific reasons why you feel the service should be considered for coverage; and
- any additional information that supports your position and will help us in the review of your appeal.

Standard Appeal Rights
You must ask for a **1st Level Formal Appeal** within 180 days of receiving this notice either orally or in writing. If you do not comply with this requirement, you may forfeit your right to an appeal. Inquiring about the appeals process does not change the time frame to submit an appeal. The 1st Level Formal Appeal is a mandatory requirement before pursuing further appeal rights. To file your verbal appeal, please contact Member Services during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area. Or, you may fax your request to (702) 266-8813. To file your written appeal, please submit your request to:

Sierra Health & Life Insurance Company, Inc. (SHL)
ATTN: Customer Response and Resolution Department/Appeals
P.O. Box 15645
Las Vegas, Nevada 89114-5645

Your appeal request should include the following:

- an explanation of what you are asking us to reconsider;
- the specific reasons why you feel the service should be considered for coverage; and
- any additional information that supports your position and will help us in the review of your appeal.

We will notify you of the decision within 30 calendar days from receipt of your request. If you disagree with the decision, there are other appeal options available to you.

Members covered under an Individual Plan

- For benefit decisions, you are only eligible for the standard appeals rights. For medical necessity denials, you may have the right to an external review. Please refer to your coverage documents for more information, or call Member Services during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

Further Appeal Rights

2nd Level Formal Appeal

- After exhaustion of 1st Level Formal Appeal, you or your authorized representative may request a 2nd Level Formal Appeal, this is a voluntary level of review at no cost to you. Please refer to your Plan document for more information. **2nd Level Formal Appeal Rights do not apply to Individual Plans.** For more information, please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

Standard External Review

After exhaustion of the mandatory 1st Level Formal Appeal, you may have a right to have our decision reviewed by independent health care professionals who have no association with us if our decision involved making judgment as to the medical necessity, appropriateness, health care setting level of care, or effectiveness of the health care services or treatment. For information regarding the external review process please call Member Services at (702) 242-7700. If you are outside Las Vegas, please call toll free at (800) 888-2264.

Other Member Rights

.If your plan is governed by the Employee Retirement Income and Security Act of 1974 (ERISA), you may have the right to file a civil action under ERISA if all required reviews of your claim have been completed.

- Your employer can tell you if ERISA governs your plan.
- Individual health Plans are not governed by ERISA.
- You may appoint a person to act on your behalf (your Authorized Representative). Your appeal request should include the name of the person, family member, attorney, that you request to appoint to represent you during the appeals process.
- You have the right to submit written comments, documents, records or other information relevant to your appeal. This information should be submitted to the Customer Response and Resolution Department by fax at (702) 266-8813 or at the below address:

Sierra Health & Life Insurance Company, Inc. (SHL)
ATTN: Customer Response and Resolution Department/Appeals
P.O. Box 15645
Las Vegas, Nevada 89114-5645

- You may request that this notification and future correspondence be translated into a non-English language. To request language translation services, please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

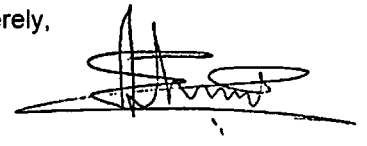
Availability of Consumer Assistance /Ombudsman Services
There may be other resources available to help you understand the appeals process. If your plan is governed by ERISA, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). If your plan is not governed by ERISA, or your state does not have a Consumer Assistance Program, you can contact the Department of Health and Human Services Health Insurance Assistance Team at 1-888-393-2789.

Your state consumer assistance program may also be able to assist you at
Office of the Governor, Consumer Health Assistance
555 East Washington Ave #4800
Las Vegas, NV 89101
Telephone: (702) 486-3587
Toll-free telephone: 1-888-333-1597
Web site: http://www.govcha.state.nv.us
E-mail: cha@govcha.state.nv.us

Please refer to your SHL Certificate of Coverage (EOC) or Agreement of Coverage (AOC) which explains your appeal rights under your plan or to obtain a copy of your coverage documents please contact the Member Services Department during normal business hours at (702) 242-7700 or toll free at (800) 888-2264 if outside the Las Vegas area.

How to Contact Us
If you have any questions regarding this notice, please contact Member Services at (702) 242-7700, Monday through Friday from 8 a.m. to 5 p.m. If you are outside the Las Vegas area, please call our toll-free number 1-800-888-2264. A Member Services Representative will be happy to assist you.

Sincerely,



Shamoon Ahmad, MD
Medical Director
UnitedHealthcare, Nevada

cc: Member
Service Provider
Facility
File

	REQUEST	SPECIFIC REQUEST	PLAN	CRITERIA
[redacted]				
	Proton Beam Radiation Therapy (PBRT)	Proton Beam Radiation Therapy - a type of radiation treatment that aims at cancer cells to destroy them		
[redacted]				

TEXT
[redacted]
TWEAK DX: Based on our UnitedHealthcare Medical Policy for Proton Beam Radiation Therapy, coverage is denied. Your provider asked for Proton Beam Radiation Therapy (i.e., a type of radiation treatment that aims at cancer cells to destroy them) for you. This is because you have sacral chordoma (i.e., malignant {cancer} tumor {growth} of the lower end of the backbone). The policy does not include sacral chordoma as an approved indication (reason) for this therapy. Therefore, the request cannot be approved at this time by your health plan.
[redacted]

MBO partners® **MBO Partners, Inc.**

Invoice: 723599
Date: 3/29/2016

Company #: 2206
Period Begin: 2/1/2016
Terms: Due Upon Receipt
Period End: 2/7/2016

Bill To: UnitedHealth Group
9900 Bren Road East
Minnetonka, Minnesota 55343

Description: Employer and Individual - Oncology Services Review Program

Payment Instructions

ACH or wire payments to:
WFBC F/A MBO Partners, Inc.
Account #: 4123805202
Routing #: 121000248

OR

Mail checks to:
MBO Partners, Inc.
P.O. Box 823673
Philadelphia PA 19182-3673

Make checks payable to MBO Partners, Inc. Do not send special delivery or overnight items to this address.

Professional Fee

Date	Description	Quantity	Unit Price	Amount
2/1/2016 - 2/5/2016	Ahmad, Shamoon(17898) - Employer and Individual - Oncology Services Review Program • 2/1/2016 Approved by: june--roberta.young@uhc.com,diane.lamba@uhc.com (Roberta Young) - 11 cases • 2/2/2016 Approved by: june--roberta.young@uhc.com,diane.lamba@uhc.com (Roberta Young) - 12 cases • 2/3/2016 Approved by: june--roberta.young@uhc.com,diane.lamba@uhc.com (Roberta Young) - 22 cases • 2/4/2016 Approved by: june--roberta.young@uhc.com,diane.lamba@uhc.com (Roberta Young) - 15 cases • 2/5/2016 Approved by: june--roberta.young@uhc.com,diane.lamba@uhc.com (Roberta Young) - 19 cases	16.5 Hour (s)	205.00/Hour	$3,382.50
	Amount for Professional Fee :	16.50 Hour (s)		$3,382.50

Total Invoice Amount Due:	$3,382.50

Status: Delivered Delivery: Do Not Send Attach Time: No Attach Exp: Yes BCM: Team

STATE OF NEW YORK
PUBLIC HEALTH AND HEALTH PLANNING COUNCIL

COMMITTEE DAY

AGENDA

March 26, 2015
10:00 a.m.

Empire State Plaza, Concourse Level
Meeting Room 6, Albany

I. COMMITTEE ON ESTABLISHMENT AND PROJECT REVIEW

Dr. Gary Kalkut, Vice Chair

A. Applications for Construction of Health Care Facilities

Ambulatory Surgery Center - Construction **Exhibit # 1**

	Number	Applicant/Facility
1.	142200 C	Long Island Digestive Endoscopy Center (Suffolk County)

Upstate Request For Applications - Certified Home Health Agencies - Construction **Exhibit # 2**

	Number	Applicant/Facility
1.	121224 C	HCR (Monroe County)

B. Applications for Competitive Review of Health Care Facilities/Agencies

Dialysis Services- Construction **Exhibit # 3**

	Number	Applicant/Facility
1.	142261 C	Faxton - St Lukes Healthcare St Lukes Division (Madison County)

Dialysis Services- Establish/Construct

	Number	Applicant/Facility
1.	142183 B	Utica Partners, LLC d/b/a Dialysis Center of Oneida (Madison County)

C. Applications for Establishment and Construction of Health Care Facilities/Agencies

Acute Care Services – Establish/Construct **Exhibit # 4**

	Number	Applicant/Facility
1.	151027 E	NYP Community Programs, Inc. (Queens County)

Ambulatory Surgery Centers - Establish/Construct **Exhibit # 5**

	Number	Applicant/Facility
1.	142197 B	Surgical Pain Center of the Adirondacks LLC (Clinton County)
2.	142272 E	Specialists' One-Day Surgery Center, LLC (Onondaga County)
3.	151035 E	Saratoga-Schenectady Endoscopy Center, LLC (Saratoga County)

Diagnostic and Treatment Services - Establish/Construct **Exhibit # 6**

	Number	Applicant/Facility
1.	142006 B	Partners Healthcare Network, LLC (Kings County)
2.	142133 B	Upstate Family Health Center Inc. (Oneida County)
3.	142212 E	S.L.A. Quality Healthcare (Kings County)
4.	142257 B	Liberty Resources, Inc. d/b/a Liberty Resources Family Health Clinic (Onondaga County)

Residential Health Care Facilities - Establish/Construct **Exhibit # 7**

	Number	Applicant/Facility
1.	131349 E	Sea Crest Acquisition I, LLC d/b/a Sea-Crest Health Care Center (Kings County)

2.	141079 E	Hollis Park Manor Nursing Home (Queens County)
3.	141153 E	River Meadows, LLC d/b/a James Square Nursing and Rehabilitation Centre (Onondaga County)
4.	141207 E	Delaware Operations Associates, LLC d/b/a Buffalo Center for Rehabilitation and Healthcare (Erie County)

Proton Bean Therapy - Establish/Construct **Exhibit # 8**

	Number	**Applicant/Facility**
1.	142213 B	The New York Proton Center (New York County)

D. Certificates

Exhibit # 9

Certificate of Dissolution

Applicant

1. Guthrie Same Day Surgery Center, Inc.

Certificate of Amendment of the Certificate of Incorporation

Applicant

1. The Hortense and Louis Rubin Dialysis Center, Inc.

E. Home Health Agency Licensures

Home Health Agency Licensures **Exhibit # 10**

Number	**Applicant/Facility**
2063 L	Ace in Home Care, Inc. (Nassau, Suffolk, and Queens Counties)
2249 L	Act On It Home Care, Inc. (Bronx, Queens, Kings, Richmond, New York and Nassau Counties)

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Acting Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

NEW YORK STATE DEPARTMENT OF HEALTH
CENTER FOR HEALTH CARE FACILITY PLANNING, LICENSURE AND FINANCE

MEMORANDUM

TO: Members of the Establishment and Project Review Committee
Public Health and Health Planning Council

FROM: Charles P. Abel
Deputy Director
Center for Health Care Facility Planning, Licensure and Finance

DATE: March 17, 2015

SUBJECT: CON #142213 The New York Proton Center

Background

In 2010, the Department announced that it would undertake a demonstration project, under the authority of 10 NYCRR Part 705, to evaluate the medical efficacy, cost-effectiveness and efficiency of, and public need for, proton beam therapy services (PBT) in New York State. The project would not only open access to needed treatment for New Yorkers but also advance needed research into PBT's applicability and effectiveness. It would also enable the Department to plan for the appropriate use of this new technology over the longer term. The demonstration project is authorized for a period of ten years.

Because they are heavier than ionized atomic particles, protons can be directed, or "beamed," in a manner that confines them more fully to the targeted tumor or other malady. This results in less collateral damage to surrounding nerves and tissue than traditional photon radiation. Precise targeting of the radiation beam is especially important in the treatment of tumors located in the skull, spinal column or near vital organs. It is perhaps most beneficial in treating head and neck cancers in children, where damage to surrounding tissue can have long-term adverse effects on growth and development.

Although PBT technology was approved by the U. S. Food and Drug Administration (FDA) in 1988, it remains most applicable and preferable to only a small number of cancers and similar conditions, most of them rare. The high cost of PBT devices and the ethical issues surrounding randomized clinical trials that involve life-saving interventions have also inhibited rigorous scientific research on PBT. This makes the growth of PBT treatment controversial, with many experts contending that, except for a few rare diagnoses, PBT is no more effective than conventional radiation therapy. Nevertheless, this medical technology continues to evolve, and the number of PBT centers in the United States, though still relatively small, is growing steadily.

CON #142213

The New York Proton Center (NYPC) was approved for the PBT demonstration project in competition with one other applicant. NYPC has submitted CON #142213 to amend its original approved application (CON #101151) to reflect the following changes:

- The withdrawal of NYU Hospitals Center and Beth Israel Medical Center (BIMC) from the project's clinical consortium, leaving Memorial Hospital for Cancer and Allied Diseases (MHCAD), The Mount Sinai Hospital (MSH) and Montefiore Medical Center (MMC) as consortium members. (BIMC, now part of The Mount Sinai Health System, will continue to participate in the project as an academic medical center within the MSH System.)

- A restructuring of the NYPC's business affiliate, New York Proton Management, LLC (NYPM), to reflect the addition of Proton Center Management, LLC, an affiliate of United Health Group, Inc.; and the removal of 21st Century Oncology as a direct member of NYPM.

Project operations and deliverables will remain unchanged, including the number of patients and types of diagnoses to be treated, and the required development of treatment protocols, clinical trials and definitive outcome studies. The changes reflected in this amendment do not negatively impact on the project components that were subject to the competitive review criteria used in the 2010 selection process.

The Department recommends approval of this application.

Public Health and Health Planning Council

Project # 142213-B
The New York Proton Center

Program: **Diagnostic and Treatment Center** ***County:*** **New York**
Purpose: **Establishment and Construction** ***Acknowledged:*** **February 4, 2015**

Executive Summary

Description

The New York Proton Center, Inc. (NYPC), a to-be-formed New York not-for-profit corporation, was contingently approved under CON # 101151 to construct and operate a Proton Beam Therapy (PBT) facility to be certified as a diagnostic and treatment center (DTC). NYPC was the selected application in a competitive process after the Department issued a Request for Applications (RFA) in 2010 for Proton Beam Therapy proposals under a Commissioner's Demonstration Project Authority that set forth review and operation criteria for NYS's first PBT Center. Since the contingent approval, the Center has had to change the approved location and financing structure of the project. On April 8, 2013, a project modification was approved to change the location. Under the current application, NYPC is submitting this project amendment to request approval for changes to its ownership. Specifically, Beth Israel Medical Center and NYU Hospitals Center are being removed as members of NYPC, though as Beth Israel Medical Center is now a part of the Mount Sinai Health System it will continue to clinically participate within TMSHS.

The PBT Center will be in a leased, to-be-constructed facility, consisting of 115,300 square feet of space. The facility will be located at 225 East 126th Street, Harlem, NY (New York County). Currently, New York Proton Management, LLC owns the land and will assign it to MM Proton 1, LLC. The applicant will lease the space from MM Proton 1, LLC. The landlord will construct the facility and will pursue financing and then recoup the costs via the lease rental payments.

NYPC is composed of three hospital members with equal representation on the Board:

- Memorial Hospital for Cancer and Allied Diseases (MHCAD),
- The Mount Sinai Hospital (MSH), and
- Montefiore Medical Center (MMC).

NYPC proposes to enter into an administrative service and license agreement with New York Proton

Management, LLC (NYPM), a to-be-formed New York limited liability company, to provide the facility equipment and day-to-day administrative/non-clinical support. NYPM will own or lease the "hard assets" of NYPC, including the building improvements, medical equipment, business equipment, furniture and fixtures. NYPM will also provide non-clinical business services to NYPC (e.g., billing/collections, HR, IT, accounting)).

The proposed members of NYPM are:

- MSKCC Proton, Inc. (36.31%),
- Mount Sinai Management Services, Inc. (23.04%),
- Montefiore Proton Acquisition, Inc. (7.02%), and
- ProHEALTH Proton Center Management, LLC (ProHealth) (33.63%).

ProHealth, an affiliate of United Health Group, Inc., will be NYPC's manager.

BFA Attachments A and B are the organizational charts of NYCP and NYPM.

OPCHSM Recommendation

Contingent Approval with an expiration of the operating certificate ten years from the date of its issuance.

Need Summary

The application requests approval to operate a PBT center composed of four gantries and one fixed-beam unit, to serve 1,150 patients in its first full year of operation and 1,500 in its third year.

The Department, in consultation with the PBT Demonstration Project Technical Advisory Group, has determined that just one PBT facility is needed at this time.

Program Summary

Based on the information reviewed, staff found nothing that would reflect adversely upon the applicant's character and competence or standing in the community.

Financial Summary

Total project cost of $238,441,379 will be met as follows: Loan of $181,194,786 at an interest rate of 10% for a six-year term. The remainder, $57,246,593, will be met as follows: ProHealth Proton Center Management, LLC ($15,359,260), MSKCC Proton, Inc. ($20,351,163), Montefiore Proton Acquisition, LLC ($5,083,497), Mount Sinai Proton Holding Company, LLC ($15,018,435), and NYU Hospitals Center (a non-refundable capital contribution of $1,434,238 toward the project). The applicant has indicated that the debt is structured as an interest only loan between the lenders and MM Proton 1, LLC. The landlord will refinance in six years with the existing lenders or new lenders.

Budget:

Revenues	$92,553,962
Expenses	86,760,621
Excess of Revenues over Expenses	$5,793,341

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner and contingent approval is recommended,

Recommendations

Health Systems Agency

There will be no HSA recommendation for this project.

