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 16 of 18

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UnitedHealthcare® Commercial
Medical Policy

PROTON BEAM RADIATION THERAPY

Policy Number: 2019T0132AA **Effective Date**: January 1, 2019

Instructions for Use

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COVERAGE RATIONALE

Note: This policy applies to persons 19 years of age and older. Proton beam radiation therapy (PBT) is covered without further review for persons younger than 19 years of age.

The following are proven and medically necessary:
- PBT for Definitive Therapy of 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)
  - Localized, unresectable hepatocellular carcinoma (HCC) in the curative setting when documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy techniques, including intensity-modulated radiation therapy (IMRT), and stereotactic body radiation therapy (SBRT), and selective internal radiation spheres, and transarterial therapy (for example, chemoembolization) is contraindicated or not technically feasible
- PBT may be covered for a diagnosis that is not listed above as proven, including recurrences or metastases in selected cases. Requests for exceptions will be evaluated on a case-by-case basis when both of the following criteria are met:
  - Documentation is provided that sparing of the surrounding normal tissue cannot be achieved with standard radiation therapy techniques; **and**
  - Evaluation includes a comparison of treatment plans for PBT, IMRT and SBRT

PBT and IMRT are proven and considered clinically equivalent for treating prostate cancer. Medical necessity will be determined based on the terms of the member's benefit plan.

PBT is unproven and not medically necessary due to insufficient evidence of efficacy for treating ALL other indications not listed above as proven, including but not limited to:
- Age related macular degeneration (AMD)
- Bladder cancer
- Brain and spinal cord tumors
- Breast cancer
- Choroidal hemangioma
- Esophageal cancer
- Gynecologic cancers
- Lung cancer
- Lymphomas
- Pancreatic cancer
- Vestibular tumors (e.g., acoustic neuroma or vestibular schwannoma)
- PBT used in conjunction with IMRT

DEFINITIONS

Definitive Therapy: Definitive Therapy is treatment with curative intent. Treatment of a local recurrence of the primary tumor may be considered definitive if there has been a long disease free interval (generally ≥2 years) and treatment is with curative intent.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies and Coverage Determination Guidelines may apply.

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, 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

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

ICD-10 Diagnosis Code	Description
C22.0	Liver cell carcinoma
C31.0	Malignant neoplasm of maxillary sinus
C31.1	Malignant neoplasm of ethmoidal sinus
C31.2	Malignant neoplasm of frontal sinus
C31.3	Malignant neoplasm of sphenoid sinus
C31.8	Malignant neoplasm of overlapping sites of accessory sinuses
C31.9	Malignant neoplasm of accessory sinus, unspecified
C41.0	Malignant neoplasm of bones of skull and face
C61.0	Malignant neoplasm of prostate
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid

ICD-10 Diagnosis Code	Description
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
D09.20	Carcinoma in situ of unspecified eye
D09.21	Carcinoma in situ of right eye
D09.22	Carcinoma in situ of left eye
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses
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, 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, 2017).

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

ECRI (2017) states that while PBT has been used for several solid cancer tumor types (breast, lung, prostate, head and neck, CNS) in adults and in certain pediatric cancers, evidence is lacking regarding its benefits for many cancers over photon-based EBRT.

Professional Societies

American Society for Radiation Oncology (ASTRO)

ASTRO's Emerging Technology Committee concluded that current data do not provide sufficient evidence to recommend PBT outside of clinical trials in lung cancer, head and neck cancer, GI malignancies (with the exception of HCC) and pediatric non-CNS malignancies. In HCC 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 (AVM)

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, fibers, 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 (AEs)of single-fraction proton beam stereotactic radiosurgery (PSRS) in patients with cerebral 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 AVMs, based on brain location or large size, who underwent planned two-fraction 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 2 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 2-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.

Ocular Tumors

In a systematic review, Wang et al. (2013) evaluated the efficacy and AEs of charged particle therapy (CPT), delivered with protons, helium ions or carbon ions, for treating uveal melanoma. Twenty-seven studies enrolling 8809 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.

In the National Comprehensive Cancer Network (NCCN) guidelines on uveal melanoma, PBT is not cited in the list of radiotherapies recommended for treatment (2018).

Skull-Based Tumors

Zhou et al. (2018) performed a meta-analysis to compare the effectiveness of photon therapy, PBT, and carbon ion therapy (CIT) for chordoma. Twenty-five studies were included, with results showing that the 3-, 5-, and 10-year overall survival (OS) rates were higher for stereotactic radiotherapy (SRT), PBT, and CIT than for conventional radiotherapy (CRT). The 10-year OS was higher for PBT than for SRT. The analysis revealed that particle therapy was more effective following surgery for chordoma than CRT. After 10 years, PBT was more beneficial than SRT. However, future studies should include more studies to enable accurate meta-analysis and a better exploration of prognosis.

Kabolizadeh et al. (2017) performed a retrospective analysis at a single institution assessing outcome and tumor response to Definitive photon/proton radiotherapy when used in cases of unresected spine and sacral chordoma. Forty patients were identified between 1975 and 2012. Except for 1 patient, all underwent proton therapy only, or predominantly proton therapy combined with photons to limit the exit dose of radiation to any adjacent normal structures at risk. Three-dimensional conformal radiotherapy (3D-CRT) was the specific photon treatment used until January 2002 when it was replaced by IMRT (primarily for skin-sparing effects). Local control (LC), OS, disease-specific survival, and distant failure at 5 years were 85.4%, 81.9%, 89.4%, and 20.2%, respectively. The authors concluded that for selected patients with unresected spine and sacral chordomas, the use of high-dose Definitive radiation Therapy can be supported with these results.

The use of PBT to treat chondrosarcoma of the skull base after surgery is widely accepted, but studies demonstrating the need for PBT and its superiority in comparison to radiotherapy with photons are lacking. In a systematic review, Amichetti et al. (2010) reported that studies of PBT for skull-based chondrosarcoma resulted in LC ranging from 75%

to 99% at 5 years. There were no prospective trials (randomized or non-randomized), but 4 uncontrolled single-arm studies with 254 patients were included. The authors concluded that PBT following surgical resection showed a very high probability of medium- and long-term cure with a relatively low risk of significant complications.

A systematic review of 7 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).

Early studies evaluating PBT for the treatment of intracranial or skull base tumors include 4 case series, 4 retrospective studies, and 2 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. LC was achieved in 71% to 100% of patients. Complications were radiation dose/volume and site dependent, and were mild to severe.

NCCN states that specialized techniques, including particle beam radiation therapy with protons, should be considered as indicated in order to allow high-dose therapy while maximizing normal tissue sparing in patients with chondrosarcoma (2019).

Age-Related Macular Degeneration (AMD)

In a Cochrane review, Evans et al. (2010) examined the effects of radiotherapy on neovascular AMD. All RCTs in which radiotherapy was compared to another treatment, sham treatment, low dosage irradiation or no treatment were included. Thirteen trials (n=1154) investigated EBRT 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 AEs 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 10 patients and that assessed the efficacy or safety of proton therapy for any indication of the eye were included. Five controlled trials, 2 comparative studies and 30 case series were found, most often reporting on uveal melanoma, choroidal melanoma and 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 RCT 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 2 dose groups.

Professional Societies

American Academy of Ophthalmology (AAO)

AAO preferred practice patterns state that radiation therapy is not recommended in the treatment of AMD (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.

NCCN guidelines do not address the use of PBT for treating bladder cancer (2018).

Brain and Spinal Cord Tumors

Petr et al. assessed structural and hemodynamic changes of healthy brain tissue in the cerebral hemisphere contralateral to the tumor following photon and proton radiochemotherapy. Sixty seven adult patients diagnosed with glioblastoma undergoing adjuvant photon (n = 47) or proton (n = 19) radiochemotherapy with temozolomide after tumor resection underwent T1-weighted and arterial spin labeling magnetic resonance imaging. Changes in volume and perfusion before and 3-6 months after were compared between therapies. A decrease in gray matter (GM) and white matter (WM) volume was observed in photon therapy patients compared to the pre-radiotherapy baseline. In contrast, for the proton therapy group, no significant differences in GM or WM volume were observed. GM volume decreased with 0.9% per 10 Gy dose increase and differed between the radiation modalities. Perfusion decreased in photon therapy patients, whereas the decrease in proton therapy patients was not statistically significant. There was no correlation between perfusion decrease and either dose or radiation modality. The authors concluded that proton therapy may reduce brain volume loss compared to photon therapy, with decrease in perfusion being comparable for both modalities (2018).

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, 12 patients had a benign tumor that was recurrent or rapidly progressive. In 2 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 LC and OS rates were 87.5 +/- 12% and 88.9 +/- 11%, respectively. Radiologically, there were 11 stable diseases and 5 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.

NCCN guidelines state that when toxicity from craniospinal irradiation is a concern during management of spinal ependymoma or medulloblastoma, proton beam radiotherapy should be considered if available (2018).

Several clinical trials studying PBT in patients with various types of brain tumors are active or recruiting. For more information, go to www.clinicaltrials.gov. (Accessed October 31, 2018)

Breast Cancer

Verma et al. (2016) performed a systematic review of clinical outcomes and toxicity of PBT for treating breast cancer. Nine original studies were analyzed, however the types of studies and the volume of patients in those studies were not specifically cited by the authors. Conventionally fractionated breast/chest wall PBT produces grade 1 dermatitis rates of approximately 25% and grade 2 dermatitis in 71%-75%. This is comparable or improved over the published rates for photons. The incidence of esophagitis was decreased if the target coverage was compromised in the medial supraclavicular volume, a finding that echoes previous results with photon radiotherapy. The rates of esophagitis were also comparable to the previous data for photons. Using PBT-based accelerated partial breast irradiation (PBI), the rates of seroma/hematoma and fat necrosis were comparable to those reported in the existing data. Radiation pneumonitis and rib fractures remain rare. PBT offers potential to minimize the risk of cardiac events, keeping the mean heart dose at ≤ 1 Gy. However, definitive clinical experiences remain sparse. Results from clinical trials in progress, comparing protons to photons, will further aid in providing conclusions.

Verma et al. (2017) conducted a retrospective single institution cohort study to evaluate acute toxicity in patients with locally advanced breast cancer (n=91) receiving comprehensive regional nodal irradiation (CRNI) with adjuvant PBT between 2011−2016. PBT consisted of a 3-dimensional uniform scanning (US) technique, and transitioned to a pencil beam scanning (PBS) technique in 2016. Change in technique was driven by anticipated dosimetric advantages including decreased dose to the skin surface and to cardiopulmonary organs, and shorter planning and treatment delivery time. Toxicities were assessed weekly during treatment, one month following treatment completion, and then every 6 months with a median follow up period of 15.5 months. The most common toxicities were dermatitis and/or skin infections, but also seen were esophagitis and fatigue. The authors concluded that PBT for breast cancer as part of CRNI appears to have appropriate toxicity. While using PBT in the setting of CRNI is presumed to be advantageous relative to cardiac dose reduction, further studies with longer follow-up are needed.

Bush et al. (2014) performed a single center study of 100 subjects who received postoperative PBI using PBT after undergoing partial mastectomy with negative margins and axillary lymph nodes. After following these individuals for an average of 5 years, the researchers concluded that ipsilateral recurrence-free survival with minimal toxicity was excellent. While the authors acknowledged that cosmetic results may be improved with PBT over those reported with photon-based techniques, there was nothing in the study demonstrating that PBT outcomes were superior to the current standard of care.

NCCN guidelines do not address the use of PBT for treating breast cancer (2018).

A phase III RCT (NCT02603341) is in progress, comparing PBT to photon therapy in patients with non-metastatic breast cancer. For more information on this and other clinical trials studying PBT and breast cancer, go to www.clinicaltrials.gov. (Accessed October 30, 2018)

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. In the collective groups, 91% were treated successfully. There was no significant difference in the outcomes between the 2 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 versus photon 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 (GI) Cancers

A systematic review by Verma et al. (2016) reported survival and toxicity outcomes where individuals with multiple types of GI cancers were treated with PBT. Thirty-eight studies published between 2010-2015 were included in the review, however the types of studies and the volume of patients in those studies were not specifically cited by the authors. Reduced toxicities with PBT versus photon therapy were identified in malignancies of the esophagus, pancreas, and in HCC. Fewer toxicities and improved PFS were also found using PBT versus transarterial chemoembolization (TACE) in a phase III trial. Survival and toxicity data for cholangiocarcinoma, liver metastases, and retroperitoneal sarcoma were nearly equivalent to photon controls. There were 2 small reports for gastric cancer and 3 for anorectal cancer identified, but these were not addressed. The authors concluded that although studies in this review were of limited quality and quantity, PBT potentially offers significant reduction in treatment-related toxicities without compromising survival in GI cancers. Several phase II/III clinical trials are now in progress conducting further research.

Esophageal Cancer

In a retrospective analysis, Wang et al. (2013) reported that advanced radiation technologies, such as IMRT or PBT significantly reduced postoperative pulmonary and GI 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 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 LC 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 PBT for locoregionally advanced esophageal cancer. Fifty-one patients were treated using PBT 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 PBT 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 LC rate for all 51 patients was 38.0% and the median LC time was 25.5 months. The authors concluded that these results suggest that PBT 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.

NCCN guidelines state that PBT is appropriate when treating esophageal and esophagogastric junction cancers in settings where dose reduction to organs at risk is necessary and cannot be achieved by 3D-CRT. Because data is early and evolving, patients should receive PBT within a clinical trial (2018).

Gastric Cancer

NCCN guidelines do not address PBT in the treatment of gastric cancers (2018).

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 PBT in the treatment of pancreatic adenocarcinoma (2018).

Numerous clinical trials are currently in progress studying the use of PBT in multiple types of GI cancer (e.g., esophageal, pancreatic, and retroperitoneal sarcoma). For more information, go to www.clinicaltrials.gov. (Accessed October 30, 2018)

Hepatocellular Carcinoma (HCC)

Fukuda et al. (2017) performed an observational study of 129 patients, concluding that PBT achieved long term (5 year) tumor control with minimal toxicity. It is a viable treatment option for localized HCC, it showed favorable long-term efficacies with mild AEs in Barcelona Clinic Liver Cancer stage 0-C, and it can be an alternative treatment for localized HCC especially when accompanied with tumor thrombi. The authors are now planning a multicenter controlled study comparing PBT and hepatectomy.

Hong et al. conducted a single-arm, phase II, multi-institutional study to evaluate the safety and efficacy of high-dose, hypofractionated PBT for HCC and intrahepatic cholangiocarcinoma (ICC). Eighty-three participants ages 18 years and over were included, and follow up continued for 5 years. The authors concluded that high-dose, hypofractionated PBT is safe and associated with high rates of LC and OS for both HCC and ICC. These data provide the strong rationale for RCT of proton versus photon radiotherapy for HCC, and for chemotherapy with or without radiation therapy for ICC (2016).

A RCT by Bush et al. (2016) compared treatment outcomes in 69 patients with newly diagnosed HCC who received either TACE or PBT over 3 weeks. The primary endpoint was progression-free survival, with secondary endpoints of OS, LC, and treatment-related toxicities as represented by post-treatment days of hospitalization. The interim analysis indicates similar OS rates for PBT and TACE. There is a trend toward improved LC and PFS with proton beam. There are significantly fewer hospitalization days after proton treatment, which may indicate reduced toxicity with PBT.