Office of Primary Care and Health Systems Management

Approval with an expiration of the operating certificate ten years from the date of its issuance, contingent upon:

1. Submission of a check for the amount enumerated in the approval letter, payable to the New York State Department of Health. Public Health Law Section 2802.7 states that all construction applications requiring review by the Public Health and Health Planning Council shall pay an additional fee of fifty-five hundredths of one percent of the total capital value of the project, exclusive of CON fees. [PMU]
2. Submission of an executed building lease, acceptable to the Department. [BFA]
3. Submission of an executed building sublease, acceptable to the Department. [BFA]
4. Submission of an executed administrative services agreement, acceptable to the Department. [BFA]
5. Submission of a final financing package, acceptable to the Department. [BFA]
6. Submission of an executed land assignment agreement, acceptable to the Department. [BFA]
7. Submission of an executed transfer and affiliation agreement, acceptable to the Department, with a local acute care hospital. [HSP]
8. Submission of an executed Administrative Services and License Agreement, acceptable to the Department. [HSP]
9. Submission of an executed Technical Advisory Agreement, acceptable to the Department [HSP]
10. The applicant is required to submit design development drawings, complying with requirements of 10NYCRR Part 710.4, for review and approval by DASNY. [DAS]
11. Submission of the executed Certificate of Incorporation of The New York Proton Center, acceptable to the Department. [CSL]
12. Submission of the finalized Bylaws of The New York Proton Center, acceptable to the Department. [CSL]
13. Submission of the Certificate of Incorporation of Memorial Hospital for Cancer and Allied Diseases and any amendments thereto, acceptable to the Department. [CSL]
14. Submission of the Bylaws of Memorial Hospital for Cancer and Allied Diseases, acceptable to the Department. [CSL]
15. Submission of the Certificate of Incorporation of The Mount Sinai Hospital and any amendments thereto, acceptable to the Department. [CSL]
16. Submission of the Bylaws of The Mount Sinai Hospital, acceptable to the Department. [CSL]
17. Submission of the Certificate of Incorporation of Montefiore Medical Center and any amendments thereto, acceptable to the Department. [CSL]
18. Submission of the Bylaws of Montefiore Medical Center, acceptable to the Department. [CSL]
19. Submission of evidence of site control, acceptable to the Department. [CSL]
20. Submission of the Administrative Service and License Agreement between The New York Proton Center and New York Proton Management, LLC, acceptable to the Department. [CSL]

Approval conditional upon:

1. The project must be completed within three years from the date of the Public Health and Health Planning Council recommendation letter. Failure to complete the project within the prescribed time shall constitute an abandonment of the application by the applicant and an expiration of the approval. [PMU]
2. The staff of the facility must be separate and distinct from staff of other entities. [HSP]
3. The signage must clearly denote the facility is separate and distinct from other adjacent entities.[HSP]
4. The entrance to the facility must not disrupt any other entity's clinical program space. [HSP]

5. The clinical space must be used exclusively for the approved purpose. [HSP]
6. The applicant is required to submit final construction documents, complying with requirements of 10NYCRR Part 710.7, to NYS DOH Bureau of Architecture and Engineering Facility Planning (BAEFP) prior to start of construction. [DAS]
7. The applicant must adhere to the Construction Start (05/01/2015) and Completion Dates (07/31/2015) provided in Schedule 8 of the application. The Department understands that unforeseen circumstances may delay the start and completion of the project. It is the responsibility of the applicant to request prior approval for any changes to the start and completion dates. [AER]

Council Action Date
April 16, 2015

Need Analysis

Background

Proton beam therapy (PBT) is a technology with demonstrated efficacy for a limited number of relatively rare cancers and tumors – providing high rates of tumor control and survival, while reducing radiation-related side effects. Despite encouraging results, there is a lack of randomized studies demonstrating PBT's effectiveness in comparison with conventional therapies. Although only eight PBT centers are currently operating in the United States, PBT continues to evolve, and the technology holds promise for broader applicability in cancer treatment. In addition, lower-cost PBT devices are under development, which is further likely to increase the number of PBT facilities in the United States.

New York State certificate of need regulations do not currently include a need methodology for proton beam therapy. The existing methodology for therapeutic radiology is not appropriate for PBT facilities, given the emerging nature of PBT and the absence of compelling evidence supporting its use for more than a few relatively rare conditions. In anticipation of receiving one or more applications for the establishment of a PBT facility in New York State, The State Hospital Review and Planning Council (SHRPC) in 2009 began discussing the policy considerations that should inform the review and evaluation of these requests. After several months of deliberation and research, the SHRPC, at its meeting of April 8, 2010, endorsed a Department policy paper on PBT and recommended to the Commissioner the operation of a PBT demonstration project. The SHRPC noted in particular the importance of using the demonstration project to promote research into the effectiveness of PBT in comparison with other therapies.

On May 5, 2010, the Commissioner announced that the Department would undertake such a demonstration project, under the authority of 10 NYCRR Part 705, to evaluate the medical efficacy, cost-effectiveness and efficiency of, and public need for, PBT services in New York State. A threshold requirement for participation in the demonstration project is a commitment to engage in research concerning the effectiveness of PBT in comparison with other treatment modalities. The project will also enable the Department to plan for the appropriate use of this new technology over the longer term

As required by Part 705, the Commissioner appointed a seven-member technical advisory group (TAG) to provide expertise in the review of applications submitted under the demonstration project.

Treatment Capacity

The conditions for which the evidence of PBT's therapeutic value is strongest (and for which insurers are most likely to authorize coverage) are:

- Intraocular melanoma
- Skull-base chordoma/chondrosarcoma
- Meningeoma
- Arteriovenous malformations
- Medulloblastoma
- Pediatric cancer
- Pituitary adenoma[1]

[1] B. Glimelius et al., Number of patients potentially eligible for proton therapy. Acta Oncologica, 2005; 44:836-849.

The following table shows the annual incidence of these cancers in New York State:

The Potential Base for Proton Beam Therapy in New York State					
	Condition	***NYS Annual Cases 2003-2007***[2]	***Projected to 2013***[3]	***Potentially Eligible for PBT*** *(from Glimelius et al., 2005)*[4]	
				%	***Cases***
Clinical Candidates	Intraocular Melanoma	150	164	20%	33
	Skull-base chordoma/	23	66	75%	49
	Meningeoma	1,423	2,091	12%	244
	Arteriovenous malformations	150	153	32%	49
	Medulloblastoma	26	47	67%	31
	Pediatric Cancer[5]	814	857	23%	200
	Pituitary adenoma	545	822	10%	82
	Totals	***3,131***	***4,199***		***688***

Based on these figures, currently there is a need for one PBT center in New York State with the capacity to provide access to approximately 700 patients. While therapeutic gain is recognized for these relatively rare cancers, additional research is required to document the effectiveness of PBT in treating more common cancers (e.g., lung, breast, and prostate).

Research Capacity

Evaluation of need under this demonstration project entails not only an assessment of the capacity of the applicant to deliver quality PBT services to patients with the relatively rare cancers for which PBT is indicated, but also a review of the applicant's capacity to conduct medical research into the effectiveness of PBT. Because a PBT center of the five- beam type under consideration for this demonstration project typically serves 1,500 patients per year, there would remain, in addition to capacity for roughly 700 patients for whom PBT is indicated based on published evidence, capacity to treat 800 patients with cancers for which the effectiveness of PBT has not been demonstrated. This provides an opportunity to advance a principal goal of the demonstration project – conducting research into the efficacy of PBT, and in particular, its efficacy in comparison with other treatments.

Number of Facilities

The Department received three applications in response to the original RFA announcement of the PBT demonstration project in 2010. The question of whether to authorize multiple facilities was addressed by the TAG, whose members unanimously concluded that the goals of the demonstration project would be best served if just one PBT facility were approved under this Part 705 demonstration. The TAG expressed concern that if two or more facilities were approved, the cases for which PBT is a preferred treatment would be dispersed, the financial viability of the facilities would be weakened, and there would be additional pressure on each to treat lucrative, high volume conditions for which there is little evidence supporting PBT, and/or for which there are other equally effective and less expensive treatments. As a result, the research objectives of the demonstration project would be compromised.

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[2] Cases reported to NYS Cancer Registry, except arteriovenous malformations (AVM). AVM estimated at 1 in 100,000 adults: C. Stapf et al., Epidemiology and natural history of arteriovenous malformations. Neurosurgical Focus, 2001; 11: (5) and M. Berman et al., Use of ICD-9 Coding for estimating the occurrence of cerebrovascular malformations. American Journal Neuradiology, 2002; 23: 700-705.

[3] Based on average annual change from 2003-2007.

[4] B. Glimelius et al., supra note 1. The potentially eligible percentages were taken principally from this paper, with supplemental data from M. Krengli et al. Medical aspects of the national centre for oncological hadrontherapy (CNAO- Centro Nationale Adroterpia Oncologica) in Italy. Radiotherapy & Oncology, 2004; 73: S21-S23. See also P.Pommier, et al. Simulating demand for innovative radiotherapies: an illustrative model based on carbon ion and proton radiotherapy. Radiotherapy & Oncology, 2010; 96: 243-249.

[5] Excludes medulloblastoma (included above) and pediatric leukemia.

The Department recognizes that, despite the low incidence of cancers amenable to PBT, a second PBT service would provide patients with a choice in PBT treatment. A second PBT center could also provide more opportunities for research to help determine PBT's long-range potential in treating a broader range of cancers. However, at this time, given the limited evidence supporting the use of PBT, the small number of cases for which it is indicated, and the ample research capacity of a single facility, these considerations are outweighed by the concerns expressed by the TAG.

Conclusion

Based on the foregoing analysis, there is a need for one PBT center in New York State at this time with the capacity to provide access to approximately 1500 patients annually for treatment and Research.

Recommendation

From a need perspective, approval is recommended.

Program Analysis

Research

The NYPC proposes to engage in clinical, translational, and outcomes research. The facility would have a research treatment room, with a dedicated proton beam line for pre-clinical research questions.

Two of the three proposed members of the NYPC are NCI-designated cancers centers based on their "scientific excellence and capability to integrate a diversity of research approaches to focus on the problem of cancer:"[6]

- Memorial Sloan-Kettering Cancer Center - comprehensive cancer center
- Albert Einstein Cancer Research Center (Montefiore) - cancer research center

The proposed principal investigators for this project are:

- **Simon Powell, M.D., Ph.D.:** Chair, Radiation Oncology, Memorial Sloan Kettering. Dr. Powell has over 30 years of clinical experience including experience at Massachusetts General Hospital, the St. Louis Children's Hospital and the Memorial Sloan-Kettering Cancer Institute. Dr. Powell is board certified in Radiation Oncology. He has experience as principal and co-investigator in National Cancer Institute and National Institutes of Health clinical trials. He has authored or co-authored nearly 100 peer-reviewed publications.

- **Kenneth Rosenzweig, M.D.:** Chair, Radiation Oncology, Mount Sinai. Dr. Rosenzweig is board certified in Radiation Oncology by the American Board of Radiology. He has 13 years of experience in radiation oncology, including academic positions at Memorial Sloan Kettering. He has authored or co-authored over 70 publications, is a co-leader on an NCI-funded project, and has contributed to a number of texts including, Cancer: Principles and Practice of Oncology and the Textbook of Radiation Oncology.

- **Shalom Kalnicki, M.D.:** Chair, Radiation Oncology, Montefiore Medical Center. Dr. Kalnicki is board certified in Radiation Oncology. He has over 33 years of clinical experience in radiation oncology including experience at the University of Pittsburgh, Allegheny General Hospital, Hahnemann School of Medicine and Mount Sinai Medical Center. He has authored or co-authored over 150 publications.

[6] National Cancer Institute, Cancer Centers Program, available at: http://cancercenters.cancer.gov/cancer_centers/index.html

Research and clinical trials at NYPC would be supervised and approved by a Clinical Governance Council appointed by the three academic medical center members. The Council would be supported by the Research Office of NYPC, which would work with disease teams and study disciplines to jointly develop clinical trials and run research programs. Trials would use a cooperative group structure, in which each protocol would be opened at all member institutions. Each member institution would independently review the protocols through its own IRB.

The research proposed includes disease-site based research, physics research, biology research, multi-institutional collaborative research, as follows:

1. Pediatric Malignancies
   - Medulloblastoma: study the efficacy of PBT and late effects in treating medulloblastoma, comparing it to historical data on 2-dimensional, 3-dimensional and IMRT therapies; and study dose escalation beyond 60 Gy for ependymoma;
   - Sarcomas: study dose escalation and reduced dosage to critical normal tissues through PBT for certain pediatric sarcomas, comparing efficacy and late effects to historical results obtained through IMRT and 3- dimensional therapy;
   - Neuroblastoma: minimizing dose to normal tissue and correlating radiation exposure to long-term clinical outcomes, and cranio-spinal radiotherapy for brain metastases;
   - Hodgkin lymphoma: treating mediastinal masses with proton therapy to minimize exposure of heart, lung and breast tissue and comparing results to control cases at NYPC member institutions or in the COG database.

2. Head & Neck Cancer and Eye/Orbital Tumors
   - Nasopharynx: for a cohort of patients with advanced T4 diseases, with bulky tumors near vital structures, development of IMPT, IGPT and adaptive proton therapy.
   - Oropharynx: for patients at high risk of locoregional recurrence, study of dose intensification, use of IMPT and IGPT, and outcomes assessment and reduction of adverse impact on swallowing and speech;
   - Glottic cancer: elimination of carotid dose, reduce volume of larynx exposed to radiation;
   - Second malignancies in aerodigestive tract: increase curative potential without over-exposure of normal tissue and adverse functional impact;
   - Skull base: study of IMPT to improve outcomes;
   - Eyes and orbit: study role of proton therapy versus eye plaque brachytherapy through the development of management algorithms for uveal melanomas of various thicknesses and a prospective clinical trial.

3. CNS Tumors
   - High grade glioma (HGG): Phase III randomized trial for HGG to compare the efficacy of proton vs. photons with a 2:1 randomization schema, using local control/survival and neuro-toxicity as endpoints;
   - Skull base brain tumors: Phase II trial using conventional doses with protons to establish baseline local control and acute and late neuro-toxicity; Phase II randomized dose escalation trial, if initial results are promising;
   - Brain metastases: Phase II trial for select brain metastases using a hypofractionated approach to establish the baseline local control and acute and late neuro-toxicity; Phase III randomized trial comparing proton beam with photon IMRT assessing neuro-cognitive outcomes;
   - Posterior fossa brain tumors: Phase II trial to establish long-term local control and survival and acute and late toxicity.

4. Thoracic Cancers
   - Early stage NSCLC: develop guidelines and techniques to treat early stage NSCLC tumors that are adjacent to the chest wall utilizing the dose drop-off of proton irradiation and compare it to stereotactic body radiation therapy; and a dose escalation protocol for central tumors using PBT;
   - Locally advanced NSCLC: Phase I/II protocol of individualized image-guided proton radiotherapy for unresectable Stage IIIA/B NSLC;
   - Small cell lung cancer: Phase I/II protocol for limited state SCLC with gross tumor volume >200 cc to receive daily proton therapy with dose constraints on major organs;
   - Thymoma: long-term Phase II protocol establishing feasibility and dose constraints.

5. Liver and Upper-GI Cancer
   - Hepatocellular carcinoma and liver metastases: engage in clinical, biologic and physics studies; Phase I/II dose escalation study of PBT for intrahepatic malignancy with incrementally escalated, guided by effective volume of liver irradiated to examine toxicity, response rates, and survival. .

6. Prostate Cancer
   - Comparison of Tumor Control Outcomes between IMRT and IMPT: prospectively evaluate and compare tumor control and late toxicity outcomes for patients treated with high-dose proton therapy and photon therapy for low- and intermediate-risk prostate cancer in a Phase III -trial setting. Goals include comparison of survival outcomes at 5 years and a longitudinal quality of life comparison.
   - Outcomes for locally-advanced disease using dose escalation techniques: Phase II study to evaluate outcomes for high-risk prostate cancer using high-dose IMPT in conjunction with ADT; Phase II trial using combining low-dose rate brachytherapy with PBT; PBT using transperineal biodegradable balloon devise;
   - Phase I study of ultra-hypofractionation techniques;
   - Image-based treatment response during and after PBT compared to IMRT photon therapy;
   - Salvage therapies after initial treatment failures: Phase I study to explore use of PBT after external beam failures and biochemical relapse following surgery and compare to brachytherapy and cryotherapy.

   According to NYPC, this disease-site research will build on existing data and ongoing research concerning toxicity profiles and quality of life outcomes at NYPC member institutions.

7. Physics Research
   - Adapt dose planning method for predicting proton dose using Monte Carlo methods;
   - Use new dual-energy GE CT scanner to identify accurately atomic number differences;
   - Investigate use of segmented ionization chamber to verify incident fluence;
   - Verification of proton range estimates using a single pencil beam at exit-side of patient;
   - Develop IGRT for protons to ensure accurate dose delivery; and
   - Automated adaptive treatment planning to accommodate changes in patient anatomy.

8. Biological Research
   - Develop an annotated tissue repository;
   - DNA damage and repair at the distal edge of a proton beam;
   - Individual susceptibility to proton therapy effects using tissue repository and radiogenomics;
   - Monitor TGF  and other cytokines to measure the response to PBT, including toxicity; and
   - Assess risks of radiotherapy-induced second cancers after PBT versus photon therapy by using markers of radiobiological damage from blood samples.

9. Outcomes Research

   The NYPC application indicates that its members have already developed Outcomes Research Centers specifically focused on cancer patients, and led by researchers whose major focus is therapy-related outcomes. The application proposes to study biological markers of late toxicity and functional outcome. The studies include:

   - Patient reported outcomes and treatment related data capture
   - Normal tissue complication probability modeling
   - Clinical outcomes and quality of life research

10. Multi-institutional collaborative research

    NYPC expresses a commitment to participating in multi-institutional research initiatives, such as the Particle Therapy Cooperative Group (PTCOG http:f/ptcog.web.psi.ch). It has been invited by the members of the PROsPER --multi-institution randomized trial which includes MGH, University of Pennsylvania, Washington University in St. Louis and MRPI in Indiana to join their planned (but not yet funded) Phase III trial of prostate cancer treatment.

    In addition, NYPC intends to carry out coordinated programmatic research collaboratively with the other major proton therapy centers, such as MGH and MD Anderson Hospital. Some of the NYPC investigators are already participating in this research as individual investigators.

Data Management

According to the applicant, all of the members of NYPC integrate data collection and analysis into large research departments. The NYPC proposes to integrate member information technology systems to as great an extent as possible and to structure an information technology network that is as compatible as possible with the Statewide Health Information Network for New York (SHIN-NY). The NYPC would use the IMPAC MOSAIQ EMR by Elekta which can identify patients by photo ID, manage bar coding of patient specific devices and import/export radiographic images and reports. The research proposal includes the development of specific databases which detail clinical outcomes and quality of life issues.

Utilization by Condition

The proposed center would serve 1,150 patients in its first year of operation and reach a capacity of 1,500 patients in its third full year. The applicant projects the following case mix:

- Adult head/neck: 27%
- Prostate: 20%
- Adult breast: 13%
- Adult lung: 13%
- Adult other: 13%
- Ocular therapy: 7%
- Pediatric: 7%

According to the applicant, the 20 percent assumed treatment volume in prostate cancer is significantly lower than other proton therapy facilities around the country.

Quality and Patient Safety

The applicant indicates that the facility would seek accreditation from the ACR. To assure correct patient identification, the facility would use photographs, as well as verbal inquiries, to match patients to treatment plans. The staff would also use a Record and Verify system with data concerning all aspects of the treatment, which would be matched against the treatment plan information before the accelerator is activated. The equipment proposal details the necessary equipment to perform image guided radiation therapy for purposes of position verification.

The applicant indicates that IBA would provide factory-based and on-site training for medical physicists, radiation oncologists, and associated staff. Training would span the entire therapy process from treatment planning and verification to treatment delivery and quality assurance. The equipment proposal from Elekta and from IBA details in- service training.

Radiation Safety

The applicant is working with Dr. Thomas Petrone, Ph.D., as its shielding design physicist/consultant. The shielding design is based on the guidelines for the Hampton University Proton Center, which is also using IBA equipment.

Services to the Under-Served, Medicaid Beneficiaries and the Uninsured

The applicant projects the following payor mix:

- Medicaid: 15%
- Medicare: 45%
- Commercial: 31%
- Self-Pay: 5%
- Bad debt: 2%
- Charity care: 2%

The operating agreement of NYPM (the business affiliate) provides that NYPM would be operated in a manner that furthers the charitable purposes of the NYPC and that the NYPC would be operated in a manner that provides access to patient care services without regard to race, religion, national origin, gender, age, sexual orientation, disability, payor source, or ability to pay. It also requires NYPM to cause NYPC to establish and maintain reasonable financial assistance policies, effectively communicate such policies, and provide reasonable levels of charity care based on need and levels of charity care in the community.

Collaboration

The applicant would be organized as consortium of three academic medical centers with a business affiliate. Each of the medical centers is a member of the not-for-profit operator and is represented equally on its board. All of the academic medical centers have committed to make an equity contribution to the project and would share in the governance of the facility and the business affiliate (NYPM) and in the revenues. Together, the academic medical centers would have an aggregate interest of 66.37 percent in NYPM.

Also, the academic medical centers would appoint a Clinical Governance Council which would oversee the “medically- related operations” of the facility, including research, clinical protocols, patient selection, staffing and quality. Each academic medical center would have equal representation on the Clinical Governance Council.

The applicant indicates that it would open to participation in the Clinical Governance Council from “other well- established members of the New York academic medical community” and will credential their physicians for the NYPC medical staff. In addition, the academic medical center participants are currently participating in multiple collaborative research studies and have committed to participating in collaborative research in PBT with other centers and groups. The applicant also indicates that it is engaged in discussions with the University of Pennsylvania’s Roberts Proton Therapy Center to collaborate on future research and multi-center trials.

Staffing

The proposed interim co-medical directors of NYPC are:

1. Simon N. Powell, M.D., MSKCC
2. Kenneth E. Rosenzweig, M.D., Mt. Sinai
3. Shalom Kalnicki, M.D., Montefiore

A single medical director would be hired as the project approaches completion.

The NYPC retained Daniel Alejandro Mazal, Ph.D., the senior medical physicist at the Institute Curie proton facility in Paris and chair of the Particle Therapy Co-Operative Group, to provide medical physics consulting concerning the development of the facility and selection, testing, and configuration of the equipment. After the facility is operational, Dr. Mazal will advise on operations, complex treatment planning and patient-specific quality assurance.

Staff of the NYPC will initially consist of 64 FTEs and is projected to expand to 131 FTEs by the end of the third year.

Transfer and affiliation agreements for emergency, inpatient and back-up support services are expected to be proved by Memorial Hospital for Cancer and Allied Diseases, Mount Sinai Hospital and Montefiore Medical Center, ranging from 1.7 to 4.2 miles and 8 to 12 minutes.

Character and Competence

The proposed Directors/Officers of The New York Proton Center (NYPC) will be:

Name	Affiliation
Simon N. Powell, MD, PhD	MHCAD/MSKCC Proton Inc.
Jose Baselga, MD	MHCAD/MSKCC Proton Inc.
Michael P. Gutnick	MHCAD/MSKCC Proton Inc.
Kenneth Rosenzweig, MD	MSH/Mount Sinai Management Services Inc.
Donald Scanlon	MSH/Mount Sinai Management Services Inc.
Burton P. Drayer, MD	MSH/Mount Sinai Management Services Inc.
Shalom Kalnicki, MD	MMC/Montefiore Proton Acquisition, Inc.
Philip O. Ozuah, MD, PhD	MMC/Montefiore Proton Acquisition, Inc.
Christopher S. Panczner	MMC/Montefiore Proton Acquisition, Inc.

New York Proton Management, LLC (NYPM), a to-be-formed New York limited liability company will own or lease the medical and business equipment, furniture and fixtures of NYPC. Additionally, NYPM will provide day-to-day administrative and non-clinical business services and support through an Administrative Services and License Agreement.

NYPM will have the following members:

Name	Affiliate	Percentage
MSKCC Proton Inc.	MHCAD	36.31%
Mount Sinai Management Services, Inc.	MSH	23.04%
Montefiore Proton Acquisition, Inc.	MMC	7.02%
ProHEALTH Proton Center Management, LLC	United Health Group, Inc.	33.63%

Because a third-party, New York Proton Management, LLC (NYPM), is intended to play a significant role in the physical plant and administrative operations of the proposed facility, the Department also conducted a Character and Competence review of NYPM.

The members of NYPC (listed above) and Members/Managers of ProHEALTH Proton Center Management, LLC— specifically, David Cooper, MD; Mark D. Ficker; and John (Jack) L. Larsen— are either board members/stock owners of the corporate members of NYPM or will serve as managers of NYPM.

Dr. Cooper, an Internist licensed to practice in New York State in 1984, currently serves as Chief Executive Officer (CEO) of ProHEALTH Medical Management, LLC, a physician practice management entity which includes diagnostic imaging centers, radiation oncology centers and an Article 28 Ambulatory Surgery Center. Mr. Ficker has over 16 years of accounting experience and is presently the Chief Financial Officer (CFO) of Local Care Delivery (a subsidiary of UnitedHealth Group, Inc.). Mr. Larsen is a member of the American Institute of Certified Public Accountants and the Minnesota Society of Certified Public Accountants. He has over 30 years of finance/accounting experience and has held a number of corporate leadership roles, including CFO, CEO and President. Mr. Larsen currently serves as the Executive Vice President for Optum, Collaborative Care.

Staff from the Division of Certification & Surveillance reviewed the disclosure information submitted regarding licenses held, formal education, training in pertinent health and/or related areas, employment history, a record of legal actions, and a disclosure of the applicant's ownership interest in other health care facilities. Licensed individuals were checked against the Office of Medicaid Management, the Office of Professional Medical Conduct, and the Education Department databases as well as the US Department of Health and Human Services Office of the Inspector General Medicare exclusion database.

Additionally, the staff from the Division of Certification & Surveillance reviewed the ten-year surveillance history of all associated facilities. Sources of information included the files, records, and reports found in the Department of Health. Included in the review were the results of any incident and/or complaint investigations, independent professional reviews, and/or comprehensive/focused inspections. The review found that any citations were properly corrected with appropriate remedial action.

In a Stipulation and Order dated March 6, 2007, Montefiore Medical Center was fined $14,000 based on a complaint investigation into the care rendered to a child who presented with signs and symptoms of child abuse but was discharged home to an unsafe environment.

Recommendation

From a programmatic perspective, contingent approval is recommended.

Financial Analysis

Lease Rental Agreement

The applicant has submitted a draft lease rental agreement, which is summarized below:

Premises:	115,300 square feet located at 225 East 126th Street, New York, New York
Lessor:	MM Proton 1, LLC
Lessee:	New York Proton Management, LLC
Term:	25 years
Rental:	Year One - $30,000,000 ($260.19 per sq. ft.) with a 2% increase thereafter.
Provisions:	The lessee shall be responsible for the real estate taxes, utilities and maintenance.

New York Proton Management, LLC currently owns the land and will assign it to MM Proton 1, LLC. As a contingency of approval, the applicant must submit an executed land assignment agreement.

Sublease Rental Agreement

The applicant has submitted a draft sublease agreement, which is summarized below:

Premises:	115,300 square feet located at 225 East 126th Street, New York, New York
Sublessor:	New York Proton Management, LLC
Sublessee:	The New York Proton Center
Term:	25 years
Rental:	The rent shall consist of the following: the payment of the "Fee" as such term is set forth in the Administrative Service and License Agreement between the Sublessor and Sublessee, and additional rent in an amount equal to any and all sums of money payable by Sublessee to Sublessor hereunder. The sublease rental payments for the first three years of operation are as follows: • Year One - $18,981,000 ($164.62 per sq. ft.), • Year Two - $33,213,840 ($288.06 per sq. ft.), • Year Three - $33,877,505 ($293.82 per sq. ft.).

The applicant has indicated via affidavit that there is no relationship between the master landlord and the sublessee.

Administrative Services Agreement

The applicant has submitted a draft administrative services agreement, which is summarized below:

Purpose:	The Center desired to engage LLC, and LLC agrees to be so engaged, to provide Center with certain facilities, equipment, supplies, personnel and administrative services necessary for the Center to provide services at the Center.
Facility:	The New York Proton Center
Consultant:	New York Proton Management, LLC
Services Provided:	The Consultant shall provide, on behalf of Center, all non-professional personnel required for the operation of Center, including, but not limited to, administrative and other staff, technicians and radiation therapists, dosimetrists, receptionists, secretaries, clerks, management personnel and/or other personnel as reasonably determined by LLC; be responsible for recruiting, training, managing supervising, compensating and terminating leased personnel, leased personnel shall remain employees and/or contractor of LLC, and not employees of Center; provide Center with such office and medical supplies as are necessary for patient care and treatment and the operation of the Center; shall provide all billing and collection services for Center's services; procure and maintain all necessary licenses and permits for the installation, use and operation of the Equipment and Center, and shall pay all related licensing, inspection and regulatory fees; shall prepare and submit to Center periodic financial reports reflecting the financial status and operations of the Center on a quarterly basis, assist the Center with the preparation of any tax forms; provide hardware and software; assist the Center in recruiting physicians and any other professional staff necessary for the Center to provide services; shall develop and implement marketing and public relations materials with respect to Center's services; shall assist Center in reviewing, evaluating, negotiating and securing contracts or agreements of Center relating to the provision of services by Center; assist the Center in the evaluation of all quality control aspects of Center's services and its operations; process invoices and payroll checks on behalf of the Center; assist the Center in gathering credentialing information relating to licensed personnel and shall credential all licensed personnel engaged by Center; assist the Center in the creation and administration of utilization review, quality assurance and peer review programs for Center; Consultant shall be responsible for all costs and expenses incurred in connection with the operation of the Center, other than the costs and expenses of Professional Personnel which shall be the responsibility of the Center; Consultant shall recommend qualified individuals, who shall be employees of Center, to

	serve as Center's Administrator and Medical Director, subject to the approval and appointment of Center and shall provide Center with a $4,500,000 working capital loan on terms mutually agreed to by the Parties.
Term:	25 years
Compensation Fee:	In consideration of the license to the Premises and the Equipment and the Services provided hereunder, the Center shall pay a fee to the Consultant Entity in an amount equal to the Collected Dollars less the sum of the Professional Collections, less the cost of the Professional Personnel, less any other expenses that the Center incurs to fulfill its obligations hereunder. The parties agree that in no event whatsoever shall the Fee include any collections received by or on behalf of Center attributable to the professional component of patient care services provided at the Center through physicians directly employed by Center or collections attributable to the professional component of patient care services performed at the Center but not physicians that are not employed by the Center. The total administrative and consultant fee during the first and third years is estimated at $40,123,634 and $62,304,860, respectively. The ASA defines the terms of the transfer from NYPC to NYPM to be revenue after the payment of NYPC's operating expenses.

Total Project Cost and Financing

Total project cost, which is for land acquisition and new construction, is estimated at $238,441,379, further broken down as follows:

Land Acquisition	$23,123,642
New Construction	120,579,689
Architect/Engineering Fees	8,963,881
Other Fees (Consultant)	10,987,432
Moveable Equipment	61,098,000
Financing Costs	1,510,805
Interim Interest Expense	10,871,687
CON Fee	2,000
Additional Processing Fee	1,304,243
Total Project Cost	$238,441,379

Total project cost will be met as follows:

Equity	$57,246,593
Bank Loan (10% for a six year term)	181,194,786

The equity contribution is broken down as follows:

ProHEALTH Proton Center Management, LLC	$15,359,260
MSKCC Proton, Inc.	$20,351,163
Montefiore Proton Acquisition, LLC	$5,083,497
Mount Sinai Proton Holding Company, LLC	$15,018,435
NYU Hospitals Center	$1,434,238

NYU Hospitals Center is no longer involved in the Project, but previously made a non-refundable capital contribution of $1,434,238 toward the project, which is being counted toward the $57.25 million equity contribution.

Operating Budget

The applicant has submitted an operating budget, in 2015 dollars, for the first and third years:

	Year One	Year Three
Revenues	$57,323,261	$92,553,962
Expenses		
Operating	$31,173,293	$49,138,276
Capital	22,725,840	37,622,345
Total Expenses	$53,899,133	$86,760,621
Excess of Revenues over Expenses	$3,424,128	$5,793,341
Utilization		
Visits	29,237	45,388
Cost Per Visit	$1,843.52	$1,911.53

Utilization by payor source during the first and third years is as follows:

	Year One	Year Three
Medicaid Managed Care	15.00%	15.00%
Medicare Managed Care	35.00%	35.00%
Commercial Managed Care	41.00%	41.00%
Private Pay	5.00%	5.00%
Charity Care	2.00%	2.00%
Bad Debt	2.00%	2.00%

Utilization assumptions are based on the case mix at the respective academic medical centers, visits, and collaboration with other proton centers around the country. Expense assumptions are based on estimates provided by vendors on a similar costs at other proton centers or New York City Hospitals.

Capability and Feasibility

Total project cost of $238,441,379 will be met as follows: Loan of $181,194,786 at an interest rate of 10% for a six year term. The remainder, $57,246,593, will be met as follows: ProHealth Proton Center Management, LLC ($15,359,260), MSKCC Proton, Inc. ($20,351,163), Montefiore Proton Acquisition, LLC ($5,083,497), Mount Sinai Proton Holding Company, LLC ($15,018,435), and NYU Hospitals Center (a non-refundable capital contribution of $1,434,238 toward the project). The applicant has indicated that the debt is structured as an interest only loan between the lenders and MM Proton 1, LLC. The landlord will refinance in six years with the existing lenders or new lenders.

Working capital requirements are estimated at $14,460,103, which is equivalent to two months of third year expenses. The applicant will provide equity to meet the working capital requirement from the following sources:

The equity contribution for the total project cost and the working capital totals $71,706,696, which is broken down as follows:

ProHEALTH Proton Center Management, LLC	$19,727,175
MSKCC Proton, Inc.	$26,164,124
Montefiore Proton Acquisition, LLC	$5,166,994
Mount Sinai Proton Holding Company, LLC	$19,214,165
NYU Hospital Center	$1,434,238

The submitted budget indicates an excess of revenues over expenses of $3,424,128 and $5,793,341 during the first and third years, respectively. Revenues are based on reimbursement rates for proton beam therapy services and additional reimbursement associated with ancillary services.

BFA Attachment C is the 2012 and 2013 certified financial statements of Memorial Sloan Kettering Cancer Center. As shown on BFA Attachment C, the entity had an average positive working capital position and an average positive net asset position from 2012 through 2013. Also, the entity achieved average income from operations of $134,846,500 from 2012 through 2013.

BFA Attachment D is the 2012 and 2013 certified financial statements of The Mount Sinai Hospital. As shown on BFA Attachment D, the entity had an average positive working capital position and an average positive net asset position from 2012 through 2013. Also, the entity achieved an average excess of operating revenues over operating expenses of $71,506,000 from 2012 through 2013.

BFA Attachment E is the 2012 and 2013 certified financial statements of Montefiore Medical Center. As shown, the entity had an average positive working capital position and an average positive net asset position. Also, the entity achieved an average income from operations of $102,606,000 from 2012 through 2013.

BFA Attachment F is the 2012 and 2013 certified financial statements of United Health Group. As shown, the entity had an average negative working capital position and an average positive shareholders equity position from 2012 through 2013. The applicant indicated that the reason for the average negative working capital position is that the entity places significant assets in long term investments, which leads to business stability and lender confidence. Also, the entity achieved average net earnings of $5,528,000,000 from 2012 through 2013.

BFA Attachment G is the September 30, 2014 internal financial statements of Memorial Sloan Kettering Cancer Center. A shown, the entity had a positive working capital position and a positive net asset position through September 30, 2014. Also, the entity achieved an income from operations of $172,025,000 through September 30, 2014.

BFA Attachment H is the December 31, 2014 internal financial statements of Mount Sinai Hospital. As shown, the entity had a positive working capital position and a positive net asset position through December 31, 2014. Also, the entity achieved an income from operations of $29,250,000 through December 31, 2014.

BFA Attachment I is the September 30, 2014 internal financial statements of Montefiore Medical Center. As shown, the entity had a positive working capital position and a positive net asset position through September 30, 2014. Also, the entity achieved an income from operations of $35,643,000 through September 30, 2014.

BFA Attachment J is the September 30, 2014 internal financial statements of United Health Group. As shown, the entity had a negative working capital position and a positive shareholders equity position through September 30, 2014. The applicant has indicated that the reason for the negative working capital position is the result of the entity places significant assets in long term investments, which leads to business stability and lender confidence. Also, the entity achieved net earnings of $1,602,000,000 through September 30, 2014.