Qi et al. (2015) performed a systematic review and meta-analysis to compare the clinical outcomes and toxicity of HCC patients treated with CPT with those of individuals receiving 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 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 HCC. Of 16 studies from 7 institutions worldwide, 7 were clinical in nature, 3 reported on treatment-related toxicity and 1 reported on both. More than 900 patients with heterogeneous stages of disease were treated with various fractionation schedules. Only 1 prospective full paper was found. LCwas approximately 80% at 3-5 years, and average OS at 5 years was 32%, with data comparable to surgery in the most favorable groups. Toxicity was low (mainly GI). 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.

NCCN guidelines state that radiotherapy with protons at an experienced center is an acceptable option for unresectable intrahepatic tumors (2018).

A phase III randomized trial comparing PBT to radiofrequency ablation (NCT02640924) and a RCT comparing PBT to TACE (NCT00857805) are both in progress. For more information on these and other clinical trials studying PBT and HCC, go to www.clinicaltrials.gov. (Accessed October 30, 2018)

Professional Societies

American Society for Radiation Oncology (ASTRO)

ASTRO's model policy lists hepatocellular cancer as an indication for PBT (2017).

American College of Radiology (ACR)

PBT is not addressed in the ACR Appropriateness Criteria discussing radiologic management of HCC (Kouri et al., 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.

NCCN guidelines do not address the use of PBT when treating any type of gynecologic cancer (2018, 2019).

Several clinical trials are recruiting or in progress studying the use of PBT in multiple types of gynecologic cancer (e.g., cervical, ovarian, and uterine). For more information, go to www.clinicaltrials.gov. (Accessed October 30, 2018)

Head and Neck Cancers (HNC)

A Hayes report assessed multiple clinical studies evaluating the efficacy and safety of PBT in patients with neck cancers. The majority of the evidence included retrospective studies, data analyses, and systematic reviews. The report concludes that the abstracts present conflicting findings regarding this technology (2016).

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 CPT with those of individuals receiving photon therapy. Primary outcomes of interest were OS, disease-free survival (DFS) and LC both 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 CPT group was 38 months and for the photon therapy group was 40 months. Pooled OS was significantly higher at 5 years for CPT than for photon therapy and at longest follow-up. At 5 years, DFS was significantly higher for CPT than for photon therapy but, at longest follow-up, this event rate did not differ between groups. LC did not differ between treatment groups at 5 years, but it was higher for CPT than for photon therapy at longest follow-up. A subgroup analysis comparing PBT with IMRT showed significantly higher DFS at 5 years and LC at longest follow-up. The authors concluded that, compared with photon therapy, CPT 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.

Holliday and Frank performed a systematic review of the use of PBT for HNC. Literature search included articles published between January 1990 and September 2013. 18 articles (4 prospective non-randomized studies and 14 retrospective reviews, n=1074) met the review criteria for inclusion in the analysis. There were no RCTs which directly compared proton with photon-based therapy. They concluded that based on the reviewed literature, PBT is safe and may be superior to photon-based treatment by reducing toxicities and maintaining or improving LC in the treatment of tumors of the skull base, nasal/paranasal area, and naso/oropharynx (2014).

Ramaekers et al. (2011) compared evidence evaluating the effectiveness of carbonion, proton and photon radiotherapy for HNC. 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 CIT and 7 proton) and eight comparative in-silico studies were included. Five-year LC after PBT 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 CIT 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 PBT 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 PBT 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.

Zenda et al. (2016) conducted a prospective phase II study to examine the efficacy and safety of PBT for mucosal melanoma of the nasal cavity or para-nasal sinuses as an alternative treatment to surgery. Thirty-two patients were enrolled from June 2008 through October 2012, receiving PBT 3 times per week with a planned total dose of 60 GyE in 15 fractions. Primary outcome measurement was LC rate at 1 year post treatment, which was 75.8%. The OS rate at 3 years was 46.1%, with the primary cause of death being cancer due to distant metastases (93.3%). The authors concluded that PBT showed sufficient LC benefits for mucosal melanoma as an alternative treatment of surgery.

Seeking to improve LC rate and reduce late AEs, Takayama et al. evaluated therapeutic results and toxicities of PBT combined with selective intra-arterial infusion chemotherapy (PBT-IACT) in patients with stage III-IVB squamous cell carcinoma of the tongue. Between February 2009 and September 2012, 33 patients were enrolled. After 2 systemic chemotherapy courses and whole-neck irradiation (36 Gy in 20 fractions), participants were administered concurrent chemoradiotherapy comprising PBT for the primary tumor and for the metastatic neck lymph node with weekly retrograde IACT of cisplatin with sodium thiosulfate by continuous infusion. The median follow-up duration was 43 months. The 3-year OS, PFS, LC rate, and regional control rate for the neck were 87%, 74.1%, 86.6%, and 83.9%, respectively. Major acute toxicities > grade 3 included mucositis in 26 cases (79 %), neutropenia in 17 cases (51 %), and dermatitis in 11 cases (33 %). Late grade 2 osteoradionecrosis was observed in 1 case (3 %). The authors concluded that PBT-IACT for stage III-IVB tongue cancer has an acceptable toxicity profile and showed good treatment results, and that this protocol should be considered as a treatment option for locally advanced tongue cancer (2016).

NCCN guidelines on HNC indicate that PBT is safe and effective and can be considered for treatment of multiple types of head and neck tumors when normal tissue constraints cannot be met by photon-based therapy. It is valuable in patients whose primary tumors are periocular in location and/or invade the orbit, skull base, and/or cavernous sinus; that extend intracranially, or exhibit extensive perineural invasion. They no longer recommend neutron therapy as a general solution for salivary gland cancers due to the diminishing demand, concerns regarding the methodologic robustness of available randomized trial data, and closure of all but one center in the U.S. (2018).

Professional Societies

American College of Radiology (ACR)

Appropriateness criteria from the ACR for the treatment of nasopharyngeal cancer states that IMPT remains experimental (Saba et al., 2015).

Lung Cancer

Chang et al. reported 5-year results of a prospective phase II single-institution study evaluating chemotherapy with concurrent high dose PBT in 64 patients with unresectable phase III non-small cell lung cancer (NSCLC). 5-year OS, PFS, actuarial distant metastases and locoregional recurrence were 29%, 22%, 54%, and 28%, respectively. Acute and late toxic effects with PBT (compared to historical studies with 3D-CRT and/or IMRT) with chemotherapy were very promising. The authors concluded that the study demonstrated that concurrent PBT and chemotherapy was safe and effective in the long term, and that further prospective studies are warranted (2017).

A Hayes report (2018) concluded that the best available studies of PBT for NSCLC do not provide sufficient evidence that PBT is safer or consistently more effective than CRT and IMRT in the treatment of NSCLC.

Liao et al. (2016) conducted a phase II single institution randomized trial comparing IMRT to passive scattering 3D proton therapy (3DPT), both with concurrent chemotherapy, for locally advanced NSCLC. Of 255 enrolled patients, 149 were randomly allocated to IMRT (n=92) or 3DPT (n=57), and 106 received non-randomized (NR)IMRT (n=70) or NR3DPT (n=36). The primary end points assessed were grade $\geq$ 3 radiation pneumonitis (RP) and local failure (LF).

Their article published in 2016 reported outcomes at 12 months. LF rates for all were 20.7%; the randomized IMRT group were 15.6% and the randomized 3DPT group was 24.6%. RP for all were 8.7%, randomized IMRT and 3DPT were 7.2% and 11%, respectively. Continued monitoring resulted in a follow up article in 2018. The median follow-up time for the IMRT group for all patients was 24 months and 36.4 months for those still alive. For the 3DPT group, the follow up time was 25.7 months for all patients and 48.8 months for those surviving. The authors concluded that there was no statistically significant difference in the primary end points after IMRT or 3DPT for patients with locally advanced NSCLC. They did state that findings from 2 ongoing trials (NCT01993810 and NCT01629498) will provide additional evidence of the efficacy of proton and photon therapies.

Harada et al. (2016) conducted a single-institutional, open label, dose escalation phase I trial to determine the recommended dose of PBT for inoperable stage III NSCLC. Two prescribed doses of PBT were tested: 66 Gy RBE in 33 fractions and 74 Gy RBE in 37 fractions in arms 1 and 2, respectively. The planning target volume included the primary tumor and metastatic lymph nodes with adequate margins. Concurrent chemotherapy included intravenous cisplatin (60 mg/m(2) , day 1) and oral S-1 (80, 100 or 120 mg based on body surface area, days 1-14), repeated as 4 cycles every 4 weeks. Dose-limiting toxicity (DLT) was defined as grade 3 (severe) toxicities related to PBT during days 1-90. Each dose level was performed in 3 patients, and then escalated to the next level if no DLT occurred. When 1 patient developed a DLT, 3 additional patients were enrolled. Overall, 9 patients were enrolled, including 6 in Arm 1 and 3 in Arm 2. The median follow-up time was 43 months, and the median PFS was 15 months. In Arm 1, grade 3 infection occurred in 1 of 6 patients, but no other DLT was reported. Similarly, no DLT occurred in Arm 2. However, one patient in Arm 2 developed grade 3 esophageal fistula at 9 months after the initiation of PBT. From a clinical perspective, the authors concluded that 66 Gy RBE is the recommended dose.

Oshiro et al. (2014) initiated a Phase II study to evaluate the safety and efficacy of high-dose PBT with concurrent chemotherapy for unresectable or medically inoperable advanced NSCLC. Patients (n=15) were treated with PBT and chemotherapy with monthly cisplatin (on Day 1) and vinorelbine (on Days 1 and 8). The treatment doses were 74 Gy RBE for the primary site and 66 Gy RBE for the lymph nodes without elective lymph nodes. The median follow-up period was 21.7 months. None of the patients experienced Grade 4 or 5 non-hematologic toxicities. Acute pneumonitis was observed in 3 patients (Grade 1 in one, and Grade 3 in two), but Grade 3 pneumonitis was considered to be non-proton-related. Grade 3 acute esophagitis and dermatitis were observed in 1 and 2 patients, respectively. Severe (≥ Grade 3) leukocytopenia, neutropenia and thrombocytopenia were observed in 10, 7, and 1 patients, respectively. Late radiation Grades 2 and 3 pneumonitis was observed in one patient each. Six patients (40%) experienced local recurrence at the primary site and were treated with 74 Gy RBE. Disease progression was observed in 11 patients, with the mean survival time being 26.7 months. The authors concluded that high-dose PBT with concurrent chemotherapy is safe to use in the treatment of unresectable stage III NSCLC.

Sejpal et al. (2011) compared the toxicity of PBT plus concurrent chemotherapy in patients with NSCLC (n=62) with toxicity for patients with similar disease given 3D-CRT plus chemotherapy (n=74) or 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 GyRBE 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 PBT 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 PBT has been initiated.

Chi et al. conducted a systematic review and meta-analysis to assess hypo-fractionated PBT's efficacy relative to that of photon SBRT for early stage NSCLC. Seventy two SBRT studies and 9 hypo-fractionated PBT studies (mostly single-arm) were included. PBT was associated with improved OS and PFS in the univariate meta-analysis. The OS benefit did not reach its statistical significance after inclusion of operability into the final multivariate meta-analysis; while the 3-year LC still favored PBT. Researchers concluded that although hypo-fractionated PBT may lead to additional clinical benefit when compared with photon SBRT, no statistically significant survival benefit from PBT over SBRT was observed in the treatment of early stage NSCLC (2017).

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 NSCLC, mainly stage I, were identified. No phase III trials were found. For PBT, 2- to 5-year LC rates varied in the range of 57%-87%. The 2- and 5-year OS and 2- and 5-year cause-specific survival rates were 31%-74% and 23% and 58%-86% and 46%, respectively. RP was observed in about 10% of patients. For CIT, the overall LC rate was 77%, but it was 95% when using a hypofractionated radiation schedule. The 5-year OS and cause-specific survival rates were 42% and 60%, respectively. Slightly better results were reported when using hypofractionation, at 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, CPT should be considered experimental.

NCCN guidelines state that advanced technologies such as PBT have been shown to reduce toxicity and increase survival in non-randomized trials. PBT is appropriate when needed for safe delivery of curative or palliative radiotherapy for NSCLC. NCCN is silent on the use of PBT in the treatment of small cell lung cancer (2018).

A phase III RCT comparing photon to proton chemoradiotherapy for patients with inoperable NSCLC (NCT01993810) is in progress. For more information, go to www.clinicaltrials.gov. (Accessed October 30, 2018)

Professional Societies

American College of Radiology (ACR)

ACR appropriateness criteria addressing nonsurgical treatment for locally advanced NSCLC states that while PBT may have the potential to spare critical normal tissues, more prospective studies are needed (Chang, et al., 2014).

Lymphoma

NCCN guidelines for Hodgkin, B-cell, and T-cell lymphomas state that PBT may be appropriate, depending on clinical circumstances. It also states that advanced radiation therapy technologies, such as PBT, 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 LC (2018).

NCCN is silent on the use of PBT in the treatment of primary cutaneous B-cell lymphoma (2018).

Prostate Cancer

A Hayes report assessed multiple clinical studies published between 1983-2016 evaluating the efficacy and safety of PBT in patients with localized prostate cancer. The report concludes that the reviewed studies found that PBT as an adjunct to X-ray therapy (XRT) usually had good or excellent safety and efficacy outcomes. Several controlled or comparative studies of PBT alone reported similar safety to IMRT, conformal XRT, and brachytherapy, but these did not assess the efficacy of PBT alone relative to other techniques for prostate cancer treatment. Additional well-designed studies are needed to establish the clinical role of PBT relative to other widely used therapies for localized prostate cancer. For patients with prostate cancer and distant metastases, PBT has no proven benefit. Published evidence shows that the technology does not improve health outcomes or patient management in this patient population. Evidence addressing the safety & efficacy of PBT compared to other common radiation therapies for this indication are inadequate (2018).

Bryant et al. (2016) performed a single-center study on 1327 men with localized prostate cancer who received image guided PBT between 2006-2010. The 5-year freedom from biochemical progression (FFBP) rates were 99% for low-risk, 94% for intermediate-risk, and 76% for high-risk patients. The authors concluded that PBT provided excellent control of disease with low rates of GU/GI toxicity. Large prospective comparative studies with longer follow-up times are necessary for a true comparison between PT and other types of radiotherapy.

Mendenhall et al. (2016) reported 5-year clinical outcomes from trials of image-guided PBT for prostate cancer conducted at a single institution. From August 2006-September 2007, low, intermediate, and high risk patients (n=211) were enrolled in one of 3 prospective trials. GI/GU toxicities as well as biochemical and clinical freedom from disease progression were outcomes measured, citing 99%, 99%, and 76% FFBP at 5 years for low, intermediate, and high risk patients, respectively. The authors concluded that image-guided PBT was highly effective and safe, reporting minimal toxicities and positive patient-reported outcomes. While outcomes were very favorable, further follow-up and larger study groups were deemed necessary.

A retrospective study by Tagaki et al. (2017) reported long-term outcomes on patients receiving Definitive PBT for localized prostate cancer between April 2001-May 2014 at a single institution. A total of 1375 individuals were included, with primary outcome measurements including freedom from biochemical relapse (FFBR) and incidence of late GI/GU toxicities. Follow-up evaluations were performed at intervals of every 3 months for 5 years and every 6 months thereafter, with the median length of follow up being 70 months. Comparing PT to other EBRTs, FFBR at 5 years for low-, intermediate-, high-, and very high-risk patients were 99%, 91%, 86%, and 66%, respectively, similar to other published research (Bryant, 2016; Mendenhall, 2014). The authors concluded that PT is a favorable radiotherapy technique with lower late GU toxicity. Patient age was cited as a prognostic factor for both late GI and GU toxicities, indicating the need to consider patient age when determining the most advantageous treatment protocol. Although the results of PT in this and other studies are favorable, RCTs directly comparing the efficacy and toxicities of PT and other EBRTs are currently underway.