Subject to the noted contingencies, it appears that the applicant has demonstrated the capability to proceed in a financially feasible manner.

Recommendation

From a financial perspective, contingent approval is recommended.

Attachments

BFA Attachment A	Organizational Chart of NYCP
BFA Attachment B	Organizational Chart of NYPM
BFA Attachment C	Financial Summary- 2012 and 2013 certified financial statements of Memorial Sloan Kettering Cancer Center
BFA Attachment D	Financial Summary- 2012 and 2013 certified financial statements of The Mount Sinai Hospital
BFA Attachment E	Financial Summary- 2012 and 2013 certified financial statements of Montefiore Medical Center
BFA Attachment F	Financial Summary- 2012 and 2013 certified financial statements of United Health Group
BFA Attachment G	Financial Summary- September 30, 2014 internal financial statements of Memorial Sloan Kettering Cancer Center
BFA Attachment H	Financial Summary- December 31, 2014 internal financial statements of Mount Sinai Hospital
BFA Attachment I	Financial Summary- September 30, 2014 internal financial statements of Montefiore Medical Center
BFA Attachment J	September 30, 2014 internal financial statements of United Health Group

Policy Name:	**Hierarchy of Coverage Review**
Accreditation Standard(s):	
Regulatory Standard(s)	
Business Unit(s):	**UnitedHealthcare Clinical Services**
Product(s):	
Effective Date:	**6/5/2013**
Cross References:	**Policy and Procedure on Hierarchy of Clinical Evidence** **Policy and Procedure on Medical Technology Assessment Committee - Function and Structure** **Policy and Procedure on New Medical Policy Development** **Policy and Procedure on Coverage Review Process for Serious Rare Diseases** **Coverage Determination Guideline on Experimental, Investigational and Unproven Services**

Purpose:	The purpose of this document is to define the hierarchy of coverage review, to ensure a transparent and consistent approach within UnitedHealthcare. When applying this document to UnitedHealthcare affiliate entities please remember that there are variations in the use of terms and language across different plans.
Background:	The UnitedHealthcare benefit document (i.e., Certificate of Coverage, Evidence of Coverage, Coverage Benefits, or Summary Plan Description) defines benefit coverage for UnitedHealthcare enrollees. While many different benefit documents are in use, our standard benefit design covers health services supported by clinical evidence (unless cosmetic, custodial or explicitly excluded from coverage) and excludes from benefit coverage any health services not supported by clinical evidence (experimental, investigational or unproven). While evidence-based science forms the basis of our determination of coverage, a hierarchy of review takes precedence over our medical policies. This hierarchy is as follows: **1. Eligibility**: The enrollee must be eligible for benefit coverage at the time the service is provided. Without benefit coverage on the date of service, the service is NOT covered, even if supported by scientific evidence. **2. Federal, State or Contractual Requirements for Coverage:** Existing federal and state mandated requirements and Medicaid contracts (the formal, written, legally enforceable contract and amendments between the state and UnitedHealthcare) regarding coverage take precedence over the benefit document or medical policy. UnitedHealth Group follows Federal and state requirements. This includes for Medicare benefit plans any applicable Centers for Medicare and Medicaid Services (CMS) requirements, such as National Coverage Determinations (NCDs) and applicable Local Coverage Determinations (LCDs) and for Medicaid benefit plans any specific contractual or state Medicaid requirements around coverage.

Background: *(continued)*	**3. Coverage/Benefit Documents – Certificate of Coverage (COC), Evidence of Coverage (EOC), Coverage of Benefits (COB) or Summary Plan Description (SPD):** Where no applicable federal, state or contractual requirements exist the coverage/benefit document determines coverage. Services that are explicitly included or excluded from coverage in the benefit document take precedence over medical policy. In the event of a conflict between the benefit document and medical policy, the enrollee's specific benefit document takes precedence over medical policy. **4. Medical and Drug Policy*:** Where no federal, state or contractual requirements exist and no explicit inclusion or exclusion exists in the benefit document (i.e., Certificate of Coverage, Evidence of Coverage, Coverage Benefits, or Summary Plan Description), a written medical or drug policy may be used to determine coverage under the enrollee's benefit plan. UnitedHealthcare medical and drug policies are based upon clinical evidence, as defined in the Hierarchy of Clinical Evidence. Some benefit plans, such as Medicare and Medicaid, may require compliance with non-UHC medical policies. UHC creates support documents to assist in interpreting benefit documents and applying medical policy: **4a. Coverage Determination Guideline (CDG)*:** A CDG is an internally developed tool to facilitate consistent and accurate interpretation of UnitedHealthcare commercial benefit plan language. It provides criteria and documentation requirements to determine whether a service falls within a benefit category or if it is excluded. The CDG may address such matters as determining whether services are skilled versus custodial, reconstructive or cosmetic, or durable medical equipment versus equipment that serves a non-medical purpose; ***Note:*** *Explicit benefit plan language always takes precedence over interpretive CDGs.* **4b. Coverage Summary (CS)*:** Coverage Summaries based on existing Medicare national coverage policies and member Evidence of Coverage (EOC) are intended to provide benefit coverage information and guidelines specific to UnitedHealthcare Medicare Advantage Plans. The Coverage Summaries are developed and reviewed by the UnitedHealthcare Medicare Benefit Interpretation Committee. Dual eligible member's Medicare coverage is subject to UnitedHealthcare Medicare Advantage Coverage Summaries. **5. Utilization Review Guideline*:** Utilization review guidelines utilize scientific evidence to determine whether the proposed health care services or the services provided for an enrollee (i.e., post service review) are medically necessary (i.e., supported by published clinical evidence, the most appropriate service for the unique enrollee and/or the most cost-effective service under the specific circumstances). Utilization review guidelines may be used to determine: a. Patient selection criteria; b. Appropriateness of admission; c. Duration of care or length of stay; d. Level of care or site of service (e.g., office, outpatient, observation or admission);

Background: *(continued)*	e. Whether diagnostic and therapeutic procedures of lower resource intensity should be used prior to those of a higher intensity of medical service (i.e., conservative therapy before a surgical procedure). ***Note:** UnitedHealthcare entities such as Oxford, River Valley and UnitedHealthcare of the West, may refer to the UHC policies addressed in numbers 4-5 using different names or terms for the "policy." Some examples are: clinical policy, coverage policy, medical management guideline and utilization guideline. Please refer to the "policy" that governs the specific platform. **6. Internally Initiated Guidelines and Externally Licensed Guidelines:** In the absence of applicable UnitedHealthCare policies mentioned in numbers 4 and 5 (above), internally initiated guidelines (e.g. Optum Transplant Review Guidelines) that have been approved by the appropriate line of service and standing committees may be used for the initial review and appeal process. For those circumstances where internally initiated guidelines are not approved, and no policies (mentioned in 4 or 5) are available or applicable, externally licensed guidelines (e.g. MCG®) would be used, where licensed by the reviewing business unit.
Coverage Review: **Commercial** ***Certificate of Coverage (2011)***	**Medically Necessary**: health care services provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance use disorder, condition, disease or its symptoms, that are all of the following as determined by us or our designee, within our sole discretion. • In accordance with *Generally Accepted Standards of Medical Practice**. • Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance use disorder, disease or its symptoms. • Not mainly for your convenience or that of your doctor or other health care provider. • Not more costly than an alternative drug, service(s) or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms. ****Generally Accepted Standards of Medical Practice*** are standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes. If no credible scientific evidence is available, then standards that are based on Physician specialty society recommendations or professional standards of care may be considered. We reserve the right to consult expert opinion in determining whether health care services are Medically Necessary. The decision to apply Physician specialty society recommendations, the choice of expert and the determination of when to use any such expert opinion, shall be within our sole discretion.

Coverage Review: **Medicare Advantage Plans** ***Evidence of Coverage (2012)***	**Medically Necessary definition (2012 EOC)**: Services, supplies, or drugs that are needed for the prevention, diagnosis, or treatment of an enrollee's medical condition and meet accepted standards of medical practice. The foreword to the Medicare National Coverage Determinations Manual states that "[a]ll decisions that items, services, etc. are not covered are based on §1862(a)(1) of the [Social Security] Act (the "not reasonable and necessary" exclusion) unless otherwise specifically noted. Chapter 13 of the Medicare Program Integrity Manual further states: In order to be covered under Medicare, a service shall be reasonable and necessary under §1862(a)(1)(A) of the Social Security Act . CMS guidance provides that a service is reasonable and necessary if the service is: • Safe and effective; and • Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and • Appropriate, including the duration and frequency, that is considered appropriate for the service, in terms of whether it is: o Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body part; o Furnished in a setting appropriate to the patient's medical needs and condition; o Ordered and furnished by qualified personnel; o One that meets, but does not exceed, the patient's medical need; and o At least as beneficial as an existing and available medically appropriate alternative. There are several exceptions to the requirement that a service be reasonable and necessary for diagnosis or treatment of illness or injury. The exceptions appear in the full text of §1862(a)(1)(A) and include but are not limited to: • Pneumococcal, influenza and hepatitis B vaccines are covered if they are reasonable and necessary for the prevention of illness; • Hospice care is covered if it is reasonable and necessary for the palliation or management of terminal illness (Note: special coverage rules apply to hospice care for Medicare Advantage enrollees); • Screening mammography is covered if it is within frequency limits and meets quality standards; • Cervical cancer screening and screening pelvic exam are covered if they are within frequency limits; • Prostate cancer screening tests are covered if within frequency limits; • Colorectal cancer screening tests are covered if within frequency limits; and • One pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an interlobular lens. Medicare Advantage programs are obligated to follow CMS medical policy in

Coverage Review: *(continued)* **Medicare Advantage Plans** ***Evidence of Coverage (2012)***	determining benefits**.** The following hierarchy should be followed in applying Medical Policy for Medicare Advantage enrollees. Service-specific instructions may be found in UHC Medicare Advantage Coverage Summaries: • Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations • General coverage guidelines included in original Medicare manuals and instructions • Local Coverage Determinations generally have jurisdiction for claims in the geographic area in which services are covered; • UHC Medical Policy, if appropriate for the Medicare population.
Coverage Review: **Medicaid**	The definition of what is experimental, investigational and unproven services for the Medicaid benefit plans may be dependent on the specific Medicaid state contractual and regulatory requirements.
Coverage Review: **Pharmacy**	OptumRx, Commercial, Medicare and Medicaid benefit units utilize Prior Authorization (PA) Guidelines to make decisions regarding coverage for select prescription medications. Prior Authorization Guidelines define coverage criteria for select prescription medication products within each unique Plan Formulary/PDL, which may include, but are not limited to the following: • Utilization Management programs, which may include, but are not limited to the following: o Prior Authorization review o Quantity Limit restrictions/overrides o Step-Therapy requirements/overrides • Non-formulary exceptions • Tier cost-sharing exceptions for member cost-sharing responsibilities • Exceptions to formulary restrictions (e.g. based on age <18 years old) The coverage policies delineated within PA Guidelines are developed based on input from multiple sources, which include, but are not limited to the following: • Clinical recommendations for coverage are made by the UHG National Pharmacy & Therapeutics Committee (NP&TC), the voting members of which are comprised entirely of external medical and pharmacy professionals, who are selected to achieve a balance of multispecialty expertise in the fields of medicine, pharmacy, and medical ethics. • The OptumRx Business Implementation Committee (BIC), Prescription Drug List (PDL) Management Committee (Commercial), Medicare Pharmacy Management Committee, and UnitedHealthcare Community & State Pharmacy Management Committee make formulary and PDL decisions for their respective businesses in regards to coverage for specific prescription products and formulations based on multiple factors, which include, but are not limited to: o Clinical recommendations made by UHG NP&TC o Pharmacoeconomic information (when available) o Specific client coverage requirements o Net cost of the medication/product

Coverage Review: *(continued)* **Pharmacy**	Coverage decisions are also subject to a variety of Administrative Guidelines, when applicable, which are based upon clinical and other factors. These Administrative Guidelines include, but are not limited to the following named policies: • Non-Formulary Exceptions Process • Prior Authorization Administrative Guidelines (for coverage decisions regarding Drugs without specific PA Guidelines) • Quantity Limit Overrides • Mandatory Generic Override Guidelines • Insulin Delivery Systems • Compounded Products • Requests for Higher than FDA-Approved Maximum Doses • Coverage of Off-Label Non-FDA Approved Indications Coverage decisions are also subject to the regulatory requirements of any authoritative state or federal government jurisdiction. Examples include, but are not limited to the following: • For Medicare Part D members, reference to the Centers for Medicaid & Medicare Services (CMS) policy regarding Medicare Part B Versus Part D Coverage Issues is required to determine coverage for some prescription products, which include, but are not limited to the following: o Vaccines o Parenteral Nutrition (TPN) o Oral Anti-Cancer Chemotherapy Agents o Durable Medical Equipment (DME) Supply Drugs that are administered by the use of a covered DME device (e.g., a nebulizer, external or implantable pump), and which include, but are not limited to Pulmozyme Inhalation Solution or Tobi (tobramycin) Inhalation Solution administered by nebulizer, and injectable Anticancer Chemotherapy Drugs, Antifungal and Antiviral Drugs, Chronic Iron Overload Therapy, or Parenteral Inotropic Therapy administered by infusion pump.
Coverage Review: **Military and Veterans**	The TRICARE Operation Manual, TRICARE Policy Manual, 32 CFR 199.4 and 32 CFR 199.15 will be used as the sources of truth for benefit inclusion for United Military and Veterans (UMV)enrollees. • **Medical Services:** Medical inpatient care managers and prior authorization nurses will use evidence-based MCG® to guide length of stay expectations and appropriate levels of care for medical services. • **Behavioral Health Services:** For behavioral health medical necessity reviews, clinician reviewers will use proprietary Level of Care, Best Practices and Psychological and Neuropsychological Testing Guidelines to make decisions related to the most appropriate type and level of care.

Business Owner: **Ed Sakamoto, MD, VP Clinical Review**
Richard Justman, MD, National Medical Director

Content Owner: **Shannon Mullen, Director, Medical Policy**

PROTON BEAM RADIATION THERAPY

Policy Number: 2015T0132T
Effective Date: December 1, 2015

Table of Contents

Related Policies:
Intensity-Modulated Radiation Therapy

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

This policy applies to persons 19 years of age and older. Proton beam radiation therapy is covered without further review for persons younger than 19 years of age.

Where proton beam therapy is deemed proven, in-network benefits may be available for what is otherwise an out-of-area or out-of-network service. The enrollee-specific benefit document must be consulted to determine what form of coverage exists.

- If an enrollee has benefits for out-of-network services ("Plus"), proton beam therapy would be covered at the out-of-network benefit level. Additional coverage for travel costs would not be allowed in this situation.
- If an enrollee does not have benefits for out-of-network services ("Standard"), no out-of-network benefit would be available for proton beam therapy as long as external beam radiation therapy is available within the network.

Some Certificates of Coverage allow coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The enrollee-specific benefit document must be consulted to make coverage decisions for this service.

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee specific benefit document to determine benefit coverage.

COVERAGE RATIONALE

Proton beam radiation therapy is proven and medically necessary for the following indications:

- Intracranial arteriovenous malformations (AVMs)
- Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid)
- Skull-based tumors (e.g., chordomas, chondrosarcomas or paranasal sinus tumors)

Proton beam radiation therapy is unproven and not medically necessary for treating ALL other indications, including but not limited to:

- Age-related macular degeneration (AMD)
- Bladder cancer
- Brain and spinal cord tumors
- Choroidal hemangioma
- Esophageal cancer
- Gynecologic cancers
- Head and neck cancers
- Hepatocellular carcinoma
- Lung cancer
- Lymphomas
- Pancreatic cancer
- Prostate cancer
- Vestibular tumors (e.g. acoustic neuroma or vestibular schwannoma)

There is limited clinical evidence that directly compares proton beam therapy (PBT) with other types of radiation therapy. Current published evidence does not allow for any definitive conclusions about the safety and efficacy of proton beam therapy to treat conditions other than those noted above as proven and medically necessary.

Proton beam radiation therapy used in conjunction with intensity-modulated radiation therapy (IMRT) is unproven and not medically necessary.
Clinical evidence is insufficient to support the combined use of these technologies in a single treatment plan. Comparative effectiveness studies including randomized controlled trials are needed to demonstrate the safety and long-term efficacy of combined therapy.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed
77520	Proton treatment delivery; simple, without compensation
77522	Proton treatment delivery; simple, with compensation
77523	Proton treatment delivery; intermediate
77525	Proton treatment delivery; complex

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HCPCS Code	Description
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs, via narrow spatially and temporally modulated beams, binary, dynamic MLC, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (e.g., 3D positional tracking, gating, 3D surface tracking), each fraction of treatment

Proven ICD-9 Codes (Discontinued 10/01/15)
The following list of codes is provided for reference purposes only. Effective October 1, 2015, the Centers for Medicare & Medicaid Services (CMS) implemented ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures), replacing the ICD-9-CM diagnosis and procedure code sets.
ICD-9 codes will not be accepted for services provided on or after October 1, 2015.

ICD-9 Diagnosis Code (Proven) (Discontinued 10/01/15)	Description
170.0	Malignant neoplasm of bones of skull and face, except mandible
190.0	Malignant neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid
190.6	Malignant neoplasm of choroid
191.9	Malignant neoplasm of brain, unspecified site
213.0	Benign neoplasm of bones of skull and face

224.0	Benign neoplasm of eyeball, except conjunctiva, cornea, retina, and choroid
224.6	Benign neoplasm of choroid
234.0	Carcinoma in situ of eye
747.81	Congenital anomaly of cerebrovascular system

ICD-10 Codes
ICD-10-CM (diagnoses) and ICD-10-PCS (inpatient procedures) must be used to report services provided on or after October 1, 2015.

ICD-10 codes will not be accepted for services provided prior to October 1, 2015.