Henderson et al. (2017) reported 5-year outcomes of a prospective trial of image-guided accelerated hypofractionated proton therapy (AHPT) for prostate cancer from a single institution. Late radiation AEs/toxicities and FFBP were the

outcome measurements for the 215 participants categorized as low and intermediate risk. Median follow-up was 5.2 years, with FFBP rates overall noted at 95.9%. For the subsets of low and intermediate risk, FFBP was 98.3% and 92.7%, respectively. Actuarial 5-year rates of significant (grade 3 or higher) late radiation-related GI AEs/toxicities were 0.5%, and 1.7% for GU AEs. The authors concluded that image-guided AHPT is highly effective with minimal toxicities in low and intermediate-risk patients, citing comparable results to the evidence published by Mendenhall (2014). Additional studies are suggested to further support these findings.

In a case-matched analysis, Fang et al. (2015) assessed prospectively collected toxicity data on patients with localized prostate cancer who received treatment with IMRT and PBT techniques and similar dose-fractionation schedules. A total of 394 patients were treated with either PBT (n=181) or IMRT (n=213). Patients were case-matched on risk group, age and prior GI and GU disorders, resulting in 94 matched pairs. The risks of acute and late GI/GU toxicities did not differ significantly after adjustment for confounders and predictive factors.

A retrospective study comparing 553 patients treated with PBT and 27,094 treated with IMRT for early stage prostate cancer detected no difference in GU 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 GI 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 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, PBT and conformal radiation therapy for primary prostate cancer treatment. The authors conducted a population-based study using SEER data. Main outcomes were rates of GI and GU 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 GI 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 PBT (n=1368), IMRT patients had a lower rate of GI morbidity. There were no significant differences in rates of other morbidities or additional therapies between IMRT and PBT.

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). LF, biochemical failure (BF) and 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 ASTRO 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.

The NCCN Panel believes that PBT and IMRT are equivalent with regard to efficacy and long-term toxicity in the treatment of prostate cancer. Conventionally fractionated PBT can be considered a reasonable alternative to x-ray based regimens at clinics with appropriate technology, physics, and clinical expertise (2018).

A randomized phase III trial (NCT01617161) is in progress, with the objective to determine if IMRT or PBT is more effective in the treatment of prostate cancer. For more information, go to www.clinicaltrials.gov. (Accessed October 30, 2018)

Professional Societies

American Urological Association (AUA)

In collaboration with the Society of Urologic Oncology (SUO) and ASTRO, the AUA guidelines for treating clinically localized prostate cancer discuss PBT as an option within the category of EBRT. The guidelines also state that PBT offers no clinical advantage over other forms of Definitive treatment (Sanda et al., 2017).

American Society for Radiation Oncology (ASTRO)

An ASTRO position statement concludes that the evidence relating to the comparative efficacy of PBT with other prostate cancer treatments is still being developed. Thus the role of PBT for localized prostate cancer within the current availability of treatment options remains unclear (2018).

American College of Radiology (ACR)

Appropriateness criteria from the ACR for the treatment of stage T1 and T2 prostate cancer states that there are only limited data comparing PBT to other methods of irradiation or to radical prostatectomy. Further studies are needed to clearly define its role for such treatment (2013).

Vestibular Tumors

The efficacy of PBT for the treatment of tumors of the vestibular system was assessed in 2 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 PBT. 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 PBT for treating vestibular schwannomas demonstrated LC 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 PBT and IMRT 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 October 30, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for Proton Beam Radiation Therapy Local Coverage Determinations (LCDs) exist; see the LCDs for Proton Beam Radiotherapy and Proton Beam Therapy. (Accessed August 29, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

01/01/2019	• Reorganized policy template:
	  ○ Simplified and relocated *Instructions for Use*
	  ○ Removed *Benefit Considerations* section
	• Revised and reformatted coverage rationale:
	  ○ Simplified content
	  ○ Added notation (previously located in the *Benefit Considerations* section) to indicate this policy applies to persons 19 years of age and older; proton beam radiation therapy (PBT) is covered without further review for persons younger than 19 years of age
	  ○ Modified language to clarify the listed services are:
	  ▪ Proven ***and*** medically necessary (as described)
	  ▪ Unproven ***and*** not medically necessary (as described)
	  ○ Added language to indicate PBT and intensity-modulated radiation therapy (IMRT) are proven and considered clinically equivalent for treating prostate cancer; medical necessity will be determined based on the terms of the member's benefit plan
	  ○ Removed language indicating PBT is unproven and not medically necessary for treating prostate cancer
	• Updated list of applicable CPT codes to reflect annual code edits; revised description for 77387
	• Updated list of applicable ICD-10 diagnosis codes; added C61.0
	• Updated supporting information to reflect the most current clinical evidence and references
	• Archived previoius policy version 2018T0132Z

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right 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. UnitedHealthcare Medical Policies 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.

Dr. Shamoon Ahmad
Labor Invoiced, 2015 - 2019

Year	Labor Invoiced
2015	$141,603.75
2016	$140,220.00
2017	$193,827.50
2018	$231,599.56
2019	$84,243.81
TOTAL	$791,494.62

UnitedHealth Group All Work Orders w/ Pay Rates
for date range 1/1/15 to 12/31/15

Num	Name	Service	Occupation	Description	Contract Name	Contract Num
17898	Ahmad, Shamoon	Vendor	Medical Reviewer	Employer & Individual - Oncology	United Health Group	3151

Contact Email	Contact Phone	Start	End	Status	Bill Rate		OT Bill Rate		Pay Rate	
shelean.sweet@uhc.com	7022408931	9/1/11	3/31/18	Inactive	205.00	Hour	0.00	Job	0.00	Hour

Labor Invoiced	Total Expense Budget	Travel Expensed	ODC Expensed	Client	Client Number	Assoc Saleforce Contact ID	Assoc MBO Record ID	Clie Serv Lev
#######	0.00	0.00	0.00	UnitedHealth Group	2206	5001A00001DdouXQAR	20110720134943195431	1

UnitedHealth Group All Work Orders w/ Pay Rates
for date range 1/1/16 to 12/31/16

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17898	Ahmad, Shamoon	Vendor	Medical Reviewer	OptumHealth - Consultant	United Health Group	3151

Contact Email	Contact Phone	Start	End	Status	Bill Rate		OT Bill Rate		Pay Rate	
shelean.sweet@uhc.com	7022408931	9/1/11	3/31/18	Inactive	205.00	Hour	0.00	Job	0.00	Hour
diane.smith12@optum.com	7022427594	11/1/16	3/31/18	Inactive	205.00	Hour	0.00	Hour	0.00	Hour

Labor Invoiced	Total Expense Budget	Travel Expensed	ODC Expensed	Client	Client Number	Assoc Saleforce Contact ID	Assoc MBO Record ID	C Sc L
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563.75	0.00	0.00	0.00	UnitedHealth Group	2206	5001A00001DdouXQAR	20110720134943195431	

UnitedHealth Group All Work Orders w/ Pay Rates
for date range 1/1/17 to 12/31/17

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17898	Ahmad, Shamoon	Vendor	Medical Reviewer	Employer & Individual - Oncology	United Health Group	3151
17898	Ahmad, Shamoon	Vendor	Medical Reviewer	OptumHealth - Consultant	United Health Group	3151

Contact Email	Contact Phone	Start	End	Status	Bill Rate		OT Bill Rate		Pay Rate	
shelean.sweet@uhc.com	7022408931	9/1/11	3/31/18	Inactive	205.00	Hour	0.00	Job	0.00	Hour
diane.smith12@optum.com	7022427594	11/1/16	3/31/18	Inactive	205.00	Hour	0.00	Hour	0.00	Hour

Labor Invoiced	Total Expense Budget	Travel Expensed	ODC Expensed	Client	Client Number	Assoc Saleforce Contact ID	Assoc MBO Record ID	C Sc L
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46,945.00	0.00	0.00	0.00	UnitedHealth Group	2206	5001A00001DdouXQAR	20110720134943195431	

UnitedHealth Group All Work Orders w/ Pay Rates
for date range 1/1/18 to 12/31/18

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17898	Ahmad, Shamoon	Vendor	Medical Reviewer	OptumHealth - Consultant	United Health Group	3151
17898	Ahmad, Shamoon	Vendor	Medical Reviewer	FG - Employer & Individual -Oncology	United Health Group	3151
17898	Ahmad, Shamoon	Vendor	Medical Reviewer	FG - OptumHealth - Consultant	United Health Group	3151

Contact Email	Contact Phone	Start	End	Status	Bill Rate		OT Bill Rate		Pay Rate	
shelean.sweet@uhc.com	7022408931	9/1/11	3/31/18	Inactive	205.00	Hour	0.00	Job	0.00	Hour
diane.smith12@optum.com	7022427594	11/1/16	3/31/18	Inactive	205.00	Hour	0.00	Hour	0.00	Hour
shelean.sweet@uhc.com	7022408931	4/1/18	7/30/19	Inactive	203.98	Hour	0.00	Job	0.00	Hour
diane.smith12@optum.com	7022427594	4/1/18	5/1/19	Inactive	203.98	Hour	0.00	Hour	0.00	Hour

Labor Invoiced	Total Expense Budget	Travel Expensed	ODC Expensed	Client	Client Number	Assoc Saleforce Contact ID	Assoc MBO Record ID	Clie Serv Lev
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UnitedHealth Group All Work Orders w/ Pay Rates
for date range 1/1/19 to 12/31/19

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17898	Ahmad, Shamoon	Vendor	Medical Reviewer	FG - OptumHealth - Consultant	United Health Group	3151

Contact Email	Contact Phone	Start	End	Status	Bill Rate		OT Bill Rate		Pay Rate	
shelean.sweet@uhc.com	7022408931	4/1/18	7/30/19	Inactive	203.98	Hour	0.00	Job	0.00	Hour
diane.smith12@optum.com	7022427594	4/1/18	5/1/19	Inactive	203.98	Hour	0.00	Hour	0.00	Hour

Labor Invoiced	Total Expense Budget	Travel Expensed	ODC Expensed	Client	Client Number	Assoc Saleforce Contact ID	Assoc MBO Record ID	Clie Serv Lev
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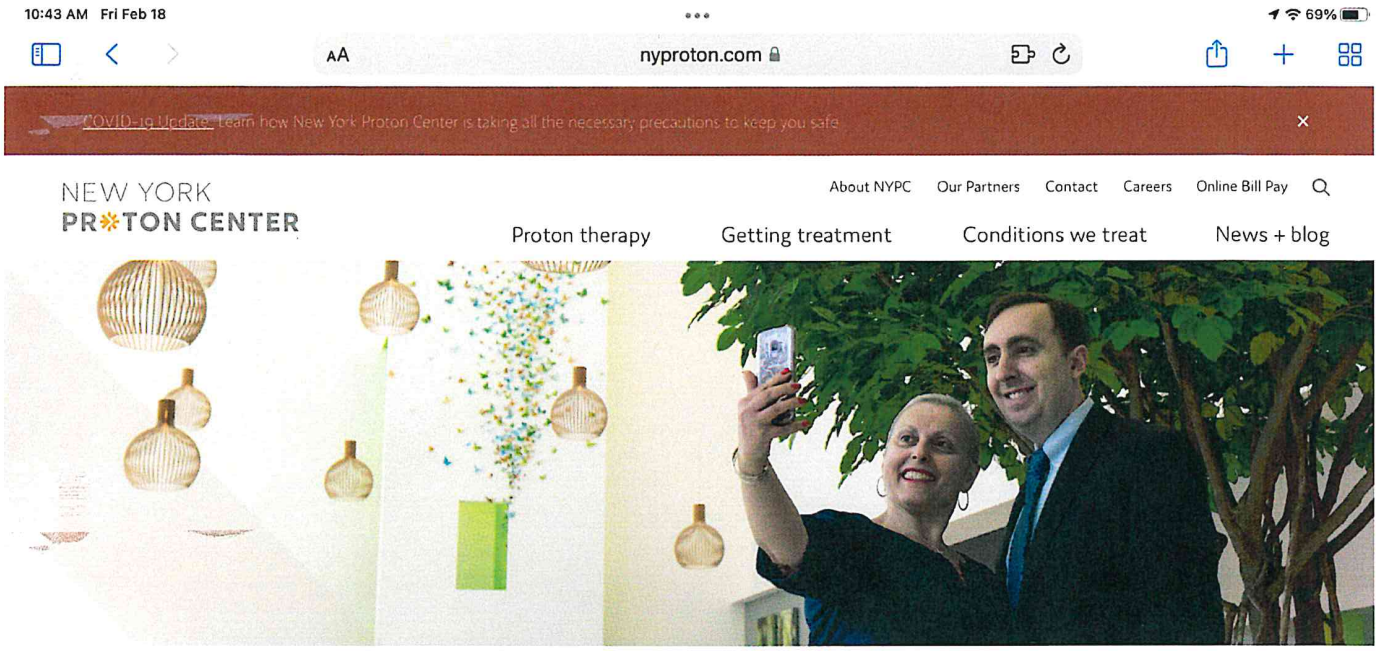

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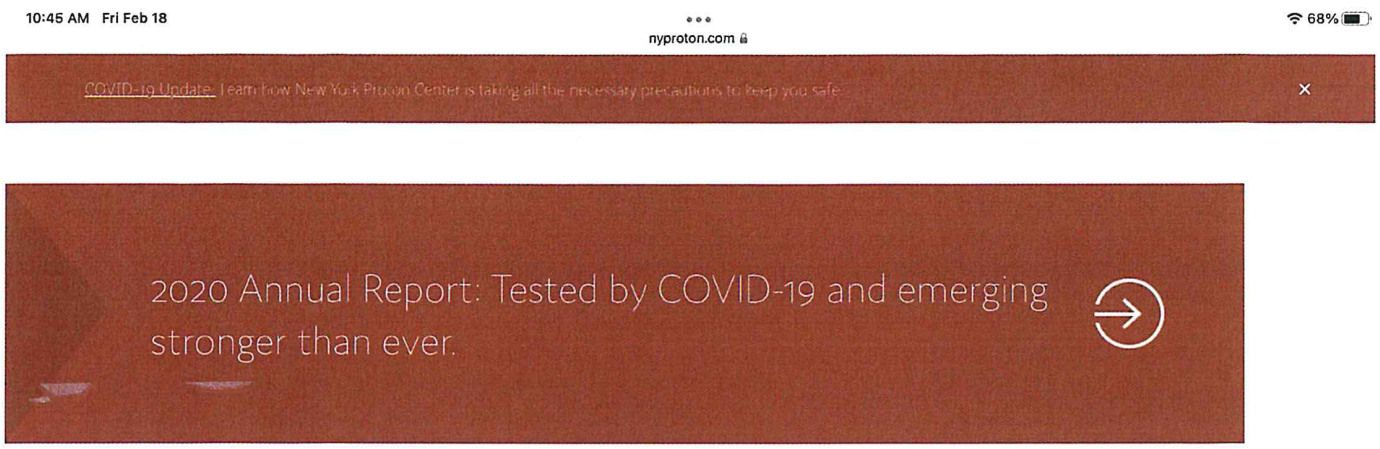
The New York Proton Center (NYPC) is the region's foremost destination for proton therapy. This is our commitment:

Establish a gold standard for this highly advanced form of radiation treatment.

Assemble a team of radiation oncology experts—including physicians and other clinical specialists with significant experience in both proton therapy and other radiation treatments—who are bound together by a commitment to the well-being of their patients.

Further the body of clinical evidence advancing proton therapy as a highly effective treatment for complex tumors and difficult-to-treat cases.