ICD-10 Diagnosis Code	Description
C41.0	Malignant neoplasm of bones of skull and face
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C71.9	Malignant neoplasm of brain, unspecified
D09.20	Carcinoma in situ of unspecified eye
D09.21	Carcinoma in situ of right eye
D09.22	Carcinoma in situ of left eye
D16.4	Benign neoplasm of bones of skull and face
D31.30	Benign neoplasm of unspecified choroid
D31.31	Benign neoplasm of right choroid
D31.32	Benign neoplasm of left choroid
D31.40	Benign neoplasm of unspecified ciliary body
D31.41	Benign neoplasm of right ciliary body
D31.42	Benign neoplasm of left ciliary body
Q28.2	Arteriovenous malformation of cerebral vessels
Q28.3	Other malformations of cerebral vessels

DESCRIPTION OF SERVICES

Unlike other types of radiation therapy that use x-rays or photons to destroy cancer cells, proton beam therapy (PBT) uses a beam of special particles (protons) that carry a positive charge. There is no significant difference in the biological effects of protons versus photons; however, protons can deliver a dose of radiation in a more confined way to the tumor tissue than photons. After they enter the body, protons release most of their energy within the tumor region and, unlike photons, deliver only a minimal dose beyond the tumor boundaries (American College of Radiology website, 2012).

The greatest energy release with conventional radiation (photons) is at the surface of the tissue and decreases exponentially the farther it travels. In contrast, the energy of a proton beam is released at the end of its path, a region called the Bragg peak. Since the energy release of the proton beam is confined to the narrow Bragg peak, collateral damage to the surrounding tissues should be reduced, while an increased dose of radiation can be delivered to the tumor.

Because of these physical properties, PBT may be useful when the target volume is in close proximity to one or more critical structures and sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiation therapy.

CLINICAL EVIDENCE

AHRQ published a report on particle beam therapy for treating a variety of cancers. More than half of the publications the AHRQ identified described treatment of ocular cancers (uveal melanoma in particular), and cancers of the head and neck (brain tumors, and tumors arising from skull base, cervical spine and nearby structures). In order of decreasing number of studies, the following types of malignancies were also described: gastrointestinal (esophageal cancer, hepatocellular carcinomas of the liver, pancreatic cancer), prostate, lung, spine and sacrum, bone and soft tissue, uterine (cervix and corpus), bladder, and miscellaneous (skin cancer or a compilation of a center's experience with a variety of cancers treated there).

According to the AHRQ report, there are many publications on particle (mainly proton) beam therapy for the treatment of cancer. However, they typically do not use a concurrent control, focus on heterogeneous populations and they employ different definitions for outcomes and harms. These studies do not document the circumstances in contemporary treatment strategies in which radiotherapy with charged particles is superior to other modalities. Comparative effectiveness studies including randomized controlled trials are needed to document the theoretical advantages of charged particle radiotherapy to specific clinical situations. At present, there is very limited evidence comparing the safety and effectiveness of PBRT with other types of radiation therapies for cancer. Therefore, it is not possible to draw conclusions about the comparative safety and effectiveness of PBRT at this time (AHRQ, 2009).

In an emerging technology report, ECRI detailed major clinical and operational issues related to proton beam radiation therapy. However, no analysis of the evidence was possible due to the lack of appropriately designed studies comparing the efficacy of proton therapy to other modes of radiation therapy (ECRI, 2010; updated 2013).

Several systematic reviews (Terasawa et al., 2009; Brada et al., 2009; Lodge et al., 2007; Olsen et al., 2007) previously reported the lack of evidence supporting proton beam therapy and the need for well-designed prospective studies comparing proton beam therapy to other forms of radiation therapy.

Professional Societies

American Society for Radiation Oncology (ASTRO)

ASTRO's Emerging Technology Committee concluded that current data do not provide sufficient evidence to recommend proton beam therapy (PBT) outside of clinical trials in lung cancer, head and neck cancer, GI malignancies (with the exception of hepatocellular carcinoma) and pediatric non-central nervous system (CNS) malignancies. In hepatocellular carcinoma and prostate cancer, there is evidence of the efficacy of PBT but no suggestion that it is superior to photon based approaches. In pediatric CNS malignancies, PBT appears superior to photon approaches, but more data is needed. In large ocular melanomas and chordomas, ASTRO states that there is evidence for a benefit of PBT over photon approaches. More robust prospective clinical trials are needed to determine the appropriate clinical setting for PBT (Allen et al., 2012).

Intracranial Arteriovenous Malformations

In a Cochrane review, Ross et al. (2010) assessed the clinical effects of various interventions to treat brain arteriovenous malformations (AVMs) in adults. Interventions include neurosurgical excision, stereotactic radiotherapy/radiosurgery (using gamma knife, linear accelerator, proton beam or CyberKnife), endovascular embolization (using glues, particles, fibres, coils or balloons) and staged combinations of these interventions. The authors concluded that there is no evidence from randomized trials with clear clinical outcomes comparing different interventional treatments for brain AVMs against each other or against usual medical therapy to guide the interventional treatment of brain AVMs in adults.

Hattangadi-Gluth et al. (2014) evaluated the obliteration rate and potential adverse effects of single-fraction proton beam stereotactic radiosurgery (PSRS) in patients with cerebral

arteriovenous malformations (AVMs). From 1991 to 2010, 248 consecutive patients with 254 cerebral AVMs received single-fraction PSRS at a single institution. The median AVM nidus volume was 3.5 cc, 23% of AVMs were in critical/deep locations (basal ganglia, thalamus or brainstem) and the most common dose was 15 Gy. At a median follow-up time of 35 months, 64.6% of AVMs were obliterated. The median time to total obliteration was 31 months, and the 5- and 10-year cumulative incidence of total obliteration was 70% and 91%, respectively. On univariable analysis, smaller target volume, smaller treatment volume, higher prescription dose and higher maximum dose were associated with total obliteration. Deep/critical location was also associated with decreased likelihood of obliteration. On multivariable analysis, critical location and smaller target volume remained associated with total obliteration. Post-treatment hemorrhage occurred in 13 cases (5-year cumulative incidence of 7%), all among patients with less than total obliteration. Three of these events were fatal. The most common complication was seizure. The authors reported that this is the largest modern series of PSRS for cerebral AVMs and concluded that PSRS can achieve a high obliteration rate with minimal morbidity. Post-treatment hemorrhage remains a potentially fatal risk among patients who have not yet responded to treatment.

Hattangadi et al. (2012) evaluated 59 patients with high-risk cerebral arteriovenous malformations (AVMs), based on brain location or large size, who underwent planned two-fraction proton stereotactic radiosurgery (PSRS). Median nidus volume was 23 cc. Seventy percent of cases had nidus volume ≥ 14 cc, and 34% were in critical locations (brainstem, basal ganglia). Many patients had prior surgery or embolization (40%) or prior PSRS (12%). The most common dose was 16 Gy in two fractions. At a median follow-up of 56.1 months, 9 patients (15%) had total and 20 patients (34%) had partial obliteration. Patients with total obliteration received higher total dose than those with partial or no obliteration. Median time to total obliteration was 62 months, and 5-year actuarial rate of partial or total obliteration was 33%. Five-year actuarial rate of hemorrhage was 22% and 14% (n = 8) suffered fatal hemorrhage. Lesions with higher AVM scores were more likely to hemorrhage and less responsive to radiation. The most common complication was headache. One patient developed a generalized seizure disorder, and two had mild neurologic deficits. The authors concluded that high-risk AVMs can be safely treated with two-fraction PSRS, although total obliteration rate is low and patients remain at risk for future hemorrhage. Future studies should include higher doses or a multistaged PSRS approach for lesions more resistant to obliteration with radiation.

In a retrospective study by Vernimmen et al. (2005), 64 patients with arteriovenous malformation were reviewed to investigate hypofractionated stereotactic proton therapy of predominantly large intracranial arteriovenous malformations (AVMs) by analyzing retrospectively the results from a cohort of patients. The AVMs were grouped by volume: <14 cc (26 patients) and > or =14 cc (38 patients). Treatment was delivered with a fixed horizontal 200 MeV proton beam under stereotactic conditions, using a stereophotogrammetric positioning system. The majority of patients were hypofractionated (2 or 3 fractions), and the proton doses are presented as single-fraction equivalent cobalt Gray equivalent doses (SFEcGyE). The overall mean minimum target volume dose was 17.37 SFEcGyE, ranging from 10.38-22.05 SFEcGyE. Analysis by volume group showed obliteration in 67% for volumes <14 cc and 43% for volumes > or =14 cc. Grade IV acute complications were observed in 3% of patients. Transient delayed effects were seen in 15 patients (23%), becoming permanent in 3 patients. One patient also developed a cyst 8 years after therapy. Vernimmen concluded that stereotactic proton beam therapy applied in a hypofractionated schedule allows for the safe treatment of large AVMs, with acceptable results and is an alternative to other treatment strategies for large AVMs.

Ocular Tumors

A report on proton beam therapy from the Institute for Clinical and Economic Review (ICER) rated the net health benefit of PBT relative to alternative treatments to be superior in ocular tumors (ICER, 2014).

In a systematic review, Wang et al. (2013) evaluated the efficacy and adverse effects of charged particle therapy (CPT), delivered with protons, helium ions or carbon ions, for treating uveal melanoma. Twenty-seven studies enrolling 8809 uveal melanoma patients met inclusion criteria. The rate of local recurrence was significantly less with CPT than with brachytherapy. There were no significant differences in mortality or enucleation rates. CPT was also associated with lower retinopathy and cataract formation rates. The authors reported that the overall quality of the evidence is low, and higher quality comparative effectiveness studies are needed to provide better evidence.

A systematic review concluded that there is evidence for a benefit of proton beam therapy over photon approaches in treating large ocular melanomas (Allen et al., 2012).

Ocular cancers are included in the AHRQ report (2009) referenced above, which states that the evidence is insufficient to draw any definitive conclusions as to whether PBT has any advantages over traditional therapies

The National Comprehensive Cancer Network (NCCN) does not address ocular cancers in a guideline.

Skull-Based Tumors

NCCN states that specialized techniques, including particle beam radiation therapy with protons, should be considered in order to allow high-dose therapy while maximizing normal tissue sparing in patients with primary bone cancer (NCCN, 2015).

A systematic review concluded that there is evidence for a benefit of proton beam therapy over photon approaches in treating chordomas (Allen et al., 2012).

A systematic review of seven uncontrolled single-arm studies concluded that the use of protons has shown better results in comparison to the use of conventional photon irradiation, resulting in the best long-term (10 years) outcome for skull-based chordomas with relatively few significant complications (Amichetti et al., 2009).

The use of proton therapy (PT) to treat chondrosarcoma (CSA) of the skull base (SB) after surgery is widely accepted, but studies demonstrating the need for PT and its superiority in comparison to radiotherapy with photons are lacking. In a systematic review, Amichetti et al. (2010) reported that studies of proton beam therapy for skull-based chondrosarcoma resulted in local control ranging from 75% to 99% at 5 years. There were no prospective trials (randomized or nonrandomized), but four uncontrolled single-arm studies with 254 patients were included. The authors concluded that PT following surgical resection showed a very high probability of medium- and long-term cure with a relatively low risk of significant complications.

Early studies evaluating PBT for the treatment of intracranial or skull base tumors include four case series, four retrospective studies, and two prospective, uncontrolled, clinical studies (Kjellberg, 1968; Suit, 1982; Hug, 1995; Al-Mefty and Borba, 1997; McAllister, 1997; Gudjonsson, 1999; Wenkel, 2000; Vernimmen, 2001). The studies included 10 to 47 patients with pituitary gland adenoma, para-CNS sarcomas, osteogenic and chondrogenic tumors, chordomas, and meningiomas. Local control was achieved in 71% to 100% of patients. Complications were radiation dose/volume and site dependent, and were mild to severe.

In a retrospective review by Weber et al. (2005), 29 patients with skull base chordomas (n=18) and low-grade chondrosarcomas (CS) (n=11) were reviewed to assess the clinical results of spot scanning proton beam radiation therapy (PT). Tumor conformal application of proton beams was realized by spot scanning technology. The median chordoma and CS dose was 74 and 68 cobalt Gy equivalent, respectively (cobalt Gy equivalent = proton Gy x 1.1). Median gross tumor volumes (GTV) were 16.4 mL (range, 1.8-48.1 mL) and 15.2 mL (range, 2.3-57.3 mL) for chordoma and CS, respectively. Median follow-up time was 29 months (range, 6-68 months).

Three year local control rates were 87.5% and 100% for chordoma and CS, respectively. Actuarial 3-year complication-free survival was 82.2%. Radiation-induced pituitary dysfunction was observed in 4 (14%) patients (CTCAE Grade 2). No patient presented with post-PT brainstem or optic pathways necrosis or dysfunction. The authors concluded that spot-scanning PT offers high tumor control rates of skull base chordoma and chondrosarcomas. These preliminary results are encouraging but should be confirmed during a longer follow-up.

Age-Related Macular Degeneration (AMD)

In a Cochrane review, Evans et al. (2010) examined the effects of radiotherapy on neovascular age-related macular degeneration (AMD). All randomized controlled trials in which radiotherapy was compared to another treatment, sham treatment, low dosage irradiation or no treatment were included. Thirteen trials (n=1154) investigated external beam radiotherapy with dosages ranging from 7.5 to 24 Gy; one additional trial (n=88) used plaque brachytherapy (15Gy at 1.75mm for 54 minutes/12.6 Gy at 4mm for 11 minutes). Most studies found effects (not always significant) that favored treatment. Overall there was a small statistically significant reduction in risk of visual acuity loss in the treatment group. There was considerable inconsistency between trials and the trials were considered to be at risk of bias, in particular because of the lack of masking of treatment group. Subgroup analyses did not reveal any significant interactions, however, there were small numbers of trials in each subgroup (range three to five). There was some indication that trials with no sham irradiation in the control group reported a greater effect of treatment. The incidence of adverse events was low in all trials; there were no reported cases of radiation retinopathy, optic neuropathy or malignancy. Three trials found non-significant higher rates of cataract progression in the treatment group. The authors concluded that this review does not provide convincing evidence that radiotherapy is an effective treatment for neovascular AMD. If further trials are to be considered to evaluate radiotherapy in AMD then adequate masking of the control group must be considered.

In a systematic review, Bekkering et al. (2009) evaluated the effects and side effects of proton therapy for indications of the eye. All studies that included at least ten patients and that assessed the efficacy or safety of proton therapy for any indication of the eye were included. Five controlled trials, two comparative studies and 30 case series were found, most often reporting on uveal melanoma, choroidal melanoma and age-related macular degeneration (AMD). Methodological quality of these studies was poor. Studies were characterized by large differences in radiation techniques applied within the studies, and by variation in patient characteristics within and between studies. Results for uveal melanoma and choroidal melanoma suggest favorable survival, although side effects are significant. Results for choroidal hemangioma and AMD did not reveal beneficial effects from proton radiation. There is limited evidence on the effectiveness and safety of proton radiation due to the lack of well-designed and well-reported studies.

A randomized controlled trial by Zambarakji et al. (2006) studied 166 patients with angiographic evidence of classic choroidal neovascularization resulting from AMD and best-corrected visual acuity of 20/320 or better Patients were assigned randomly (1:1) to receive 16-cobalt gray equivalent (CGE) or 24-CGE proton radiation in 2 equal fractions. Complete ophthalmological examinations, color fundus photography, and fluorescein angiography were performed before and 3, 6, 12, 18, and 24 months after treatment. At 12 months after treatment, 36 eyes (42%) and 27 eyes (35%) lost three or more lines of vision in the 16-CGE and 24-CGE groups, respectively. Rates increased to 62% in the 16-CGE group and 53% in the 24-CGE group by 24 months after treatment. Radiation complications developed in 15.7% of patients receiving 16-CGE and 14.8% of patients receiving 24-CGE. The authors concluded that no significant differences in rates of visual loss were found between the two dose groups.

A randomized, sham-controlled, double-blind study by Ciulla et al. (2002) studied 37 patients to examine the effect of proton beam irradiation on subfoveal choroidal neovascular membranes (CNVM) associated with age-related macular degeneration. Patients were randomly assigned to 16-Gy proton irradiation delivered in two fractions 24 hours apart or to sham control treatment. Recruitment was halted at 37 subjects for ethical reasons regarding randomization to sham

treatment when U.S. Food and Drug Administration approval of Visudyne® (verteporfin) was anticipated. Proton irradiation was associated with a trend toward stabilization of visual acuity, but this association did not reach statistical significance. The authors concluded that with the acceptance of photodynamic therapy, future studies will require more complex design and larger sample size to determine whether radiation can play either a primary or adjunctive role in treating these lesions. In addition, newer more effective therapies for AMD, e.g., Lucentis® (ranibizumab) and Avastin® (bevacizumab) have made previously available therapies obsolete.

Professional Societies

American Academy of Ophthalmology (AAO)

AAO preferred practice patterns do not address PBT as a treatment option for age-related macular degeneration (AMD) but do state that there is insufficient data to demonstrate clinical efficacy of radiation therapy in general (AAO, 2015).

Bladder Cancer

Miyanaga et al. (2000) conducted a prospective uncontrolled clinical study to assess the efficacy and safety of PBT and/or photon therapy for bladder cancer. The study involved 42 patients who received PBT to the small pelvic space following intra-arterial chemotherapy. At 5-year follow-up, the bladder was preserved in 76% of patients and 65% were free of disease. The disease-specific survival rate was 91%. Patients with large and multiple tumors were more at risk of cancer recurrence than patients with single, small tumors. Nausea and vomiting, irritable bladder and ischialgia were the main side effects.

Bladder cancer is included in the AHRQ report (2009) referenced above, which states that the evidence is insufficient to draw any definitive conclusions as to whether PBT has any advantages over traditional therapies.

Brain and Spinal Cord Tumors

NCCN suggests considering protons over photons for craniospinal irradiation in adults with medulloblastoma when toxicity is a concern (NCCN, 2015).