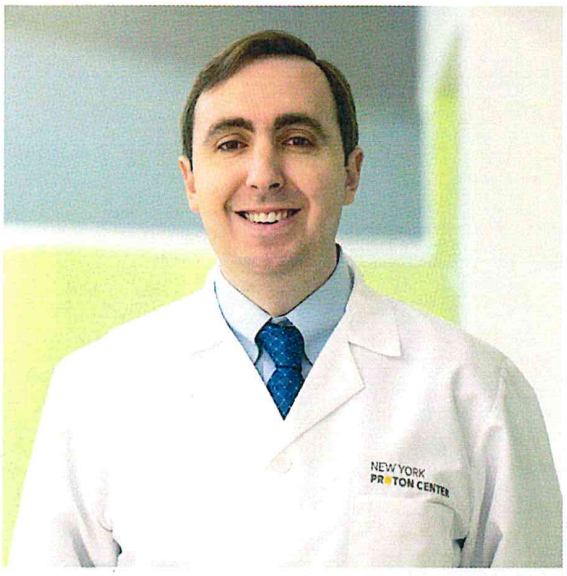
Create a welcoming and reassuring environment for patients, from the comfort of our physical space to the warmth and sincerity of our clinical staff.



Our senior leadership team

The New York Proton Center is a brand-new facility, the first of its kind for proton therapy in New York state.

Yet it is run by a veteran leadership team with deep clinical knowledge and professional expertise in both conventional radiotherapy and proton therapy, with decades of combined experience running proton centers around the country.

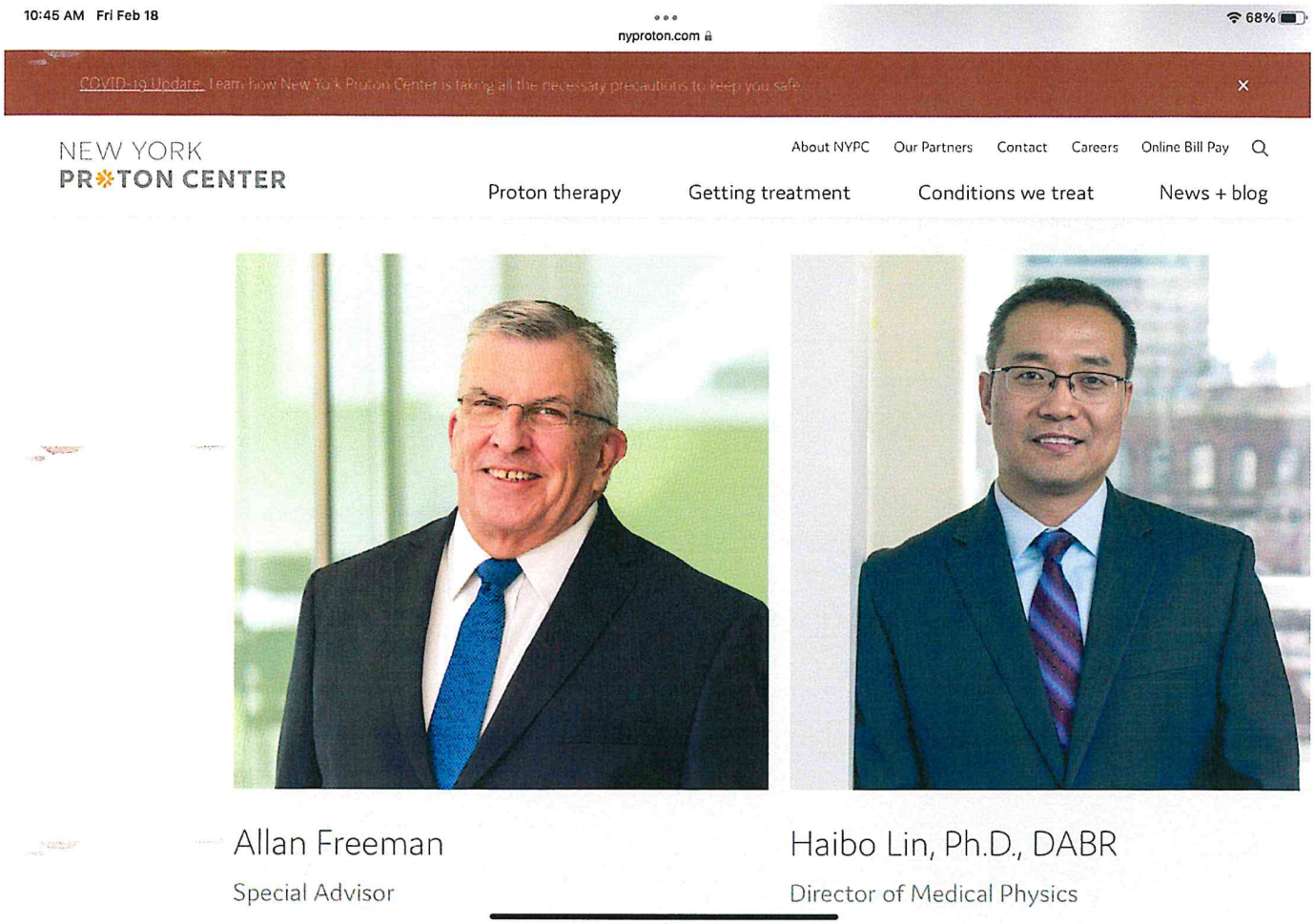


Charles B. Simone, II, MD, FACRO

Chief Medical Officer

Jonathan Weinbach

Chief Executive Officer


10:45 AM Fri Feb 18
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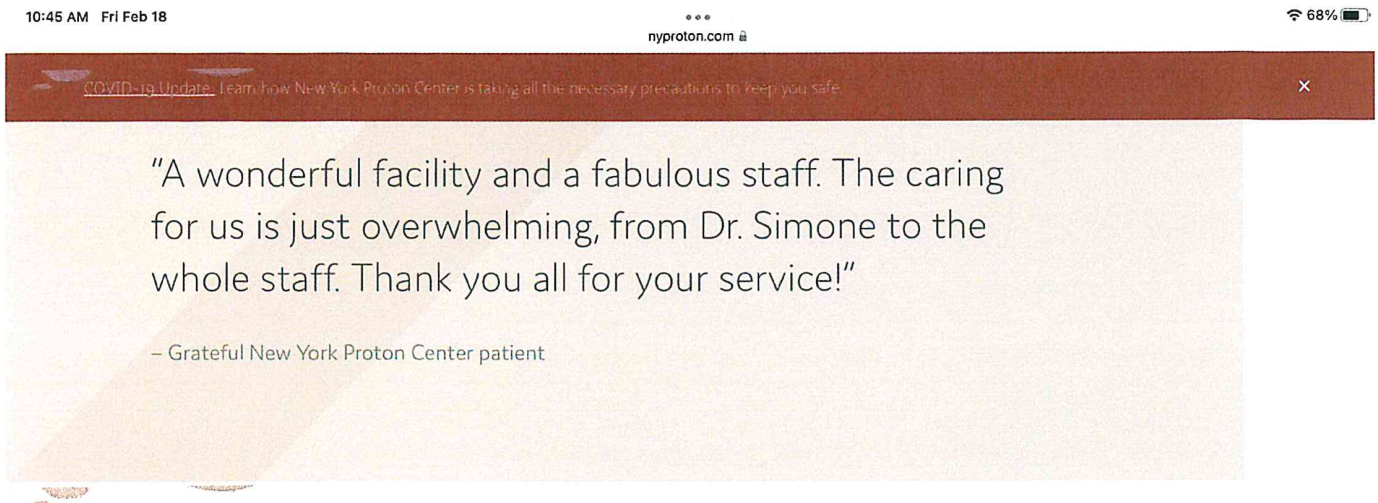
Getting treatment
Conditions we treat
News + blog
Allan Freeman
Special Advisor
Haibo Lin, Ph.D., DABR
Director of Medical Physics



Meet our partners in care

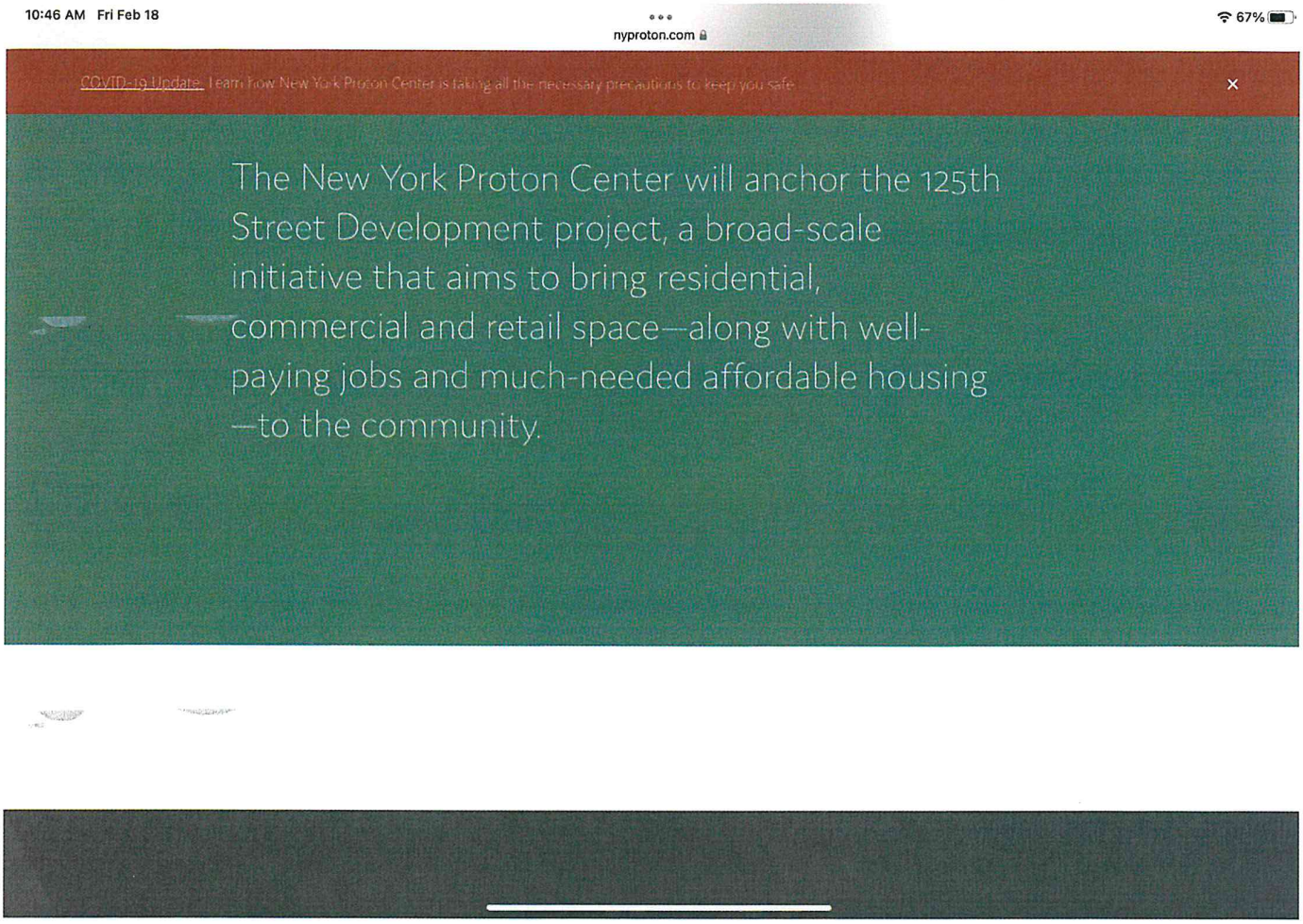
Learn more about our partners →

The New York Proton Center is partnered with leading academic medical centers Memorial Sloan Kettering Cancer Center, Montefiore Health System, and Mount Sinai Health System – and ProHEALTH as manager.

10:46 AM Fri Feb 18 nyproton.com 68%

COVID-19 Update: Learn how New York Proton Center is taking all the necessary precautions to keep you safe.

The New York Proton Center will anchor the 125th Street Development project, a broad-scale initiative that aims to bring residential


10:46 AM Fri Feb 18
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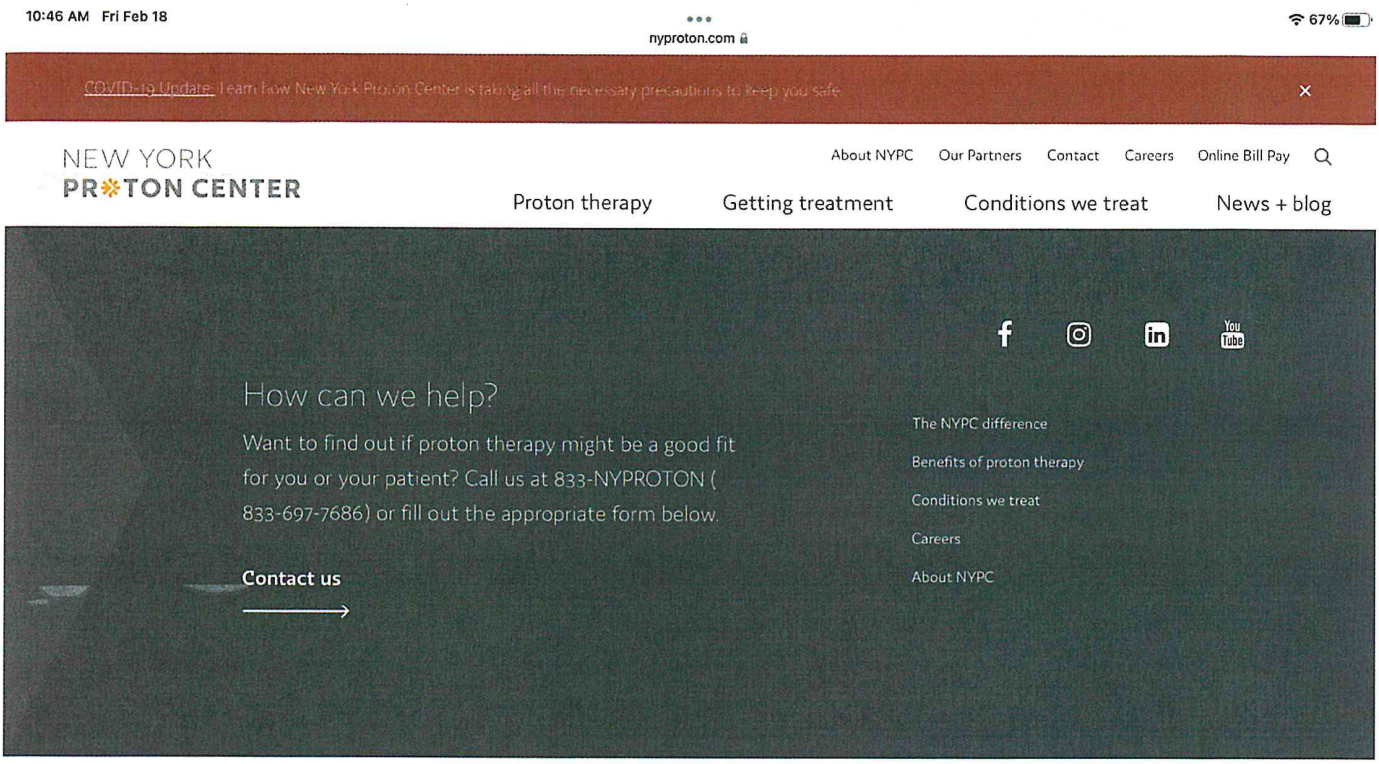
67%
COVID-19 Update: Learn how New York Proton Center is taking all the necessary precautions to keep you safe
The New York Proton Center will anchor the 125th Street Development project, a broad-scale initiative that aims to bring residential, commercial and retail space—along with well-paying jobs and much-needed affordable housing—to the community.



225 East 126th Street, New York, NY 10035

Privacy & Confidentiality

Memorial Sloan Kettering Cancer Center · Montefiore · Mount Sinai · ProHEALTH

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Home > Benefits of proton therapy

A cancer treatment unlike any other_____

Proton therapy at a glance

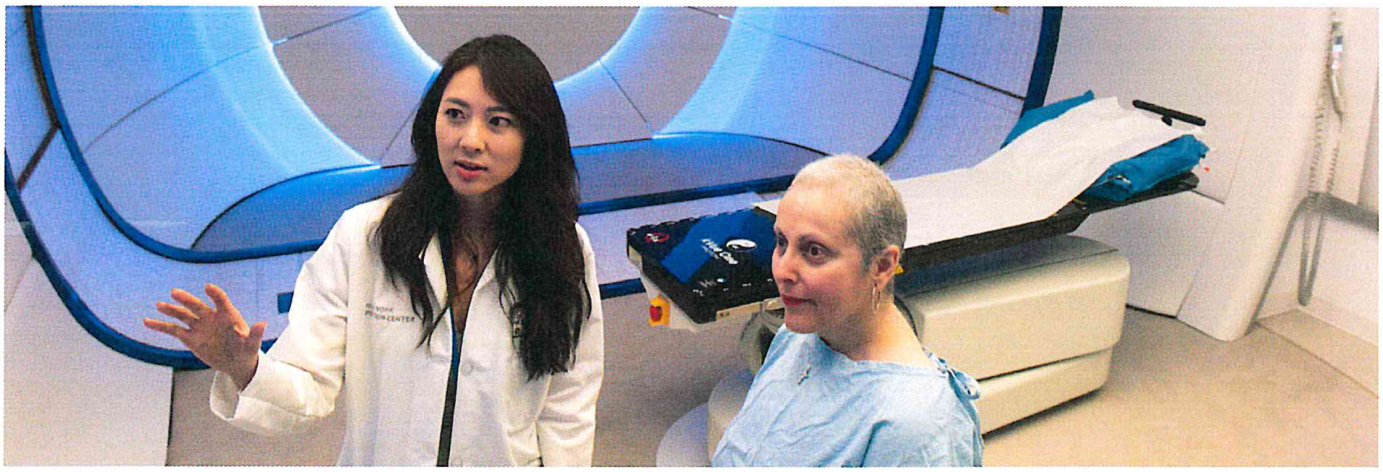
Remarkable precision. Ultimate control. Fewer treatment-related complications.

These are the defining features of proton therapy cancer treatment, an advanced form of radiation treatment that targets and destroys cancer tumors while reducing the risks of harmful side-effects. For patients with complex tumors, patients with tumors that come back after prior treatment, and children with cancer, proton therapy is an ideal and uniquely effective alternative to traditional radiation.

Watch one child's journey with proton therapy →

Patients at the New York Proton Center receive Pencil Beam Scanning, a highly sophisticated and precise type of proton therapy.

As the name implies, Pencil Beam Scanning uses an extremely narrow beam to "dot" the protons onto the tumor. The process is repeated, layer by layer, like paint applied by the tip of an incredibly fine brush.



Noteworthy benefits

Because it's so precise, Pencil Beam Scanning is highly effective at treating the most challenging tumors:

- Complex
- Irregularly shaped
- Wrapped around other structures
- Difficult-to-reach
- Close to vital tissues in the brain, spine, head and neck, or chest
- Recurring following prior treatment

Regardless of tumor type, the advantages of proton beam therapy are three-fold:

Passing through with barely a trace

Targeting the tumor and only the tumor

A highly concentrated dose

Not all proton therapy is created equal

Most proton centers use "volumetric" beams that deliver a fixed quantity of energy to the entire tumor. But the pencil beam scanners at the New York Proton Center deliver "intensity-modulated proton therapy," or IMPT.

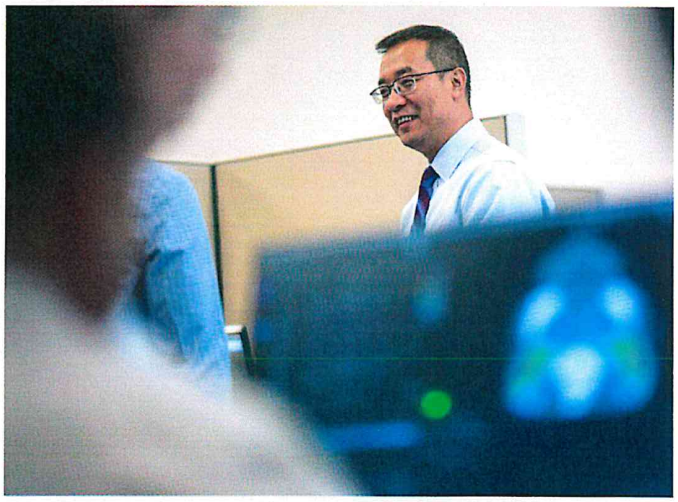
Widely considered the most advanced form of proton therapy, IMPT can target different parts of the tumor with different radiation dose levels to most precisely and effectively treat the tumor. That's particularly valuable when treating the most complicated tumors, such as those residing in brain or spine, head and neck, lungs and chest, and abdomen.

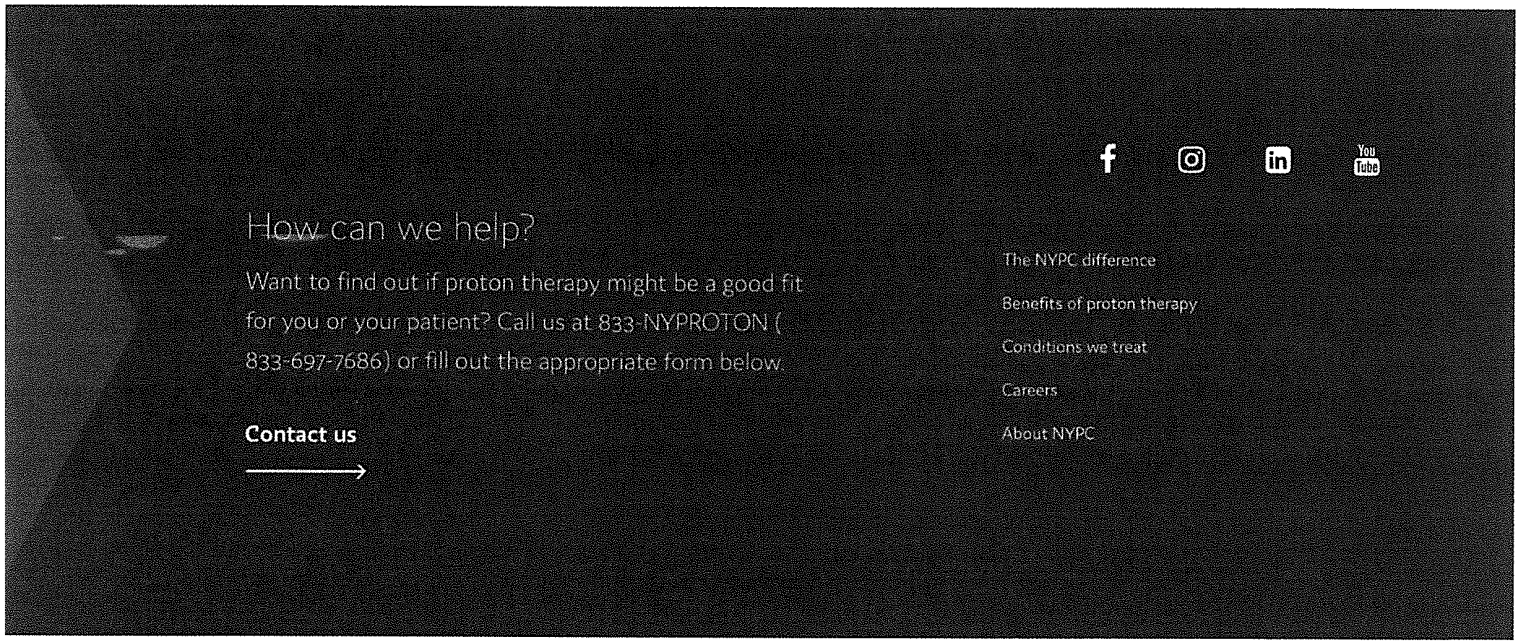
"I would like to thank the staff for their uttermost patience and kindness. Considering my sickness, this proton center is to be highly commended. I looked forward to coming each day because this is a great staff."

Forging the future of proton therapy

The New York Proton Center is part of a large medical community working to advance the body of research on intensity modulated proton therapy and further its effectiveness and efficiency for treating cancer.

Read about the research supporting proton therapy





How can we help?

Want to find out if proton therapy might be a good fit for you or your patient? Call us at 833-NYPROTON (833-697-7686) or fill out the appropriate form below.

Contact us

The NYPC difference

Benefits of proton therapy

Conditions we treat

Careers

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Montefiore

Mount Sinai

ProHEALTH

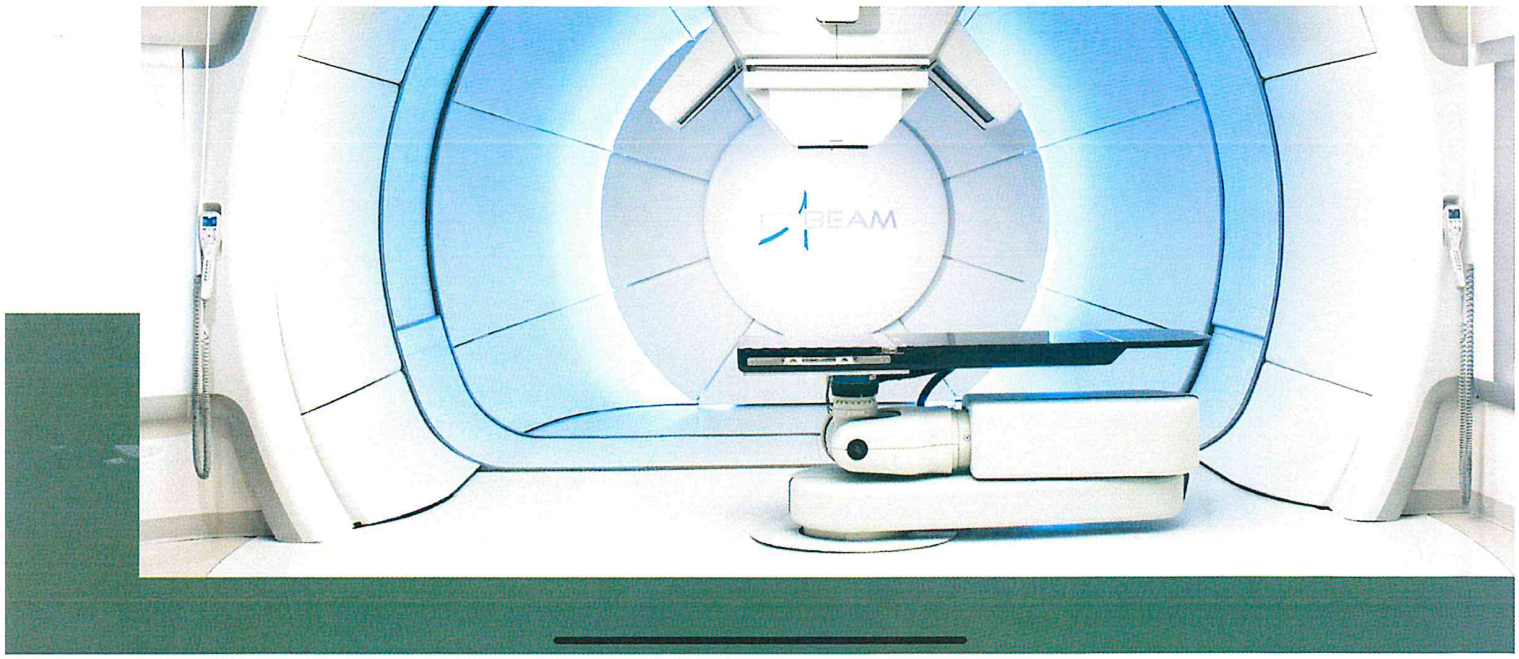
Proton therapy for lung and thoracic tumors

When lung cancer is treated with conventional radiation, it is difficult to deliver a high enough radiation dose to control the cancer without also damaging the normal lungs, esophagus, heart and spinal cord.

Proton therapy can more effectively treat these tumors—particularly larger ones—while better protecting critical structures from radiation. As a result, protons can minimize side effects such as lung inflammation (pneumonitis) or scarring (fibrosis), difficulty swallowing, heart complications, hospitalizations, and other side effects that are commonly seen with conventional lung cancer treatment.

Lung and thoracic cancers we treat with proton radiation therapy include

- Non-small lung cancer
- Small cell lung cancer
- Malignant mesothelioma
- Thymomas and and thymic carcinomas
- Cardiac tumors
- Thoracic sarcoma
- Recurrent thoracic cancers

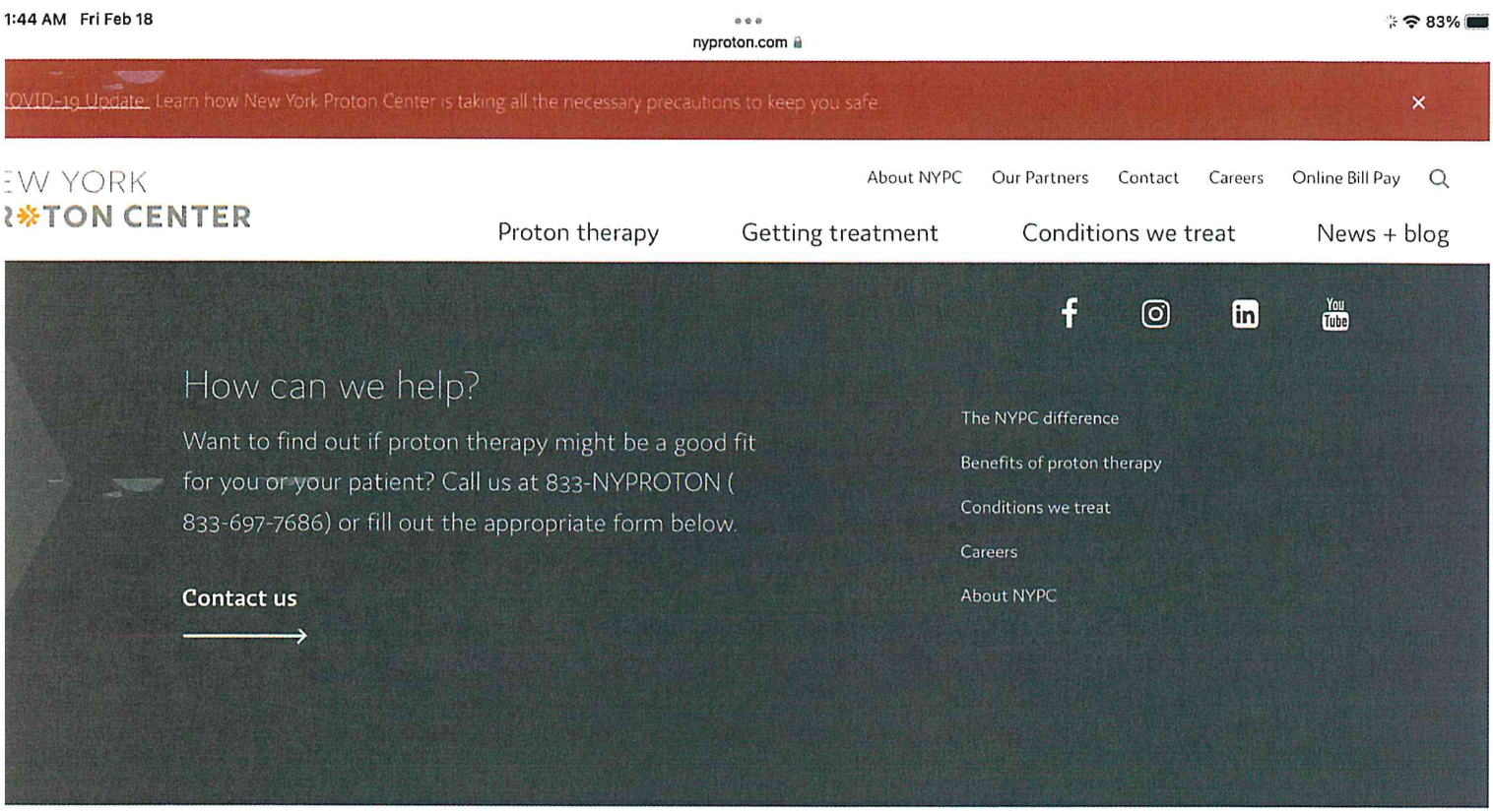


Patients at the New York Proton Center receive Pencil Beam Scanning, a highly sophisticated and most precise type of proton therapy. As the name implies, proton Pencil Beam Scanning uses an extremely narrow beam to "dot" the protons onto the tumor. The process is repeated, layer by layer, like paint applied by the tip of an incredibly fine brush.