Noel et al. (2002) conducted a retrospective review of 17 patients with meningioma to evaluate the efficacy and the tolerance of an escalated dose of external conformal fractionated radiation therapy combining photons and protons. Five patients presented a histologically atypical or malignant meningioma, twelve patients a benign one that was recurrent or rapidly progressive. In two cases radiotherapy was administered in the initial course of the disease and in 15 cases at the time of relapse. A highly conformal approach was used combining high-energy photons and protons for approximately 2/3 and 1/3 of the total dose. The median total dose delivered within gross tumor volume was 61 Cobalt Gray Equivalent CGE (25-69). Median follow-up was 37 months (17-60). The 4-year local control and overall survival rates were 87.5 +/- 12% and 88.9 +/- 11%, respectively. One patient failed locally within the clinical tumor volume. One patient died of intercurrent disease. Radiologically, there were eleven stable diseases and five partial responses. The authors concluded that in both benign and more aggressive meningiomas, the combination of conformal photons and protons with a dose escalated by 10-15% offers clinical improvements in most patients as well as radiological long-term stabilization.

Choroidal Hemangiomas

Hocht et al. (2006) conducted a single-center, retrospective study of 44 consecutive patients with choroid hemangiomas treated with photon therapy (n=19) or proton therapy (n=25). Outcomes were measured by visual acuity, tumor thickness, resolution of retinal detachment, and post-treatment complications. Mean follow-up was 38.9 months and 26.3 months, and median follow-up was 29 months and 23.7 months for photon and proton patients, respectively. Tumor thickness was greater in the photon group than in the proton group. Ninety-one percent of all patients were treated successfully. There was no significant difference in the outcomes between the two groups. The authors concluded that radiotherapy is effective in treating choroidal hemangiomas

with respect to visual acuity and tumor thickness but a benefit of proton therapy could not be detected.

Three additional studies showed some improvement in tumor regression and visual acuity following PBT; however, these studies were small and retrospective in nature (Chan et al., 2010); Levy-Gabriel et al., 2009; Frau et al., 2004).

Gastrointestinal Cancers
A systematic review concluded that there is insufficient evidence to recommend proton beam therapy outside of clinical trials for gastrointestinal malignancies (Allen et al., 2012).

Gastrointestinal cancers are included in the AHRQ report (2009) referenced above, which states that the evidence is insufficient to draw any definitive conclusions as to whether PBT has any advantages over traditional therapies.

Esophageal Cancer
ICER identified no comparative studies of the clinical effectiveness of primary PBT in esophageal cancer. Evidence is limited and inadequate to compare the potential harms of PBT relative to other radiation modalities in patients with esophageal cancer, particularly in comparison to IMRT (ICER, 2014).

In a retrospective analysis, Wang et al. (2013) reported that advanced radiation technologies, such as IMRT or PBT significantly reduced postoperative pulmonary and gastrointestinal complication rates compared to 3D-CRT in esophageal cancer patients. These results need to be confirmed in prospective studies.

Lin et al. (2012) reported preliminary results using concurrent chemotherapy and PBT (CChT/PBT) in 62 patients with esophageal cancer. The median follow-up time was 20.1 months for survivors. Acute treatment-related toxicities and perioperative morbidities were relatively low and the tumor response and disease related outcomes were encouraging. The authors concluded that CChT/PBT holds promise in the management of esophageal cancers. This study is limited by retrospective design, lack of randomization and short-term follow-up.

Mizumoto et al. (2011) evaluated the efficacy and safety of hyperfractionated concomitant boost proton beam therapy (PBT) in 19 patients with esophageal cancer. The overall 1- and 5-year actuarial survival rates for all 19 patients were 79.0% and 42.8%, respectively. The median survival time was 31.5 months. Of the 19 patients, 17 (89%) showed a complete response within 4 months after completing treatment and 2 (11%) showed a partial response, giving a response rate of 100% (19/19). The 1- and 5-year local control rates for all 19 patients were 93.8% and 84.4 %, respectively. The results suggest that hyperfractionated PBT is safe and effective for patients with esophageal cancer. Further studies are needed to establish the appropriate role and treatment schedule for use of PBT for esophageal cancer.

Mizumoto et al. (2010) evaluated the efficacy and safety of proton-beam therapy for locoregionally advanced esophageal cancer. Fifty-one patients were treated using proton beams with or without X-rays. All but one had squamous cell carcinoma. Of the 51 patients, 33 received combinations of X-rays and protons as a boost. The other 18 patients received proton-beam therapy alone. The overall 5-year actuarial survival rate for the 51 patients was 21.1% and the median survival time was 20.5 months. Of the 51 patients, 40 (78%) showed a complete response within 4 months after completing treatment and seven (14%) showed a partial response, giving a response rate of 92% (47/51). The 5-year local control rate for all 51 patients was 38.0% and the median local control time was 25.5 months. The authors concluded that these results suggest that proton-beam therapy is an effective treatment for patients with locally advanced esophageal cancer. Further studies are required to determine the optimal total dose, fractionation schedules and best combination of proton therapy with chemotherapy.

Koyama and Tsujii (2003) evaluated the efficacy of PBT combined with photon radiation for the treatment of esophageal cancer in a prospective uncontrolled study. The study included 30 patients with superficial and advanced esophageal cancer. PBT increased 5- and 10-year survival rates from a range of 6 % to10% (reported in the medical literature) to 67.1% and 61.0%, respectively, and were significantly improved for patients with superficial esophageal cancer (100%; 87.5%) compared with patients with advanced-stage tumors (49.0%; 38.1%). The main long-term side effect was esophageal ulceration in 2 patients.

NCCN guidelines do not address the use of proton beam radiation therapy for treating esophageal cancer (NCCN, 2015).

Hepatocellular Carcinoma (HCC)
ICER concluded that PBT is comparable to alternative treatment options for patients with liver cancer; however, the strength of the evidence is low (ICER, 2014).

Qi et al. (2015) performed a systematic review and meta-analysis to compare the clinical outcomes and toxicity of HCC patients treated with charged particle therapy (CPT) with those of individuals receiving conventional radiotherapy (CRT). A total of 73 cohorts from 70 non-comparative observational studies were included. The clinical evidence for HCC indicates that survival rates for CPT are significantly higher than those for CRT, but are similar to stereotactic body radiotherapy (SBRT). Toxicity tends to be lower for CPT when compared to photon radiotherapy. The authors reported that the overall quantity and quality of data regarding carbon-ion and proton therapy is poor, and there is a potential risk of bias in comparisons between observation studies. Therefore, the reported results do not allow for definite conclusions. Prospective randomized studies, comparing survival and toxicity between particle and photon radiotherapy, are strongly encouraged.

In another systematic review, Dionisi et al. (2014) assessed the use of proton therapy in the treatment of hepatocellular carcinoma. Of 16 studies from seven institutions worldwide, seven were clinical in nature, three reported on treatment-related toxicity and one reported on both. More than 900 patients with heterogeneous stages of disease were treated with various fractionation schedules. Only one prospective full paper was found. Local control was approximately 80% at 3-5 years, and average overall survival at 5 years was 32%, with data comparable to surgery in the most favorable groups. Toxicity was low (mainly gastrointestinal). The authors reported that the good clinical results are counterbalanced by a low level of evidence. The rationale to enroll patients in prospective studies appears to be strong.

An AHRQ comparative effectiveness review of 13 local hepatic therapies and their combinations for unresectable hepatocellular carcinoma (HCC) concluded that there is insufficient evidence to permit conclusions on the comparative effectiveness of PBT. Additional randomized controlled trials are necessary for all comparisons (Belinson et al., 2013).

A systematic review concluded that there is evidence for the efficacy of proton beam therapy for treating hepatocellular carcinoma but no suggestion that it is superior to photon based approaches (Allen et al., 2012).

NCCN guidelines state that PBT may be appropriate in specific situations and reference the ASTRO model policy (NCCN, 2015).

Professional Societies

American Society for Radiation Oncology (ASTRO)
ASTRO's model policy lists primary hepatocellular cancer treated in a hypofractionated regimen as an indication for PBT (ASTRO, 2014).

Pancreatic Cancer
Studies evaluating PBT for the treatment of pancreatic cancer are in the very early stages (Hong et al., 2014; Terashima et al., 2012; Hong et al., 2011). Further research from prospective studies is needed to determine the long-term safety and efficacy of this treatment modality.

NCCN guidelines do not address the use of proton beam radiation therapy for treating pancreatic cancer (NCCN, 2015).

Gynecologic Cancers
The efficacy of PBT combined with photon radiation for the treatment of cervical cancer was investigated in a prospective uncontrolled study involving 25 patients (Kagei et al., 2003). In this study, 5-year and 10-year survival rates were similar to conventional therapies as reported in the literature. The 10-year survival rate was higher for patients with low stage (89%) compared with advanced stages (40%) of cervical cancer. The treatment caused severe late complications in 4% of patients.

Uterine cancers are included in the AHRQ report (2009) referenced above, which states that the evidence is insufficient to draw any definitive conclusions as to whether PBT has any advantages over traditional therapies.

NCCN guidelines do not address the use of proton beam radiation therapy for treating gynecologic cancers.

Head and Neck Cancers
A systematic review concluded that there is insufficient evidence to recommend proton beam therapy outside of clinical trials for head and neck cancer (Allen et al., 2012).

NCCN states that the role of proton therapy in treating sinus tumors is being investigated (NCCN, 2015).

Patel et al. (2014) conducted a systematic review and meta-analysis comparing the clinical outcomes of patients with malignant tumors of the nasal cavity and paranasal sinuses treated with charged particle therapy with those of individuals receiving photon therapy. Primary outcomes of interest were overall survival, disease-free survival and locoregional control, at 5 years and at longest follow-up. A total of 43 cohorts from 41 non-comparative observational studies were included. Median follow-up for the charged particle therapy group was 38 months and for the photon therapy group was 40 months. Pooled overall survival was significantly higher at 5 years for charged particle therapy than for photon therapy and at longest follow-up. At 5 years, disease-free survival was significantly higher for charged particle therapy than for photon therapy but, at longest follow-up, this event rate did not differ between groups. Locoregional control did not differ between treatment groups at 5 years, but it was higher for charged particle therapy than for photon therapy at longest follow-up. A subgroup analysis comparing proton beam therapy with intensity-modulated radiation therapy showed significantly higher disease-free survival at 5 years and locoregional control at longest follow-up. The authors concluded that, compared with photon therapy, charged particle therapy could be associated with better outcomes for patients with malignant diseases of the nasal cavity and paranasal sinuses. Prospective studies emphasizing collection of patient-reported and functional outcomes are strongly encouraged.

Head and neck cancers are included in the AHRQ report (2009) referenced above, which states that the evidence is insufficient to draw any definitive conclusions as to whether PBT has any advantages over traditional therapies.

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review on radiation therapy for head and neck cancer concluded that the strength of evidence comparing

proton beam therapy to other techniques is insufficient to draw conclusions (Samson et al., 2010). A 2014 update did not identify any new evidence for PBT (Ratko et al., 2014).

Ramaekers et al. (2011) compared evidence evaluating the effectiveness of carbon-ion, proton and photon radiotherapy for head and neck cancer. A systematic review and meta-analyses were performed to retrieve evidence on tumor control, survival and late treatment toxicity. Eighty-six observational studies (74 photon, 5 carbon-ion and 7 proton) and eight comparative in-silico studies were included. Five-year local control after proton therapy was significantly higher for paranasal and sinonasal cancer compared to intensity modulated photon therapy (88% versus 66%). Although poorly reported, toxicity tended to be less frequent in carbon-ion and proton studies compared to photons. In-silico studies showed a lower dose to the organs at risk, independently of the tumor site. Except for paranasal and sinonasal cancer, survival and tumor control for proton therapy were generally similar to the best available photon radiotherapy. In agreement with included in-silico studies, limited available clinical data indicates that toxicity tends to be lower for proton compared to photon radiotherapy. Since the overall quantity and quality of data regarding proton therapy is poor, the authors recommend the construction of an international particle therapy register to facilitate definitive comparisons.

van de Water et al. (2011) reviewed the literature regarding the potential benefits of protons compared with the currently used photons in terms of lower doses to normal tissue and the potential for fewer subsequent radiation-induced side effects. Fourteen relevant studies were identified and included in this review. Four studies included paranasal sinus cancer cases, three included nasopharyngeal cancer cases and seven included oropharyngeal, hypopharyngeal, and/or laryngeal cancer cases. Seven studies compared the most sophisticated photon and proton techniques: intensity-modulated photon therapy versus intensity-modulated proton therapy (IMPT). Four studies compared different proton techniques. All studies showed that protons had a lower normal tissue dose, while keeping similar or better target coverage. Two studies found that these lower doses theoretically translated into a significantly lower incidence of salivary dysfunction. The results indicate that protons have the potential for a significantly lower normal tissue dose, while keeping similar or better target coverage. The authors concluded that scanned IMPT offers the most advantage and allows for a substantially lower probability of radiation-induced side effects. The results of these studies should be confirmed in properly designed clinical trials.

Lung Cancer

ICER concluded that PBT is comparable to alternative treatment options for patients with lung cancer. The strength of the evidence is moderate (ICER, 2014).

An AHRQ systematic review evaluated the comparative effectiveness of local nonsurgical therapies in patients with non-small cell lung cancer (NSCLC). Proton beam radiation therapy was one method reviewed. Evidence on localized nonsurgical therapies for patients with stage I NSCLC who are not surgical candidates or who decline surgery consists only of single-arm studies, with no direct comparisons among interventions. Overall, evidence was insufficient to reach conclusions about the relative effectiveness and safety of the interventions in terms of overall survival, cancer-specific survival, local control, quality of life, symptomatic relief and toxicities (Ratko et al., 2013).

A Blue Cross Blue Shield technology assessment evaluated health outcomes following proton beam therapy (PBT) compared to stereotactic body radiotherapy (SBRT) for the management of non-small-cell lung cancer. The report concluded that, overall, evidence is insufficient to permit conclusions about the results of PBT for any stage of non-small-cell lung cancer. All PBT studies are case series, and there are no studies directly comparing proton beam therapy (PBT) and stereotactic body radiotherapy (SBRT). In the absence of randomized, controlled trials, the comparative effectiveness of PBT and SBRT is uncertain (BCBS, 2011b).

A systematic review concluded that there is insufficient evidence to recommend proton beam therapy outside of clinical trials for lung cancer (Allen et al., 2012).

Sejpal et al. (2011) compared the toxicity of proton therapy plus concurrent chemotherapy in patients with NSCLC (n=62) with toxicity for patients with similar disease given 3-dimensional conformal radiation therapy (3D-CRT) plus chemotherapy (n = 74) or intensity-modulated radiation therapy (IMRT) plus chemotherapy (n = 66). Median follow-up times were 15.2 months (proton), 17.9 months (3D-CRT) and 17.4 months (IMRT). Median total radiation dose was 74 Gy(RBE) for the proton group versus 63 Gy for the other groups. Rates of severe (grade ≥ 3) pneumonitis and esophagitis in the proton group (2% and 5%) were lower despite the higher radiation dose (3D-CRT, 30% and 18%; IMRT, 9% and 44%). The authors found that higher doses of proton radiation could be delivered to lung tumors with a lower risk of esophagitis and pneumonitis. Tumor control and survival were not evaluated due to the short follow-up time. A randomized comparison of IMRT versus proton therapy has been initiated.

Chang et al. (2011) reported early results of a phase 2 study of high-dose proton therapy and concurrent chemotherapy in terms of toxicity, failure patterns and survival. Forty-four patients with stage III NSCLC were treated with proton therapy with weekly carboplatin and paclitaxel. Median follow-up time was 19.7 months, and median overall survival time was 29.4 months. The most common nonhematologic grade 3 toxicities were dermatitis (n = 5), esophagitis (n = 5) and pneumonitis (n = 1). Nine (20.5%) patients experienced local disease recurrence, but only 4 (9.1%) had isolated local failure. Four (9.1%) patients had regional lymph node recurrence, but only 1 (2.3%) had isolated regional recurrence. Nineteen (43.2%) patients developed distant metastasis. The overall survival and progression-free survival rates were 86% and 63% at 1 year. The authors concluded that concurrent high-dose proton therapy and chemotherapy are well tolerated, and the median survival time of 29.4 months is encouraging for unresectable stage III NSCLC.

Widesott et al. (2008) reviewed the literature to determine if proton therapy (PT) has a role in the treatment of non-small-cell lung cancer (NSCLC). The authors assessed safety and efficacy and evaluated the main technical issues related to this treatment. Seventeen studies were included in the analysis. There were no prospective trials (randomized or non-randomized). Nine uncontrolled single-arm studies were available from three PT centers, providing clinical outcomes for 214 patients in total. These reports were mainly related to stage I-II tumors. The authors concluded that from a physical point of view PT is a good option for the treatment of NSCLC; however, limited data are available on its application in the clinical practice. Furthermore, the application of PT to lung cancer does present technical challenges. Because of the small number of institutions involved in the treatment of this disease, number of patients and methodological weaknesses of the trials, it is not possible to draw definitive conclusions about the superiority of PT with respect to the photon techniques currently available for the treatment of NSCLC.

Grutters et al. (2010) conducted a metaanalysis of observational studies comparing radiotherapy with photons, protons and carbon-ions in the treatment of non-small-cell lung cancer (NSCLC). Eligible studies included conventional radiotherapy (CRT), stereotactic radiotherapy (SBRT), concurrent chemoradiation (CCR), proton therapy and carbon-ion therapy. Corrected pooled estimates for 2-year overall survival in stage I inoperable NSCLC ranged from 53% for CRT to 74% for carbon-ion therapy. Five-year overall survival for CRT (20%) was statistically significantly lower than that for SBRT (42%), proton therapy (40%) and carbon-ion therapy (42%). However, caution is warranted due to the limited number of patients and limited length of follow-up of the particle studies.

Pijls-Johannesma et al. (2010) conducted a systematic review to test the theory that radiotherapy with beams of protons and heavier charged particles (e.g., carbon ions) leads to superior results, compared with photon beams. The authors searched for clinical evidence to justify implementation of particle therapy as standard treatment in lung cancer. Eleven studies, all dealing with non-small cell lung cancer (NSCLC), mainly stage I, were identified. No phase III

trials were found. For proton therapy, 2- to 5-year local tumor control rates varied in the range of 57%-87%. The 2- and 5-year overall survival (OS) and 2- and 5-year cause-specific survival (CSS) rates were 31%-74% and 23% and 58%-86% and 46%, respectively. Radiation-induced pneumonitis was observed in about 10% of patients. For carbon ion therapy, the overall local tumor control rate was 77%, but it was 95% when using a hypofractionated radiation schedule. The 5-year OS and CSS rates were 42% and 60%, respectively. Slightly better results were reported when using hypofractionation, 50% and 76%, respectively. The results with protons and heavier charged particles are promising. However, the current lack of evidence on the clinical effectiveness of particle therapy emphasizes the need to further investigate the efficiency of particle therapy. The authors concluded that until these results are available for lung cancer, charged particle therapy should be considered experimental.

The efficacy and safety of PBT for the treatment of non-small-cell lung cancer was assessed in a prospective, uncontrolled, nonrandomized study, with results described in two reports (Bush, 1998; Bonnet, 2001). The study involved 37 patients who received either PBT alone or PBT combined with photon therapy. Efficacy and safety was assessed in all patients; the effect of dose escalation on pulmonary function was tested in a subset of 25 patients (Bonnet, 2001). In these studies, the 2-year disease-free survival for stage I and stage IIIa patients was 86% and 19%, respectively. PBT dose escalation did not impede lung function and two patients experienced side effects. Both patients developed pneumonitis.

Lung cancers are included in the AHRQ report (2009) referenced above, which states that the evidence is insufficient to draw any definitive conclusions as to whether PBT has any advantages over traditional therapies.

NCCN states that the use of more advanced technologies, such as proton therapy, is appropriate when needed to deliver curative radiation therapy safely in patients with non-small-cell lung cancer. Nonrandomized comparisons of using advanced technologies versus older techniques demonstrate reduced toxicity and improved survival (NCCN, 2015).

Professional Societies

American College of Radiology (ACR)

ACR appropriateness criteria state that the physical characteristics of the proton beam would seem to allow for greater sparing of normal tissues, although there are unique concerns about its use for lung tumors due to respiratory motion and low lung parenchymal density. There are uncertainties about proton therapy in lung cancer and much improvement and optimization is still needed. Protons may not be suitable for all lung cancer patients, and proper case selection and proper proton techniques based on motion and anatomy are crucial to improve the therapeutic ratio. ACR is hopeful that larger prospective controlled trials that are underway will clarify the role of proton beam for lung cancer in the near future (ACR, 2014).

Lymphoma

NCCN guidelines state that advanced radiation therapy technologies, such as proton therapy, may offer significant and clinically relevant advantages in specific instances to spare important organs at risk and decrease the risk for late, normal tissue damage while still achieving the primary goal of local tumor. However, the supporting evidence is limited (NCCN, 2015).

Prostate Cancer

An American Society for Radiation Oncology (ASTRO) position statement concludes that the comparative efficacy evidence of proton beam therapy with other prostate cancer treatments is still being developed. Thus the role of proton beam therapy for localized prostate cancer within the current availability of treatment options remains unclear (ASTRO, 2013).

NCCN states that there is no clear evidence supporting a benefit or decrement to proton therapy over intensity-modulated radiation therapy for either treatment efficacy or long-term toxicity (NCCN, 2015).

ICER concluded that PBT is comparable to alternative treatment options for patients with prostate cancer. The strength of the evidence is moderate (ICER, 2014).

An AHRQ update on therapies for clinically localized prostate cancer concluded that the body of evidence for treating prostate cancer continues to evolve, but the evidence for most treatment comparisons is largely inadequate to determine comparative risks and benefits. Although limited evidence appears to favor surgery over watchful waiting or external beam radiation therapy, or favors radiotherapy plus hormonal therapy over radiotherapy alone, the patients most likely to benefit and the applicability of these study findings to contemporary patients and practice remain uncertain. More randomized controlled trials and better-designed observational studies that reflect contemporary practice and can control for many of the known/unknown confounding factors that can affect long-term outcomes may be needed to evaluate comparative risks and benefits of therapies for clinically localized prostate cancer (Sun et al., 2014).

A systematic review concluded that there is evidence for the efficacy of proton beam therapy for treating prostate cancer but no suggestion that it is superior to photon based approaches (Allen et al., 2012).

A retrospective study comparing 553 patients treated with proton beam therapy and 27,094 treated with IMRT for early stage prostate cancer detected no difference in genitourinary toxicity at 12 months post-treatment (Yu et al., 2013).

A meta-analysis of randomized dose escalation trials demonstrated that late toxicity rates increase with radiation therapy dose. Series where dose escalated radiation is delivered using IMRT or PBT have relatively short follow up but report lower late gastrointestinal toxicity rates than those employing 3-D radiation therapy (Ohri et al., 2012).

In a large cohort study using Surveillance Epidemiology and End Results (SEER) data, Kim et al. (2011) reported that patients treated with radiation therapy are more likely to have procedural interventions for gastrointestinal (GI) toxicities than patients with conservative management. The elevated risk persists beyond 5 years. Results showed higher GI morbidity rates in patients treated with PBT therapy relative to IMRT patients.

Sheets et al. (2012) evaluated the comparative morbidity and disease control of IMRT, proton therapy and conformal radiation therapy for primary prostate cancer treatment. The authors conducted a population-based study using Surveillance, Epidemiology, and End Results-Medicare-linked data. Main outcomes were rates of gastrointestinal and urinary morbidity, erectile dysfunction, hip fractures and additional cancer therapy. In a comparison between IMRT and conformal radiation therapy (n=12,976), men who received IMRT were less likely to experience gastrointestinal morbidity and fewer hip fractures but more likely to experience erectile dysfunction. IMRT patients were also less likely to receive additional cancer therapy. In a comparison between IMRT and proton therapy (n=1368), IMRT patients had a lower rate of gastrointestinal morbidity. There were no significant differences in rates of other morbidities or additional therapies between IMRT and proton therapy.

A Blue Cross Blue Shield technology assessment compared the effects of proton beam therapy, with or without x-ray external beam radiotherapy, against alternative radiotherapy modalities and other treatments of prostate cancer. The report concluded that there is inadequate evidence from comparative studies to permit conclusions. Whether proton beam therapy improves outcomes in any setting in prostate cancer has not yet been established (BCBS, 2011a).

An updated AHRQ review on radiation therapy for localized prostate cancer did not identify any comparative studies evaluating the role of particle radiation therapy (e.g., proton). Definitive benefits of radiation treatments compared to no treatment or no initial treatment for localized prostate cancer could not be determined because available data were insufficient. Data on

comparative effectiveness between different forms of radiation treatments (brachytherapy (BT), external beam radiation therapy (EBRT), stereotactic body radiation therapy (SBRT)) are also inconclusive whether one form of radiation therapy is superior to another form in terms of overall or disease-specific survival. Studies suggest that higher EBRT dose results in increased rates of long-term biochemical control than lower EBRT dose. EBRT administered as a standard fractionation or moderate hypofractionation does not appear to differ with respect to biochemical control and late genitourinary and gastrointestinal toxicities. However, more and better quality studies are needed to either confirm or refute these suggested findings (AHRQ, 2010).

Zietman et al. (2010) tested the hypothesis that increasing radiation dose delivered to men with early-stage prostate cancer improves clinical outcomes. Men (n=393) with T1b-T2b prostate cancer and prostate-specific antigen </= 15 ng/mL were randomly assigned to a total dose of either 70.2 Gray equivalents (GyE; conventional) or 79.2 GyE (high). Local failure (LF), biochemical failure (BF) and overall survival (OS) were outcomes. Median follow-up was 8.9 years. Men receiving high-dose radiation therapy were significantly less likely to have LF. The 10-year American Society for Therapeutic Radiology and Oncology BF rates were 32.4% for conventional-dose and 16.7% for high-dose radiation therapy. This difference held when only those with low-risk disease (n = 227; 58% of total) were examined: 28.2% for conventional and 7.1% for high dose. There was a strong trend in the same direction for the intermediate-risk patients (n = 144; 37% of total; 42.1% v 30.4%). Eleven percent of patients subsequently required androgen deprivation for recurrence after conventional dose compared with 6% after high dose. There remains no difference in OS rates between the treatment arms (78.4% v 83.4%). Two percent of patients in both arms experienced late grade >/= 3 genitourinary toxicity, and 1% of patients in the high-dose arm experienced late grade >/= 3 GI toxicity.

Schulte et al. (2000) retrospectively compared outcomes for patients who received proton beam therapy or XRT with a proton boost with patients who underwent radical prostatectomy. The study included 911 patients with stage T1 to T3 prostate cancer. Patients in the proton therapy group received a total dose of 74 to 75 CGE. The estimated 5-year disease-free rate was 82.2%. Using an evidence-based theoretical model to estimate and compare disease-free rates, patients with localized prostate cancer treated with radical prostatectomy and those treated with external proton irradiation had equivalent disease-free rates. The 3-year actuarial incidence of grade 2 toxicities was 3.5% for gastrointestinal and 5.4% for genitourinary symptoms. No late grade 3 and 4 side effects were observed.

Gardner et al. (2002) retrospectively reviewed the side effects in 39 men of a pool of 167 men who were originally treated at the Harvard Cyclotron Laboratory (Duttenhaver, 1983; Shipley, 1995). This study was a long-term follow-up of prostate cancer patients who had received conventional XRT (50.4 Gy) followed with a proton boost (to a total dose of 77.4 Gy). The most common complications were rectal bleeding and hematuria. The incidence of gastrointestinal morbidity was stable for 5 years, but new genitourinary complications continued to appear. These findings suggest that high-dose conformal radiation will not result in a high incidence of late normal tissue sequelae, but that hematuria may be common.

Rossi et al. (2004) conducted a retrospective review to evaluate the impact of age on bNED survival in 1038 patients with organ-confined prostate cancer who underwent conformal PBT. The investigators reported that there were no statistically significant differences in bNED survival with regard to patient age. For patients younger than 60 years, 5- and 8-year bNED survival rates were 82% and 75%, respectively, compared with 75% and 74%, respectively, for patients 60 years and older. As expected, significant predictors of treatment outcome were pretreatment PSA level, clinical stage at diagnosis, and Gleason score. These results are consistent with the findings of other studies. The authors concluded that patient age alone should not be used to recommend one type of treatment over another.

Slater et al. (2004) conducted a retrospective review to evaluate the effect of conformal PBT on biochemical relapse and toxicity in 1255 patients with localized prostate cancer. Patients received

either proton therapy alone or a combination of proton and photon therapy (both administered conformally). The investigators reported that conformal PBT yielded disease-free (bNED) survival rates that were comparable with other forms of local treatment (based on historical information), and treatment-related morbidity was minimal.

In a phase II clinical trial, comparative study by Vargas et al. (2008), 10 consecutive patients were studied to evaluate the contrast in dose distribution between proton radiotherapy (RT) and intensity-modulated RT (IMRT), particularly in regard to critical structures such as the rectum and bladder. The patients were treated to 78 Gray-equivalents (GE) in 2-GE fractions with a biologically equivalent dose of 1.1. All rectal and rectal wall volumes treated to 10-80 GE (percentage of volume receiving 10-80 GE [V(10)-V(80)]) were significantly lower with proton therapy ($p < 0.05$). The rectal V(50) was reduced from 31.3% +/- 4.1% with IMRT to 14.6% +/- 3.0% with proton therapy for a relative improvement of 53.4% and an absolute benefit of 16.7%. The mean rectal dose decreased 59% with proton therapy. For the bladder and bladder wall, proton therapy produced significantly smaller volumes treated to doses of 10-35 GE with a non-significant advantage demonstrated for the volume receiving < or =60 GE. The bladder V(30) was reduced with proton therapy for a relative improvement of 35.3% and an absolute benefit of 15.1%. The mean bladder dose decreased 35% with proton therapy. The authors concluded that compared with IMRT, proton therapy reduced the dose to the dose-limiting normal structures while maintaining excellent planning target volume coverage.

Professional Societies

American Urological Association (AUA)

The AUA discusses proton beam therapy as an option within the category of external beam radiotherapy and states that dose escalation can be performed safely to 78 to 79 Gy. Such techniques include a computed tomography (CT) scan for treatment planning and either a multileaf collimator, intensity-modulated radiation therapy (IMRT) or proton radiotherapy using a high-energy (6 mV or higher) photon beam. However, study outcomes data do not provide clear-cut evidence for the superiority of any one treatment (Thompson et al., 2007; reaffirmed 2011).

Vestibular Tumors

The efficacy of PBT for the treatment of tumors of the vestibular system was assessed in two prospective uncontrolled studies involving 30 patients with acoustic neuromas (Bush et al., 2002) and 68 patients with vestibular schwannomas (Harsh et al., 2002). Fractionated PBT effectively controlled tumor growth in all patients with acoustic neuroma, and 37.5% of patients experienced tumor regression. Hearing was preserved in 31% of patients. The actuarial 5-year tumor control rate for patients with vestibular schwannomas was 84%; 54.7% of tumors regressed, 39.1% remained unchanged, and 3 tumors enlarged. The procedure caused some serious side effects in patients with vestibular schwannoma (severe facial weakness), but most side effects were either transient or could be successfully treated.

In a critical review, Murphy and Suh (2011) summarized the radiotherapeutic options for treating vestibular schwannomas, including single-session stereotactic radiosurgery, fractionated conventional radiotherapy, fractionated stereotactic radiotherapy and proton beam therapy. The comparisons of the various modalities have been based on single-institution experiences, which have shown excellent tumor control rates of 91-100%. Early experience using proton therapy for treating vestibular schwannomas demonstrated local control rates of 84-100% but disappointing hearing preservation rates of 33-42%. The authors report that mixed data regarding the ideal hearing preservation therapy, inherent biases in patient selection and differences in outcome analysis have made comparison across radiotherapeutic modalities difficult.

Combined Therapies

No evidence was identified in the clinical literature supporting the combined use of proton beam radiation therapy and intensity-modulated radiation therapy in a single treatment plan.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Radiation therapy is a procedure and, therefore, is not subject to FDA regulation. However, the accelerators and other equipment used to generate and deliver proton beam radiation therapy are regulated by the FDA. See the following website for more information (use product code LHN): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed July 24, 2015.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Proton Beam Therapy (PBT). Local Coverage Determinations (LCDs) do exist. Refer to the following LCDs:

- Category III Codes
- Category III CPT Codes
- Grenz Ray Treatment
- Intensity Modulated Radiation Therapy (IMRT)
- Proton Beam Radiotherapy
- Proton Beam Therapy
- Radiation Oncology Including Intensity Modulated Radiation Therapy (IMRT)
- Radiation Oncology: External Beam /Teletherapy
- Radiation Therapy for T1 Basal Cell and Squamous Cell Carcinomas of the Skin
- Radiation Therapy Services
- Radiology: Proton Beam Therapy
- Stereotactic Body Radiation Therapy
- Stereotactic Body Radiation Therapy (SBRT)
- Radiation Therapy Services

(Accessed May 29, 2015)

REFERENCES

Agency for Healthcare Research and Quality (AHRQ). Technology Assessment. Comparative evaluation of radiation treatments for clinically localized prostate cancer: an update. August 2010. Available at: http://www.cms.gov/coveragegeninfo/downloads/id69ta.pdf. Accessed July 24, 2015.

Agency for Healthcare Research and Quality (AHRQ). Trikalinos TA, Terasawa T, Ip S, Raman G, Lau J. Particle beam radiation therapies for cancer. Technical Brief No. 1. (Prepared by Tufts Medical Center Evidence-based Practice Center under Contract No. HHSA-290-07-10055.) Rockville, MD: AHRQ. Revised November 2009. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/58/173/particle%20beam%20mainreptrev11-09(r).pdf. Accessed July 24, 2015.

Allen AM, Pawlicki T, Dong L, et al. An evidence based review of proton beam therapy: the report of ASTRO's emerging technology committee. Radiother Oncol. 2012 Apr;103(1):8-11.

Al-Mefty O, Borba LAB. Skull base chordomas: a management challenge. J Neurosurg. 1997;86:182-189.

American Academy of Ophthalmology. Preferred Practice Pattern® Guidelines. Age-related macular degeneration. January 2015. Available at: http://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp-2015. Accessed July 24, 2015.

American College of Radiology (ACR). ACR Appropriateness Criteria. Nonsurgical treatment for locally advanced non-small-cell lung cancer. Last reviewed 2014. Available at: http://www.acr.org/ac. Accessed July 24, 2015.

American College of Radiology (ACR) website. Proton therapy. May 2013. Available at: http://www.radiologyinfo.org/en/info.cfm?PG=protonthera&bhcp=1. Accessed July 24, 2015.

American Society for Radiation Oncology (ASTRO). Position Statement. Use of proton beam therapy for prostate cancer. February 2013. Available at: https://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/ProtonProstateStatement.pdf. Accessed July 24, 2015.

American Society for Radiation Oncology (ASTRO). Model policy. Proton beam therapy. May 2014. Available at: https://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/ASTRO%20PBT%20Model%20Policy%20FINAL.pdf. Accessed July 24, 2015.

Amichetti M, Amelio D, Cianchetti M, et al. A systematic review of proton therapy in the treatment of chondrosarcoma of the skull base. Neurosurg Rev. 2010 Apr;33(2):155-65.

Amichetti M, Cianchetti M, Amelio D, et al. Proton therapy in chordoma of the base of the skull: a systematic review. Neurosurg Rev. 2009 Oct;32(4):403-16.

Bekkering GE, Rutjes AW, Vlassov VV, et al. The effectiveness and safety of proton radiation therapy for indications of the eye: a systematic review. Strahlenther Onkol. 2009 Apr;185(4):211-21.

Belinson S, Yang Y, Chopra R, et al. Local therapies for unresectable primary hepatocellular carcinoma. Comparative Effectiveness Review No. 114. (Prepared by the Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center under Contract No. 290-2007-10058-I.) AHRQ Publication No. 13-EHC069-EF. Rockville, MD: Agency for Healthcare Research and Quality. May 2013. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/360/1512/liver-cancer-unresectable-report-130524.pdf. Accessed July 24, 2015.

Blue Cross Blue Shield. Technology Evaluation Center. TEC Assessment Program. Proton beam therapy for prostate cancer. 2011a Jun;25(10):1-36.

Blue Cross Blue Shield. Technology Evaluation Center. TEC Assessment Program. Proton beam therapy for non-small-cell lung cancer. 2011b March;25(7):1-30.

Bonnet RB, Bush D, Cheek GA, et al. Effects of proton and combined proton/photon beam radiation on pulmonary function in patients with resectable but medically inoperable non-small cell lung cancer. Chest. 2001;120(6):1803-1810.