Not all proton therapy is created equal

Most proton centers use "volumetric" beams that deliver a fixed quantity of energy to the entire tumor. But the pencil beam scanning technology at the New York Proton Center delivers "intensity-modulated proton therapy," or IMPT.

Widely considered the most advanced form of proton therapy, IMPT can target different parts of the tumor with different radiation dose levels based on the prescription and tumor's exact location, while better protecting the surrounding normal tissues from irradiation. That's particularly valuable when treating the most complicated tumors, those residing in the fissures of the head, neck and skull base.



ct Language

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Montefiore
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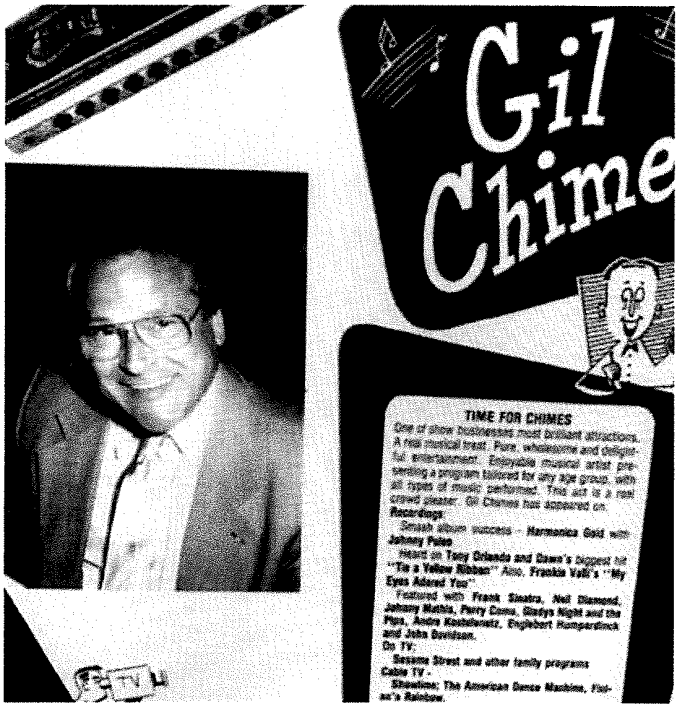
ProHEALTH

With a career on the line, Gil made his choice

Across his seven decades as a professional musician, Gil Chimes had done it all: Sung in bands, performed on Broadway, written commercial jingles, even played harmonica on Tony Orlando's mega #1 hit, "Tie a Yellow Ribbon."

Then in 2019, at the age of 77, Gil received the diagnosis: a three-centimeter lesion on his lung. Because it was too close to his heart for a biopsy, his medical oncologist and thoracic surgeon recommended a resection. But losing more than half of his left lung would have meant permanently "giving up the mic"—a trade-off Gil simply wasn't willing to make.

And thanks to the New York Proton Center, he didn't have to.



The top doctor personally reaches out

The first indication of a problem came during a routine physical, when his primary care doctor detected that Gil was breathing irregularly. She referred him for imaging which revealed his lung cancer.

As he weighed his treatment options, Gil was reminded of a local news story he'd recently seen about the newly opened New York Proton Center in Manhattan. So he phoned and left a message for its Chief Medical Officer and internationally renowned lung cancer expert, Dr. Charles Simone—expecting the receptionist would call back a few days later to set up an appointment. But in fact, the call came that very night.

From Dr. Simone, himself.

"That was so impressive. My original surgeon had spent a grand total of about 10 minutes with me, then sent me on my way. But here was Dr. Simone, the head of the whole center, personally calling me at home. Completely unheard of."

"This place is the best kept secret in the world. You've got to get the word out. They're saving people, they're curing people. It's beyond phenomenal."

A pervading optimism

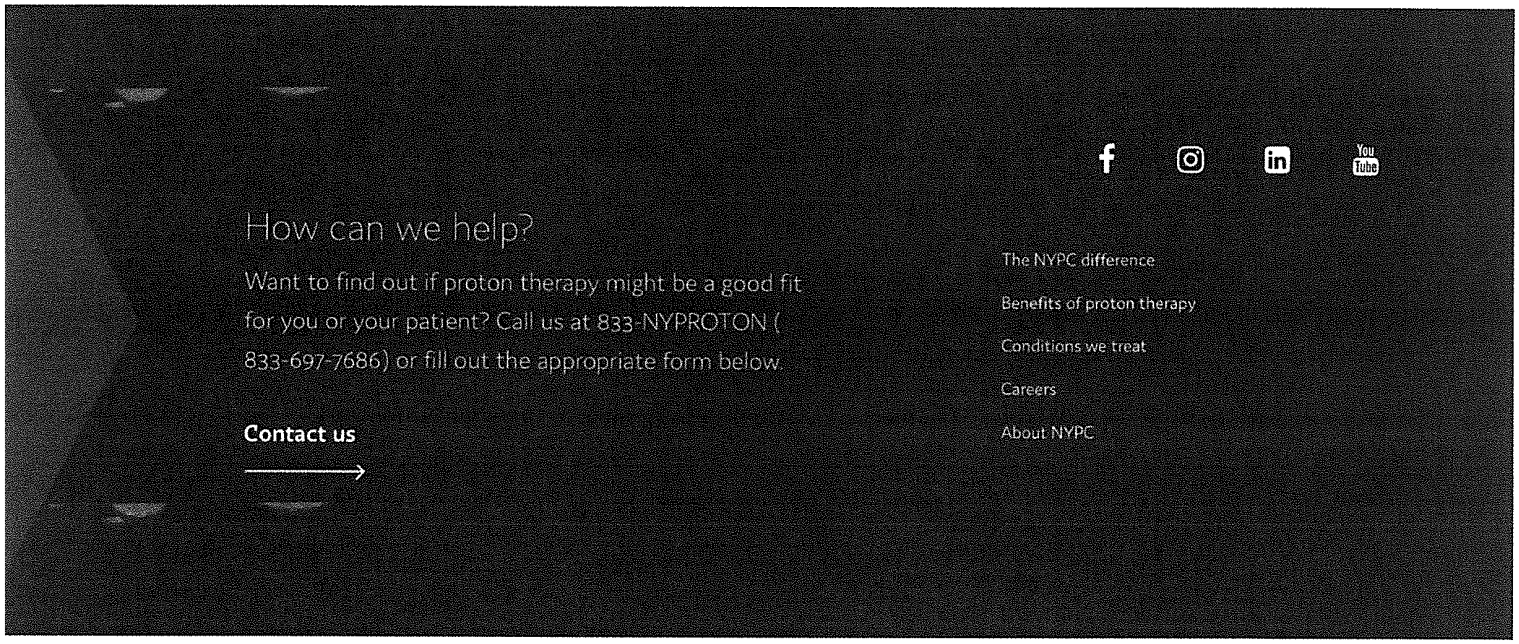
What struck Gil from the moment he arrived at the NYPC was that every interaction—with the front desk personnel, with the nursing staff, with Dr. Simone himself—was, in his words, "amazing from A to Z." Even the other patients he encountered were noticeably upbeat, hardly characteristic of people facing a cancer diagnosis.

"Normally, when you sit in an oncologist's office, everyone is getting bad news. It's heartbreaking. But over at New York Proton Center, everybody's happy and feeling great."

Gil's proton therapy lasted just one week. Other than the discomfort of lying on the hard treatment table—during which, per his request, they piped in Frank Sinatra music—the sessions were painless and the side-effects nonexistent. In fact, the disruption was so minimal that he actually continued performing on stage during his treatment.

Although Gil is enormously grateful for the care he received at the New York Proton Center, it's a gratitude tinged with regret. His sister had been diagnosed with breast cancer a year earlier, but by the time she learned about proton therapy, it was no longer an option. Her disease was too advanced.

"She went through a year of radiation and chemo. She got sick, lost her hair, the whole bit. It's God's blessing that I discovered this advanced treatment, because I suffered zero. I wish she could have too."



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Date: 11/08/2019
Time: 07:16:19
User Id: krosstedt

Case Number: 160360744

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: 68
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 DO NOT USE
Product Eff Dt: 1/1/2016

Diagnosis Information

Diag	Description
C3411	Malignant neoplasm of upper lobe, right bronchus or lung
C7951	Secondary malignant neoplasm of bone

Service Information

Requesting Provider Info
A02900003345 - LIAO, ZHONGXING

Servicing Provider Info
C09900000894 - MD ANDERSON CANCER CENTER

Facility Provider Info
C09900000894 - MD ANDERSON CANCER CENTER

PCP Provider Info

Authorization Information

From	To	Ref\Auth	Procedure	Service	Svc Grp	Req	Auth	Status	Recd Dt
02/05/2016	06/05/2016	A	77263	RTO		999	999	UP	2/5/2016
02/05/2016	06/05/2016	A	77301	RTO		999	999	UP	2/5/2016
02/05/2016	06/05/2016	A	77293	RTO		999	999	UP	2/5/2016
02/05/2016	06/05/2016	A	77470	RTO		999	999	UP	2/5/2016
02/05/2016	06/05/2016	A	77370	RTO		999	999		

UP 2/5/2016						
02/05/2016 06/05/2016 A		77300	RTO		999	999
UP 2/5/2016						
02/05/2016 06/05/2016 A		77338	RTO		999	999
UP 2/5/2016						
02/05/2016 06/05/2016 A		77334	RTO		999	999
UP 2/5/2016						
02/05/2016 06/05/2016 A		77427	RTO		999	999
UP 2/5/2016						
02/05/2016 06/05/2016 A		77336	RTO		999	999
UP 2/5/2016						
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UP 2/5/2016						
02/05/2016 06/05/2016 A		77386	RTO		999	999
UP 2/5/2016						
02/05/2016 06/05/2016 A				OFAC	999	999
UP 2/5/2016						

Note Section
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UserId: agonzales1
Date: 02/05/2016 14:39:31.216

Notes:

STAT
PTS # 702-885-3019
SHL-SNV
64M RECV'D FAX 2/5/2016
REQ: DR.ZHONGXING LIAO UHC-CONT/RAD ONC
SVC: MD ANDERSON CANCER CNTR NONCONT/HOSP
PX: OUTPT-IMRT
DX: Malignant neoplasm of upper lobe, right bronchus or lung, Secondary malignant neoplasm of bone
DOS: TBD
ROUTED TO RN FOR REVIEW

Liao, Zhongxing, MD
1515 Holcombe Blvd
Houston, TX 77030
713-792-6161
Map | Send to My Phone | Add to Address Book
In Network: Yes
View Physician Details
RADIATION ONCOLOGY-Board Certified

UserId: lamogawi
Date: 02/05/2016 14:53:36.323

Notes:

SHL-SNV with UHC Benefit.
Req: AUTHORIZATION REQUEST FOR RADIATION THERAPY: IMRT RADIATION TREATMENT
RADIATION SITE: LUNG
RADIATION TYPE:IMRT
Number of fractions 30
Energy per Dose: 66 cGy
Sent to Med Director for Review.

LA/RN

UserId: lamogawi
Date: 02/05/2016 16:44:20.143

Notes:

From: shamoonahmad@yahoo.com [mailto:shamoonahmad@yahoo.com]
Sent: Friday, February 05, 2016 4:38 PM
To: Amogawin, Lou Ann
Subject: RE:Secure message from Lou-Ann.Amogawin@uhc.com--160360744--Approve

Reviewer: Shamoon Ahmad MD, FACP
Criteria used: INTENSITY-MODULATED RADIATION THERAPY (IMRT)
Protocol: RAD026 Effective Date: 10/1/2015 NCCNguidelines for radiation therapy version 2015

Case Summary: As described below. Lung and mediastinal tumor The requested procedure meetscurrent HPN policy
Decision: IMRT and all associated codes are a covered benefit

Req: AUTHORIZATION REQUEST FOR RADIATION THERAPY: IMRTRADIATION TREATMENT
RADIATION SITE: LUNG
RADIATION TYPE: IMRT
Number of fractions 30
Energy per Dose: 66 cGy

Approved under SHL/UHCBenefit by Dr. Ahmad.

LA/RN

UserId: twilber
Date: 02/05/2016 17:06:04.843

Notes:

UserId: AUTO
Date: 02/05/2016 17:06:39.840

Notes:

Decision Logged on 02/05/2016 at: 5:06PM

UserId: twilber
Date: 02/05/2016 17:57:03.180

Notes:

Member Call Completed - Answering Machine - HIPAA compliant message left - Hello, We Are calling at the request of HPN SHL SHO SD SS Thisis the verbal notice that the requested service has been approved. Theauthorization expires on 6/4/16. If you have questions about this message, you may call 702-240-1510. 8am-5pm, Monday through Friday, excluding holidays. Thank you. Goodbye.

Contact Section
------- -------

Contact:	LYNN		
Phone:	7137921056	Ext:	
Fax:	7137451417	Ext:	

INTENSITY-MODULATED RADIATION THERAPY (IMRT)

Protocol: RAD026
Effective Date: October 1, 2015

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INSTRUCTIONS FOR USE

This protocol 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 Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol 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.

COMMERCIAL COVERAGE RATIONALE

This policy applies to persons 19 years of age and older. Intensity-modulated radiation therapy (IMRT) is covered without further review for persons 18 years and younger.

IMRT is medically necessary for treating the primary site of the following diagnoses:

- Anal cancer
- Breast cancer when the patient has a separation of 25.5 cm or more in the intra-thoracic distance from the midpoint of the posterior light field border of the medial tangential field to the midpoint of the posterior light field of the lateral tangential field.

- Cervical cancer in patients who have had a hysterectomy
- Esophageal cancer
- Head and neck cancers, including the following areas: pharynx (nasopharynx, oropharynx and hypopharynx), larynx, salivary glands, oral cavity (includes the tongue), nasal cavity and paranasal sinuses
- Pancreatic cancer
- Primary or benign bone tumors
- Primary or benign tumors of the central nervous system including the brain, brainstem and spinal cord
- Prostate cancer
- Tracheal cancer

IMRT may be covered for a diagnosis that is not listed above as medically necessary when at least one of the following conditions is present:

- A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity.
- The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

Requests for these exceptions will be evaluated on a case-by-case basis.

The use of compensator based beam modulation treatment is medically necessary when done in combination with an IMRT indication that is listed above as medically necessary.

IMRT used in conjunction with proton beam radiation therapy is 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.

Continuous/real-time intra-fraction localization and tracking systems are not medically necessary for use in image-guided radiation therapy. Larger, prospective studies are needed to determine whether image-guided radiation therapy using continuous or real-time tracking systems improves health outcomes in patients receiving IMRT

BENEFIT CONSIDERATIONS

This protocol applies to persons 19 years of age and older. IMRT is covered without further review for persons 18 years and younger.

For purposes of benefit administration, when IMRT is considered to be **medically necessary** non-preferentially, the following 2 conditions apply:

1. If an enrollee has benefits for out-of-network services, and external beam radiation therapy is available in-network, out-of-network intensity-modulated radiation therapy would be covered at the out-of-network benefit level. Travel costs would not be covered in this situation.

2. If an enrollee does not have benefits for out-of-network services ("Standard"), no out-of network benefit would be available for out-of-network intensity-modulated radiation therapy as long as external beam radiation therapy is available within the network.

Where IMRT is **medically necessary** preferentially, out of network service could be covered at an in-network level of benefits if IMRT is not available as an in-network service. The enrollee-specific benefit document must be consulted to determine what form of coverage exists.

When deciding coverage for use of IMRT for a person who has a life-threatening health condition, refer to the member specific benefit document language for further information. In some benefit documents, coverage exists for **not medically necessary** services for persons with life-threatening conditions, under certain circumstances.

Some benefit documents allow coverage of experimental/investigational/unproven services for life-threatening illnesses when certain conditions are met. The enrollee specific benefit document must be consulted to make coverage decisions for this service. Benefit coverage for an otherwise not medically necessary service for the treatment of serious rare diseases may occur when certain conditions are met.

MEDICARE & MEDICAID COVERAGE RATIONALE

Medicare does not have a National Coverage Determination for Intensity Modulated Radiation Therapy (IMRT). Medicare does have a Local Coverage Determination for Intensity Modulated Radiation Therapy (IMRT) for Nevada (L33531), accessed August 2015.

The Local Coverage Determination is as follows:
Intensity Modulated Radiation Therapy (IMRT) (LCD L33531)

Coverage Indications, Limitations, and/or Medical Necessity

Intensity Modulated Radiation Therapy (IMRT) is a technology in radiation oncology that delivers radiation more precisely to the tumor while relatively sparing the surrounding normal tissues. It is an advanced form of three-dimensional conformal radiation therapy (3D CRT) that allows for varying intensities of radiation to produce dose distributions that are more conformal than those possible with standard 3D CRT. It introduces inverse planning and computer-controlled radiation deposition, and normal tissue avoidance in contrast to the conventional trial-and-error approach.

The clinical objectives are defined mathematically and the IMRT optimization process determines the beam parameters that will lead to the desired solution while sparing normal tissues.

Examples of situations where IMRT **is covered** include tumors of the prostate, head and neck, brain, and paraspinal regions when needed to reduce the incidence and severity of the side effects of radiation, including compromise of visual function, mucositis, and xerostomia.

An IMRT candidate includes a patient who has already received a maximum amount of radiation delivered by conventional means. IMRT allows these patients to receive additional radiation safely, which can result in a prolonged survival and an improved quality of life.

Coverage:
One or more of the following required criteria for coverage must be documented in the medical record:

- The target volume is irregularly shaped and in close proximity to critical structures that must be protected.
- The volume of interest is in such location that its parameters can only be defined by MRI or CT.
- Important structures adjacent to, but outside the volume of interest are sufficiently close to the margin such that IMRT is required for additional safety and morbidity reduction related to radiation.
- An immediately adjacent area has been irradiated and abutting portals must be established with high precision.
- Tumor volume margins are concave and in close proximity to critical structures.
- IMRT is covered when the tumor tissue lies in areas associated with target motion caused by cardiac and pulmonary cycles, and the IMRT is necessary in order to protect adjacent normal tissues.
- Non-IMRT techniques would cause grade 2 or grade 3 radiation toxicity in greater than 15 percent of radiated cases.
- IMRT is the only option to cover the volume of interest with narrow margins and protect immediately adjacent structures.
- Only IMRT can produce dose distributions that can cover extremely concave target geometries.

For Medicare and Medicaid Service Determinations Related to States Outside of Nevada:
Please review Local Coverage Determinations that apply to other states outside of Nevada.
http://www.cms.hhs.gov/mcd/search

Important Note: Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Service's Website.

DESCRIPTION OF SERVICES

External beam radiation therapy delivers x-rays that are generated using a machine called a linear accelerator. Three-dimensional conformal radiation therapy (3D-CRT) uses very sophisticated computer software and advanced treatment machines to deliver radiation to very precisely shaped target areas. IMRT is an advanced form of conformal external beam radiation therapy that uses computer-controlled linear accelerators to deliver precise radiation doses to the target area while minimizing the dose to surrounding normal critical structures. IMRT allows for the radiation dose to conform more precisely to the shape of the tumor by modulating – or controlling – the intensity of the radiation beam. The ratio of normal tissue dose to tumor dose is reduced to a minimum with IMRT, allowing delivery of higher radiation doses with potentially fewer side effects than conventional radiation therapy techniques. IMRT differs from conventional conformal radiation therapy in that it has the ability to adjust the beam intensity by using multiple beamlets. This kind of dose modulation allows different areas of a tumor or nearby tissues to receive different doses of radiation (National Cancer Institute (NCI), 2010; American College of Radiology (ACR) website, 2013; ACR website, 2014a).

Image-guided radiation therapy (IGRT) is often used in conjunction with IMRT and other advanced forms of radiation therapy. IGRT uses frequent imaging during a course of radiation therapy to more precisely target radiation at the tumor and avoid healthy surrounding tissue. It is used to treat tumors in areas of the body that are prone to movement, such as the lungs, as well as tumors located close to critical organs. Using specialized computer software, these images are then compared to the reference images taken during treatment planning. IGRT may be performed prior to the start of treatment (interfraction) or continuously/real-time during treatment sessions (intrafraction). Computed tomography (CT), magnetic resonance imaging (MRI), ultrasound (US) and x-ray imaging may be used by visualizing boney or soft-tissue anatomy. Other methods use markers placed on the surface of the body or implanted in the body (e.g., optical surface imaging or electromagnetic localization) (ACR website, 2014b; ACR/ASTRO, 2014).

CLINICAL EVIDENCE

A systematic review by De Neve et al. (2012) concluded that while some studies show lower toxicity in IMRT-treated patients, further studies are needed to evaluate efficacy endpoints, like overall survival, disease-specific survival or local control.

Veldeman et al. (2008) conducted a systematic review of the evidence behind the use of IMRT for various disease sites. Forty-nine comparative studies on head and neck, prostate, gynecological, CNS, breast and lung cancer were reviewed. The authors reported that the generally positive findings for toxic effects and quality of life are consistent with the ability of IMRT to better control the dose distribution inside (i.e., dose homogeneity and simultaneous integrated boost) and outside (i.e., selective sparing of organs at risk (OAR)) the planning target volume.

The National Cancer Institute (NCI) published guidelines for the utilization of IMRT treatment techniques in clinical trial protocols (NCI 2005). These guidelines and protocol requirements were updated in 2006 to include IMRT in anatomical regions where target motion can have a significant effect (NCI 2006).

Anal Cancer

Kachnic et al. (2013) conducted a prospective, multi-institutional phase II trial (RTOG 0529) assessing dose-painted intensity modulated radiation therapy (DP-IMRT) for anal cancer. The primary outcome was reducing grade 2+ combined acute gastrointestinal and genitourinary adverse events (AEs) of 5-fluorouracil (5FU) and mitomycin-C (MMC) chemoradiation for anal cancer by at least 15% compared with the conventional radiation/5FU/MMC arm from RTOG 9811. Of 52 evaluable patients, the grade 2+ combined acute adverse event rate was 77%. However, significant reductions were seen in acute grade 2+ hematologic events (73% vs. 85%), grade 3+ gastrointestinal events (21% vs. 36%) and grade 3+ dermatologic events (23% vs. 49%) with DP-IMRT. Although the trial did not meet its primary endpoint, the authors reported that DP-IMRT was associated with significant sparing of acute grade 2+ hematologic and grade 3+ dermatologic and gastrointestinal toxicity. The authors also emphasized the importance of real-time radiation quality assurance for IMRT trials**.**

In a retrospective comparative study, Dasgupta et al. (2013) compared IMRT (n=45) and conventional radiotherapy (CRT) (n=178) outcomes in patients with anal squamous cell carcinoma (ASCC). Primary outcomes were local recurrence-free survival (LRFS), distant metastases-free survival

(DMFS) and overall survival (OS). The 2-year LRFS, DMFS and OS were 87%, 86% and 93%, respectively, for IMRT; and 82%, 88% and 90%, respectively, for CRT. The authors concluded that outcomes were not compromised by more conformal radiotherapy. In the absence of prospective, multi-institutional, randomized trials of IMRT in ASCC, retrospective data, using methods to minimize bias, help to establish the role of IMRT in the definitive therapy of ASCC.

DeFoe et al. (2012) reported the clinical outcomes of 78 patients with anal carcinoma treated with intensity-modulated radiation therapy (IMRT) and concurrent chemotherapy. The median follow-up for the entire cohort was 16 months (range 0-72 months). Acute grade ≥3 toxicity included 27.7% gastrointestinal and 29.0% dermatological. Acute grade 4 hematological toxicity occurred in 12.9% of patients. Sixty-four (88.9%) patients experienced a complete response. The 2 year colostomy-free survival, overall survival, freedom from local failure and freedom from distant failure rates were 81.2, 86.9, 83.6 and 81.8%, respectively.

Forty-three patients were treated with dose-painted IMRT (DP-IMRT) and concurrent chemotherapy for squamous cell carcinoma of the anal canal. Median follow-up was 24 months (range, 0.6-43.5 months). Acute Grade ≥3 toxicity included: hematologic 51%, dermatologic 10%, gastrointestinal 7% and genitourinary 7%. Two-year local control, overall survival, colostomy-free survival and metastasis-free survival were 95%, 94%, 90% and 92%, respectively (Kachnic et al., 2012).

A retrospective review by Bazan et al. (2011) compared IMRT (n=29) with conventional radiation therapy (n=17) for the treatment of anal cancer. Patients treated with conventional radiation required more treatment breaks and longer treatment duration. The 3-year overall survival (OS), locoregional control (LRC) and progression-free survival were 87.8%, 91.9% and 84.2%, respectively, for the IMRT groups and 51.8%, 56.7% and 56.7%, respectively, for the CRT group

A study conducted by Saarilahti et al. (2008) compared the use of IMRT and 3D-CRT in 59 patients with anal squamous cell cancer. IMRT resulted in a significant reduction in skin and mucosal eruptions and late radiation proctitis.

Salama et al. (2007) reported a multicenter experience treating anal canal cancer patients with concurrent chemotherapy and IMRT. Eighteen-month colostomy-free survival, overall survival, freedom from local failure and freedom from distant failure were 83.7%, 93.4%, 83.9% and 92.9%, respectively. The investigators concluded that preliminary outcomes suggest that concurrent chemotherapy and IMRT for anal canal cancers is effective and tolerated favorably compared with historical standards.

ACR Appropriateness Criteria recommend that, although IMRT is still undergoing study for treating anal cancer, its use is usually appropriate (ACR, 2013).

NCCN guidelines state that IMRT may be used in place of 3D conformal radiation therapy in the treatment of anal carcinoma. Multiple pilot studies have demonstrated reduced toxicity while maintaining local control using IMRT. IMRT requires expertise and careful target design to avoid reduction in local control by so-called “marginal miss.” Specific protocols are referenced in the guidelines (NCCN, Clinical Practice Guidelines in Oncology, Anal Cancer 2015).

Bone Tumors
NCCN guidelines for bone cancer state that specialized radiation therapy techniques, such as IMRT, should be considered as indicated in order to allow high-dose therapy while maximizing normal tissue sparing (NCCN, Clinical Practice Guidelines in Oncology, Bone Cancer 2015).

Breast Cancer
Rusthoven et al. (2008) compared dose distribution and normal tissue sparing in partial-breast treatment using 3D-CRT vs. IMRT in 63 patients with breast cancer. The investigators concluded that in T1N0 patients treated with external beam partial-breast radiotherapy, IMRT improves normal tissue sparing in the ipsilateral breast compared with 3D-CRT, without compromising dose delivery to the lumpectomy cavity and clinical target volume.

A multicenter, double-blind, randomized controlled trial was performed to determine whether breast IMRT would reduce the rate of acute skin reaction, decrease pain and improve quality of life compared with standard radiotherapy using wedges. A total of 331 patients were included in the analysis. The authors reported that IMRT improved the homogeneity of the radiation dose distribution and decreased acute toxicity (Pignol et al., 2008).

Donovan et al. (2007) evaluated 306 women who underwent whole breast radiotherapy after tumor excision for early stage cancer and were randomized to 3D IMRT (test arm) or 2D radiotherapy delivered using standard wedge compensators (control arm). Eligibility criteria included patients judged to be at higher than average risk of radiation-induced normal tissue changes by virtue of breast size and/or breast shape. The greatest dose variation appears to occur in large-breasted women. Patients were evaluated yearly for 5 years after treatment. A total of 240 (79%) patients with 5-year photographs were available for analysis. Change in breast appearance was identified in 71/122 (58%) allocated to standard treatment compared to only 47/118 (40%) patients allocated to 3D IMRT. No significant differences between treatment groups were found in patient reported breast discomfort, breast hardness or quality of life. The investigators concluded that the use of IMRT reduces late adverse effects.

McDonald et al. (2008) evaluated long-term outcomes of adjuvant breast IMRT with a comparison cohort receiving conventional radiation (CRT) during the same period. A total of 245 breasts were treated in 240 patients: 121 with IMRT and 124 with CRT. Median follow-ups were 6.3 years for patients treated with IMRT and 7.5 years for those treated with CRT. Treatment with IMRT decreased acute skin toxicity of Radiation Therapy Oncology Group Grade 2 or 3 compared with CRT (39% vs. 52%). For patients with Stages I-III (n = 199), 7-year Kaplan-Meier freedom from ipsilateral breast tumor recurrence (IBTR) rates were 95% for IMRT and 90% for CRT. For patients with Stage 0 (ductal carcinoma in situ, n = 46), 7-year freedom from IBTR rates were 92% for IMRT and 81% for CRT. Comparing IMRT with CRT, there were no statistically significant differences in overall survival, disease-specific survival, or freedom from IBTR, contralateral breast tumor recurrence, distant metastasis, late toxicity, or second malignancies. The investigators concluded that patients treated with IMRT had decreased acute skin toxicity, and long-term follow-up shows excellent local control similar to a contemporaneous cohort treated with CRT.

Bhatnagar et al. (2006a) studied 83 breast cancer patients and found that primary breast irradiation with tangential IMRT technique significantly reduces the dose to the contralateral breast compared to

conventional tangential field techniques. The authors also found that the primary breast size significantly affects the scatter dose to the contralateral breast but not the ipsilateral lung or heart dose when using IMRT for breast irradiation.