Brada M, Pijls-Johannesma M, De Ruysscher D. Current clinical evidence for proton therapy. Cancer J. 2009 Jul-Aug;15(4):319-24.

Bush DA, McAllister CJ, Loredo LN, et al. Fractionated proton beam radiotherapy for acoustic neuroma. Neurosurgery. 2002;50(2):270-275.

Bush DA, Slater JD, Bonnet R, et al. Proton-beam radiotherapy for early-stage lung cancer. Chest.1999;116(5):1313-1319.Castelluci L. Proton therapy faces high hurdles to general use. J Natl Cancer Inst. 1998;90(23):1768-1769.

Chan RV, Yonekawa Y, Lane AM, et al. Proton beam irradiation using a light-field technique for the treatment of choroidal hemangiomas. Ophthalmologica. 2010;224(4):209-16.

Chang JY, Komaki R, Lu C, et al. Phase 2 study of high-dose proton therapy with concurrent chemotherapy for unresectable stage III nonsmall cell lung cancer. Cancer. 2011 Oct 15;117(20):4707-13.

Ciulla TA, Danis RP, Klein SB, et al. Proton therapy for exudative age-related macular degeneration: a randomized, sham-controlled clinical trial. Am J Ophthalmol. 2002;134(6):905-906.

Dionisi F, Widesott L, Lorentini S, Amichetti M. Is there a role for proton therapy in the treatment of hepatocellular carcinoma? A systematic review. Radiother Oncol. 2014 Apr;111(1):1-10.

Duttenhaver JR, Shipley WU, Perrone T, et al. Protons or megavoltage x-rays as boost therapy for patients irradiated for localized prostatic carcinoma: an early phase I/II comparison. Cancer. 1983;51(9):1599-1604.

ECRI Institute. Health Technology Forecast. Proton beam therapy for treating cancer. July 2014. Updated June 2015.

ECRI Institute. Hotline Service. Intensity-modulated radiation therapy compared with proton beam radiation therapy for treating prostate cancer. February 2014.

ECRI Institute. Hotline Service. Proton beam therapy for bone cancer. May 2013.

ECRI Institute. Hotline Service. Proton beam therapy for spinal and sacral cancers. May 2013.

ECRI Institute. Hotline Service. Proton beam therapy for cancers of the brain, head, neck and skull base. May 2013.

ECRI Institute. Hotline Service. Proton beam therapy for age-related macular degeneration. September 2011.

ECRI Institute. Hotline Service. Proton beam therapy for prostate cancer. September 2013.

ECRI Institute. Emerging Technology Report. Proton beam radiation therapy (overview). March 2010. Updated January 2013.

Evans JR, Sivagnanavel V, Chong V. Radiotherapy for neovascular age-related macular degeneration. Cochrane Database Syst Rev. 2010 May 12;5:CD004004.

Frau E, Rumen F, Noel G, et al. Low-dose proton beam therapy for circumscribed choroidal hemangiomas. Arch Ophthalmol. 2004 Oct;122(10):1471-5.

Gardner BG, Zietman AL, Shipley WU, et al. Late normal tissue sequelae in the second decade after high dose radiation therapy with combined photons and conformal protons for locally advanced prostate cancer. J Urol. 2002;167(1):123-126.

Gewanter RM, Rosenzweig KE, Chang JY, et al. ACR Appropriateness Criteria: nonsurgical treatment for non-small-cell lung cancer: good performance status/definitive intent. Curr Probl Cancer. 2010 May-Jun;34(3):228-49.

Grutters JP, Kessels AG, Pijls-Johannesma M, et al. Comparison of the effectiveness of radiotherapy with photons, protons and carbon-ions for non-small cell lung cancer: a meta-analysis. Radiother Oncol. 2010 Apr;95(1):32-40.

Gudjonsson O, Blomquist E, Nyberg G, et al. Stereotactic irradiation of skull base meningiomas with high energy protons. Acta Neurochir (Wien). 1999;141(9):933-940.

Harsh GR, Thornton AF, Chapman PH, et al. Proton beam stereotactic radiosurgery of vestibular schwannomas. Int J Radiat Oncol Biol Phys. 2002;54(1):35-44.

Hattangadi-Gluth JA, Chapman PH, Kim D, et al. Single-fraction proton beam stereotactic radiosurgery for cerebral arteriovenous malformations. Int J Radiat Oncol Biol Phys. 2014 Jun 1;89(2):338-46.

Hattangadi JA, Chapman PH, Bussière MR, et al. Planned two-fraction proton beam stereotactic radiosurgery for high-risk inoperable cerebral arteriovenous malformations. Int J Radiat Oncol Biol Phys. 2012 Jun 1;83(2):533-41.

Hayes, Inc. Hayes Search and Summary. Proton beam therapy for prostate cancer. Lansdale, PA: Hayes, Inc.; May 2015.

Hocht S, Wachtlin J, Bechrakis NE, et al. Proton or photon irradiation for hemangiomas of the choroid? A retrospective comparison. Int J Radiat Oncol Biol Phys. 2006 Oct 1;66(2):345-51.

Hong TS, Ryan DP, Borger DR, et al. A phase 1/2 and biomarker study of preoperative short course chemoradiation with proton beam therapy and capecitabine followed by early surgery for resectable pancreatic ductal adenocarcinoma. Int J Radiat Oncol Biol Phys. 2014 Jul 15;89(4):830-8.

Hong TS, Ryan DP, Blaszkowsky LS, et al. Phase I study of preoperative short-course chemoradiation with proton beam therapy and capecitabine for resectable pancreatic ductal adenocarcinoma of the head. Int J Radiat Oncol Biol Phys. 2011 Jan 1;79(1):151-7.

Hug EB, Fitzek MM, Liebsch NJ, et al. Locally challenging osteo- and chondrogenic tumors of the axial skeleton: results of combined proton and photon radiation therapy using three-dimensional treatment planning. Int J Radiat Oncol Biol Phys. 1995;31(3):467-476.

Institute for Clinical and Economic Review. Technology Assessment. Proton beam therapy. March 2014. http://www.icer-review.org/wp-content/uploads/2014/07/pbt_final_report_040114.pdf. Accessed July 24, 2015.

Kagei K, Tokuuye K, Okumura T, et al. Long-term results of proton beam therapy for carcinoma of the uterine cervix. Int J Radiat Oncol Biol Phys. 2003;55(5):1265-1271.

Kim S, Shen S, Moore DF, et al. Late gastrointestinal toxicities following radiation therapy for prostate cancer. Eur Urol. 2011 Nov;60(5):908-16.

Kjellberg RN. Stereotactic Bragg peak proton beam radiosurgery for cerebral arteriovenous malformations. Ann Clin Res. 1986;18:17-19.

Koyama S, Tsujii H. Proton beam therapy with high-dose irradiation for superficial and advanced esophageal carcinomas. Clin Cancer Res. 2003;9:3571-3577.

Levy-Gabriel C, Rouic LL, Plancher C, et al. Long-term results of low-dose proton beam therapy for circumscribed choroidal hemangiomas. Retina. 2009 Feb;29(2):170-5.

Lin SH, Komaki R, Liao Z, et al. Proton beam therapy and concurrent chemotherapy for esophageal cancer. Int J Radiat Oncol Biol Phys. 2012 Jul 1;83(3):e345-51.

Lodge M, Pijls-Johannesma M, Stirk L, et al. A systematic literature review of the clinical and cost-effectiveness of hadron therapy in cancer. Radiother Oncol. 2007 May;83(2):110-22.

McAllister B, Archambeau JO, Nguyen MC, et al. Proton therapy for pediatric cranial tumors: preliminary report on treatment and disease-related morbidities. Int J Radiat Oncol Biol Phys. 1997;39:455-460.

Miyanaga N, Akaza H, Okumura T, et al. A bladder preservation regimen using intra-arterial chemotherapy and radiotherapy for invasive bladder cancer: a prospective study. Int J Urol. 2000;7(2):41-48.

Mizumoto M, Sugahara S, Okumura T, et al. Hyperfractionated concomitant boost proton beam therapy for esophageal carcinoma. Int J Radiat Oncol Biol Phys. 2011 Nov 15;81(4):e601-6.

Mizumoto M, Sugahara S, Nakayama H, et al. Clinical results of proton-beam therapy for locoregionally advanced esophageal cancer. Strahlenther Onkol. 2010 Sep;186(9):482-8.

Murphy ES, Suh JH. Radiotherapy for vestibular schwannomas: a critical review. Int J Radiat Oncol Biol Phys. 2011 Mar 15;79(4):985-97.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Central nervous system cancers. v1.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Esophageal and esophagogastric junction cancers. v3.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Pancreatic adenocarcinoma. v2.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Head and neck cancers. v1.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Hodgkin lymphoma. v2.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Non-Hodgkin's lymphoma. v2.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Prostate cancer. v1.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Hepatobiliary cancers. v2.2015.

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Non-small cell lung cancer. v7.2015. .

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology. Bone cancer. v1.2015.

Noel G, Habrand JL, Mammar H, Haie-Meder C, et al.. Highly conformal therapy using proton component in the management of meningiomas. Preliminary experience of the Centre de Protontherapie d'Orsay. Strahlenther Onkol. 2002 Sep;178(9):480-5.

Ohri N, Dicker AP, Showalter TN. Late toxicity rates following definitive radiotherapy for prostate cancer. Can J Urol. 2012 Aug;19(4):6373-80.

Olsen DR, Bruland OS, Frykholm G, Norderhaug IN. Proton therapy - a systematic review of clinical effectiveness. Radiother Oncol. 2007 May;83(2):123-32.

Patel SH, Wang Z, Wong WW, et al. Charged particle therapy versus photon therapy for paranasal sinus and nasal cavity malignant diseases: a systematic review and meta-analysis. Lancet Oncol. 2014 Aug;15(9):1027-38.

Pijls-Johannesma M, Grutters JP, Verhaegen F, et al. Do we have enough evidence to implement particle therapy as standard treatment in lung cancer? A systematic literature review. Oncologist. 2010;15(1):93-103.

Qi WX, Fu S, Zhang Q, Guo XM. Charged particle therapy versus photon therapy for patients with hepatocellular carcinoma: a systematic review and meta-analysis. Radiother Oncol. 2015 Mar;114(3):289-95.

Ramaekers BL, Pijls-Johannesma M, Joore MA, et al. Systematic review and meta-analysis of radiotherapy in various head and neck cancers: comparing photons, carbon-ions and protons. Cancer Treat Rev. 2011 May;37(3):185-201.

Ratko TA, Douglas GW, de Souza JA, et al. Radiotherapy treatments for head and neck cancer: update. Comparative Effectiveness Review No. 144. (Prepared by Blue Cross and Blue Shield Association Evidence-based Practice Center under Contract No. 290-2007-10058.) AHRQ Publication No. 15-EHC001-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2014. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/569/2018/head-neck-cancer-update-report-141208.pdf. Accessed July 24, 2015.

Ratko TA, Vats V, Brock J, et al. Local nonsurgical therapies for stage I and symptomatic obstructive non–small-cell lung cancer. Comparative Effectiveness Review No. 112. (Prepared by Blue Cross and Blue Shield AssociationTechnology Evaluation Center Evidence-based Practice Center under Contract No. 290-2007-10058-I.) AHRQ Publication No. 13-EHC071-EF. Rockville, MD: Agency for Healthcare Research and Quality; June 2013. Available at : http://www.effectivehealthcare.ahrq.gov/ehc/products/366/1531/lung-cancer-nonsurgical-therapies-report-130612.pdf. Accessed July 24, 2015.

Ross J, Al-Shahi Salman R. Interventions for treating brain arteriovenous malformations in adults. Cochrane Database Syst Rev. 2010 Jul 7;7:CD003436.

Rossi Jr CJ, Slater JD, Yonemoto LT, et al. Influence of patient age on biochemical freedom from disease in patients undergoing conformal proton radiotherapy of organ-confined prostate cancer. Urology. 2004;64(4):729-732.

Samson DJ, Ratko TA, Rothenberg BM, et al. Comparative effectiveness and safety of radiotherapy treatments for head and neck cancer. Comparative Effectiveness Review No. 20. (Prepared by Blue Cross and Blue Shield Association Technology Evaluation Center Evidence-based Practice Center under Contract No. 290-02-0026.) Rockville, MD: Agency for Healthcare Research and Quality. May 2010. Updated August 2012 Available at: http://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=448. Accessed July 24, 2015.

Schulte RW, Slater JD, Rossi CJ Jr, et al. Value and perspectives of proton radiation therapy for limited stage prostate cancer. Strahlenther Onkol. 2000;176:3-8.

Sejpal S, Komaki R, Tsao A, et al. Early findings on toxicity of proton beam therapy with concurrent chemotherapy for non-small cell lung cancer. Cancer. 2011 Jul 1;117(13):3004-13.

Sheets NC, Goldin GH, Meyer AM, et al. Intensity-modulated radiation therapy, proton therapy, or conformal radiation therapy and morbidity and disease control in localized prostate cancer. JAMA. 2012 Apr 18;307(15):1611-20.

Shipley WU, Verhey LJ, Munzenrider JE, et al. Advanced prostate cancer: the results of a randomized comparative trial of high dose irradiation boosting with conformal protons compared with conventional dose irradiation using photons alone. Int J Radiat Oncol Biol Phys. 1995;32(1):3-12.

Slater JD, Rossi CJ, Jr., Yonemoto LT, et al. Proton therapy for prostate cancer: the initial Loma Linda University experience. Int J Radiat Oncol Biol Phys. 2004;59(2):348-352.

Suit HD, Goitein M, Munzenrider JE, et al. Definitive radiation therapy for chordoma and chondrosarcoma of base of skull and cervical spine. J Neurosurg. 1982;56:377-385.

Sun F, Oyesanmi O, Fontanarosa J, et al. Therapies for clinically localized prostate cancer: update of a 2008 systematic review. Comparative Effectiveness Review No. 146. (Prepared by the ECRI Institute–Penn Medicine Evidence-based Practice Center under Contract No. 290-2007-10063.) AHRQ Publication No. 15-EHC004-EF. Rockville, MD: Agency for Healthcare Research and Quality; December 2014. Available at: http://www.effectivehealthcare.ahrq.gov/ehc/products/521/2023/prostate-cancer-therapies-update-report-141216.pdf. Accessed July 24, 2015.

Terasawa T, Dvorak T, Ip S, et al. Systematic review: charged-particle radiation therapy for cancer. Ann Intern Med. 2009 Oct 20;151(8):556-65.

Terashima K, Demizu Y, Hashimoto N, et al. A phase I/II study of gemcitabine-concurrent proton radiotherapy for locally advanced pancreatic cancer without distant metastasis. Radiother Oncol. 2012 Apr;103(1):25-31.

Thompson I, Thrasher JB, Aus G, AUA Prostate Cancer Clinical Guideline Update Panel et al. Guideline for the management of clinically localized prostate cancer. 2007 (reaffirmed 2011). J Urol. 2007 Jun;177(6):2106-31.

van de Water TA, Bijl HP, Schilstra C, et al. The potential benefit of radiotherapy with protons in head and neck cancer with respect to normal tissue sparing: a systematic review of literature. Oncologist. 2011;16(3):366-77.

Vargas C, Fryer A, Mahajan C, et al. Dose-volume comparison of proton therapy and intensity-modulated radiotherapy for prostate cancer. Int J Radiat Oncol Biol Phys. 2008 Mar 1;70(3):744-51.

Vernimmen FJ, Harris JK, Wilson JA, et al. Stereotactic proton beam therapy of skull base meningiomas. Int J Radiat Oncol Biol Phys. 2001;49(1):99-105.

Vernimmen FJ, Slabbert JP, Wilson JA, et al. Stereotactic proton beam therapy for intracranial arteriovenous malformations. Int J Radiat Oncol Biol Phys. 2005 May 1;62(1):44-52.

Wang J, Wei C, Tucker SL, et al. Predictors of postoperative complications after trimodality therapy for esophageal cancer. Int J Radiat Oncol Biol Phys. 2013 Aug 1;86(5):885-91.

Wang Z, Nabhan M, Schild SE, et al. Charged particle radiation therapy for uveal melanoma: a systematic review and meta-analysis. Int J Radiat Oncol Biol Phys. 2013 May 1;86(1):18-26.

Weber DC, Rutz HP, Pedroni ES, et al. Results of spot-scanning proton radiation therapy for chordoma and chondrosarcoma of the skull base: the Paul Scherrer Institut experience. Int J

RAug 9, Oncol Biol Phys. 2005 Oct 1;63(2): 401-9.

Wenkel E, Thornton AF, Finkelstein D, et al. Benign meningioma: partially resected, biopsied, and recurrent intracranial tumors treated with combined proton and photon radiotherapy. Int J Radiat Oncol Biol Phys. 2000;48(5):1363.

Widesott L, Amichetti M, Schwarz M. Proton therapy in lung cancer: clinical outcomes and technical issues. A systematic review. Radiother Oncol. 2008 Feb;86(2):154-64.

Yu JB, Soulos PR, Herrin J, et al. Proton versus intensity-modulated radiotherapy for prostate cancer: patterns of care and early toxicity. J Natl Cancer Inst. 2013 Jan 2;105(1):25-32.

Zambarakji, H. J., Lane, A. M., Ezra, et al.Proton beam irradiation for neovascular age-related macular degeneration. Ophthalmology. 2006;113(11):2012-9.

Zietman AL, Bae K, Slater JD, et al. Randomized trial comparing conventional-dose with high-dose conformal radiation therapy in early-stage adenocarcinoma of the prostate: long-term results from Proton Radiation Oncology Group/American College of Radiology 95-09. J Clin Oncol. 2010 Mar 1;28(7):1106-11.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
12/01/2015	• Updated benefit considerations; removed language indicating benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met • Revised coverage rationale: o Updated list of proven/medically necessary indications; expanded list of examples of skull based tumors to include “paranasal sinus tumors” o Updated list of unproven/not medically necessary indications: ▪ Removed/replaced: - Gastrointestinal cancers, including esophageal and pancreatic ▪ Added: - Esophageal cancer - Pancreatic cancer • Updated supporting information to reflect the most current clinical evidence, CMS information, and references • Archived previous policy version 2015T0132S