Freedman et al. (2006) evaluated 73 patients to determine the incidence and severity of acute skin toxicity with breast IMRT, and to compare the results with a matched cohort of patients treated by conventional radiation therapy. The authors concluded that IMRT for breast cancer was associated with a decrease in acute desquamation compared with a matched control group treated with conventional radiation therapy. The authors also concluded that further study of patient symptoms, quality of life, and cosmesis is needed to evaluate the benefit of IMRT for breast cancer.

Several studies comparing IMRT to standard radiotherapy found that IMRT delivers substantially lower amounts of radiation to the contralateral breast (Prabhakar et al., 2007; Bhatnagar et al., 2006a; Bhatnagar et al., 2006b; Bhatnagar et al., 2004).

Woo et al. (2006) evaluated the radiation body exposure during breast radiotherapy in a prospective cohort of 120 women. The use of physical wedges as a compensation technique was the most significant factor associated with increased scattered dose, resulting in approximately three times more exposure compared with breast IMRT and dynamic wedge. The investigators concluded that the amount of radiation that is scattered to a patient's body is consistent with exposure reported to be associated with excess of leukemia, and recommend using breast IMRT or virtual wedging for the radiotherapy of breast cancer receiving high-dose anthracycline chemotherapy.

NCCN guidelines for breast cancer state that target definition in whole breast radiation is best done by both clinical assessment and CT-based treatment planning to limit irradiation exposure of the heart and lungs. A uniform dose distribution and minimal normal tissue toxicity are the goals and can be accomplished using compensators such as wedges, forward planning using segments, IMRT, respiratory gating or prone positioning (NCCN, Clinical Practice Guidelines in Oncology, Breast Cancer 2014).

Central Nervous System (CNS) Tumors
Milker-Zabel et al. (2007) evaluated 94 patients with meningiomas of the skull base who were treated with IMRT. Median follow-up was 4.4 years and overall local control was 93.6%.

The potential benefits and limitations of different radiation techniques (stereotactic arc therapy (SRS/T), IMRT, helical tomotherapy (HT), cyberknife and intensity-modulated multiple arc therapy (AMOA) were assessed using comparative treatment planning methods on 12 patients presenting with benign brain tumors. For the class of tumors investigated, HT, AMOA and IMRT had better target coverage with HT providing the best combination of indeces. Between AMOA and IMRT, target coverage was comparable and, considering organs at risk, AMOA was slightly preferable (Cozzi 2006)

NCCN guidelines for central nervous system cancers state that every attempt should be made to decrease the radiation dose outside the target volume. This can be achieved with 3D planning or IMRT (NCCN, Clinical Practice Guidelines in Oncology, Central Nervous System Cancers 2014).

Cervical Cancer

Hasselle et al. (2011) evaluated disease outcomes and toxicity in cervical cancer patients treated with pelvic IMRT. Patients treated with extended field or conventional techniques were excluded. IMRT plans were designed to deliver 45 Gy in 1.8-Gy daily fractions to the planning target volume while minimizing dose to the bowel, bladder and rectum. Toxicity was graded according to the Radiation Therapy Oncology Group system. The study included 111 patients with Stage I-IVA cervical carcinoma. Of these, 22 were treated with postoperative IMRT, 8 with IMRT followed by intracavitary brachytherapy and adjuvant hysterectomy, and 81 with IMRT followed by planned intracavitary brachytherapy. Of the patients, 63 had Stage I-IIA disease and 48 had Stage IIB-IVA disease. The median follow-up time was 27 months. The 3-year overall survival rate and the disease-free survival rate were 78% and 69%, respectively. The 3-year pelvic failure rate and the distant failure rate were 14% and 17%, respectively. Estimates of acute and late grade 3 toxicity or higher were 2% and 7%, respectively. The authors concluded that IMRT is associated with low toxicity and favorable outcomes, supporting its safety and efficacy for cervical cancer. Prospective clinical trials are needed to evaluate the comparative efficacy of IMRT vs. conventional techniques.

Chen et al. (2007a) assessed 68 patients at high risk of cervical cancer after hysterectomy who were treated with adjuvant pelvic radiotherapy and concurrent chemotherapy. Thirty-three patients received adjuvant radiotherapy by IMRT. Before the IMRT series was initiated, 35 other patients underwent conventional four-field radiotherapy (Box-RT). IMRT provided compatible local tumor control compared with Box-RT. The actuarial 1-year locoregional control for patients in the IMRT and Box-RT groups was 93% and 94%, respectively. IMRT was well tolerated, with significant reduction in acute gastrointestinal (GI) and genitourinary (GU) toxicities compared with the Box-RT group (GI 36 vs. 80%; GU 30 vs. 60%). The IMRT group had lower rates of chronic GI and GU toxicities than the Box-RT patients. The investigators concluded that their results suggest that IMRT significantly improved the tolerance to adjuvant chemoradiotherapy with compatible locoregional control compared with conventional Box-RT. However, longer follow-up and more patients are needed to confirm the benefits of IMRT.

ACR Appropriateness Criteria state that IMRT has not been tested prospectively and is not recommended for the routine treatment of advanced cervical cancer at this time due to significant organ motion issues. However, IMRT may be appropriate to reduce acute toxicities in patients who have had a hysterectomy (ACR, 2012b).

NCCN guidelines for cervical cancer state that IMRT and similar highly conformal methods of dose delivery may be helpful in minimizing the dose to the bowel and other critical structures in the post-hysterectomy setting and in treating the para-aortic nodes when necessary. These techniques can also be useful when high doses are required to treat gross disease in regional lymph nodes. IMRT should not be used as a routine alternative to brachytherapy for treatment of central disease in patients with an intact cervix. Very careful attention to detail is required for proper delivery. Issues regarding target definition, patient and target immobilization, tissue deformation, toxicity and reproducibility remain to be validated (NCCN, Clinical Practice Guidelines in Oncology, Cervical Cancer 2015).

Esophageal Cancer

Lin et al. (2012) performed an analysis of long-term clinical outcomes comparing 3D-CRT (n=413) vs. IMRT (n=263) for esophageal cancer. Primary outcomes were overall survival time, interval to local failure and interval to distant metastasis. Compared with IMRT, 3D-CRT patients had a significantly

greater risk of dying (72.6% vs. 52.9%) and of locoregional recurrence. No difference was seen in cancer-specific mortality or distant metastasis. An increased cumulative incidence of cardiac death was seen in the 3D-CRT group, but most deaths were undocumented.

In a small study (n=19), Kole et al. (2012) reported that treating patients with distal esophageal cancer using IMRT significantly decreased the exposure of the heart and right coronary artery when compared with 3D-CRT.

Chandra et al. (2005) studied 10 patients in a retrospective treatment planning study to evaluate the feasibility whether IMRT can be used to reduce doses to normal lung than three-dimensional conformal radiotherapy (3D-CRT) in treating distal esophageal malignancies. The authors noted that dose-volume of exposed normal lung can be reduced with IMRT, although clinical investigations are warranted to assess IMRT treatment outcome of esophageal cancers.

NCCN guidelines for esophageal cancer state that IMRT may be appropriate in selected cases to reduce dose to normal structures such as heart and lungs. Retrospective studies comparing 3D conformal versus IMRT for patients with esophageal cancer have generally shown superior dose conformity and homogeneity with IMRT and reduction of radiation dose to the lungs and heart (NCCN, Clinical Practice Guidelines in Oncology, Esophageal and Esophagogastric Junction Cancers 2014).

Head and Neck Cancer

An Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review of radiotherapy for head and neck cancer found that while IMRT is more successful than traditional radiation therapy in avoiding side effects, such as xerostomia (dry mouth), it is unknown whether IMRT is better or worse at reducing tumor size (Samson et al., 2010).

Nutting et al. (2011) assessed whether parotid-sparing IMRT reduced the incidence of severe xerostomia, a common late side-effect of radiotherapy to the head and neck. Ninety-four patients with pharyngeal squamous cell carcinoma were randomly assigned to receive IMRT (n=47) or conventional radiotherapy (n=47). The primary endpoint was the proportion of patients with grade 2 or worse xerostomia at 12 months. Median follow-up was 44.0 months. Six patients from each group died before 12 months and seven patients from the conventional radiotherapy and two from the IMRT group were not assessed at 12 months. At 12 months, xerostomia side-effects were reported in 73 of 82 patients. Grade 2 or worse xerostomia at 12 months was significantly lower in the IMRT group (38%) than in the conventional radiotherapy group (74%). The only recorded acute adverse event of grade 2 or worse that differed significantly between the treatment groups was fatigue, which was more prevalent in the IMRT group. At 24 months, grade 2 or worse xerostomia was significantly less common with IMRT than with conventional radiotherapy. At 12 and 24 months, significant benefits were seen in recovery of saliva secretion with IMRT compared with conventional radiotherapy, as were clinically significant improvements in dry-mouth-specific and global quality of life scores. At 24 months, no significant differences were seen between randomized groups in non-xerostomia late toxicities, locoregional control or overall survival. The authors concluded that sparing the parotid glands with IMRT significantly reduces the incidence of xerostomia and leads to recovery of saliva secretion and improvements in associated quality of life.

Fifty-one patients with early-stage nasopharyngeal carcinoma took part in a randomized controlled clinical study and received IMRT or CRT. The investigators found that IMRT was significantly better than CRT in terms of parotid sparing and improved QOL for early-stage disease (Pow et al., 2006).

Sixty patients with early-stage nasopharyngeal carcinoma (NPC) were randomly assigned to receive either IMRT or two-dimensional radiation therapy (2DRT). At 1 year after treatment, patients in IMRT arm had lower incidence of observer-rated severe xerostomia than patients in the 2DRT arm (39.3% v 82.1%). The investigators concluded that IMRT is superior to 2DRT in preserving parotid function and results in less severe delayed xerostomia in the treatment of early-stage NPC. Incomplete improvement in patient's subjective xerostomia with parotid-sparing IMRT reflects the need to enhance protection of other salivary glands (Kam et al., 2007).

Lee et al. (2006) compare toxicity and efficacy of conventional radiotherapy using delayed accelerated concomitant boost radiotherapy (CBRT) vs. IMRT in the setting of concurrent chemotherapy (CT) for locally advanced oropharyngeal carcinoma in 293 patients. In total, 41 were treated with IMRT/CT and 71 were treated with CBRT/CT. The investigators found that in the setting of CT for locally advanced oropharyngeal carcinoma, IMRT results in lower toxicity and similar treatment outcomes when compared with CBRT.

Fang et al. (2008) investigated the changes of quality of life (QOL) and survival outcomes for 203 newly diagnosed nasopharyngeal carcinoma (NPC) patients who were curatively treated by 3D-CRT (n = 93) or IMRT (n = 110). The 3-year locoregional control, metastasis-free survival and overall survival rates were 84.8%, 76.7% and 81.7% for the 3D-CRT group, respectively, compared with 84.2%, 82.6%, and 85.4% for the IMRT group. A general trend of maximal deterioration in most QOL scales was observed during radiotherapy, followed by a gradual recovery thereafter. There was no significant difference in most QOL scales between the 2 groups at each time point. The exception was that patients treated by IMRT had a both statistically and clinically significant improvement in global QOL, fatigue, taste/smell, dry mouth and feeling ill at 3 months after radiotherapy. The investigators concluded that the potential advantage of IMRT over 3D-CRT in treating NPC patients might occur in QOL outcome during the recovery period from the treatment.

Chen et al. (2007b) evaluated 127 patients with sinonasal carcinoma who underwent radiotherapy. Fifty-nine patients were treated by conventional radiotherapy; 45 patients by three-dimensional conformal radiotherapy; and 23 patients by IMRT. No differences in survival at 5 years follow-up were noted, but 3D-CRT had fewer side effects than conventional radiotherapy, and IMRT had even fewer side effects than 3D-CRT.

Rades et al. (2007) evaluated 148 head-and-neck cancer patients treated with surgery plus RT, IMRT, 3D-conformal RT, and conventional RT. The 3 radiation techniques had similar disease control and had similar toxicity profiles. IMRT was associated with less xerostomia than conformal RT and conventional RT (17% versus 63% and 73%).

A retrospective chart review was completed for 34 patients with pituitary adenomas who were treated with IMRT. With a median follow-up of 42.5 months, the treatment was well tolerated, with performance status remaining stable in 90% of patients. Radiographic local control was 89%, and among patients with secretory tumors, 100% had a biochemical response. One patient required salvage

surgery for progressive disease, giving a clinical progression free survival of 97% (Mackley et al., 2007).

NCCN guidelines for head and neck cancers state that IMRT or other conformal techniques may be used to treat head and neck cancers as appropriate depending on the stage, tumor location, physician training/experience and available physics support. IMRT has been shown to be useful in reducing long-term toxicity in oropharyngeal, paranasal sinus and nasopharyngeal cancers by reducing the dose to salivary glands, temporal lobes, auditory structures (including cochlea) and optic structures. The application of IMRT to other head and neck cancers is evolving and may be used at the discretion of the treating physicians (NCCN, Clinical Practice Guidelines in Oncology, Head and Neck Cancer 2014).

Pancreatic Cancer

Yovino et al. (2011) evaluated whether improved dose distributions from using IMRT resulted in decreased toxicity when compared to patients who received a similar 5-fluoruracil-based protocol with 3D conformal radiation in the RTOG 97- 04 trial. Forty-six patients with pancreatic/ampullary cancer were treated with concurrent chemoradiation (CRT) using IMRT. Rates of acute gastrointestinal (GI) toxicity for the IMRT treated patients were compared with those from RTOG 97-04, where all patients were treated with 3D conformal techniques. The overall incidence of Grade 3-4 acute GI toxicity was low in patients receiving IMRT-based CRT. When compared with patients who had 3D treatment planning (RTOG 97-04), IMRT significantly reduced the incidence of Grade 3-4 nausea and vomiting (0% vs. 11%) and diarrhea (3% vs. 18%). The authors concluded that IMRT is associated with a statistically significant decrease in acute upper and lower GI toxicity among patients treated with CRT for pancreatic/ampullary cancers. Future clinical trials plan to incorporate the use of IMRT, given that it remains a subject of active investigation.

Milano et al. (2004) assessed the efficacy and toxicity of IMRT in 25 patients with pancreatic and bile duct (cholangiocarcinoma) malignancies. Twenty-three received concurrent 5-fluoruracil. One patient with a pancreatic primitive neuroectodermal tumor received concurrent etoposide and ifosfamide. Eight patients had resected tumors, and 17 had unresectable primary (n = 14) or recurrent (n = 3) tumors. Six patients underwent treatment planning with conventional three-dimensional four-field techniques for dosimetric comparison with IMRT. Compared with conventional radiotherapy, IMRT reduced the mean dose to the liver, kidneys, stomach, and small bowel. IMRT was well tolerated, with 80% experiencing Grade 2 or less acute upper GI toxicity. At a median follow-up of 10.2 months, no resected patients had local failure, and only 1 of 10 assessable patients with unresectable cancer had local progression. The median survival and distant metastasis-free survival of the 24 patients with adenocarcinoma was 13.4 and 7.3 months, respectively. Grade 4 late liver toxicity occurred in 1 patient surviving >5 years. The remainder of the assessable patients experienced no (n = 9) or Grade 1 (n = 4) late toxicity. Local control was not compromised, despite efforts to increase conformality and avoid doses to normal structures.

NCCN guidelines for pancreatic adenocarcinoma state that IMRT with breathhold/gating techniques can result in improved planning target volume (PTV) coverage with decreased dose to OAR. IMRT is increasingly being applied for therapy of pancreatic adenocarcinoma in the adjuvant setting with the aim of increasing radiation dose to the gross tumor while minimizing toxicity to surrounding tissues.

There is no clear consensus on appropriate maximum dose of radiation when IMRT used (NCCN, Clinical Practice Guidelines in Oncology, Pancreatic Adenocarcinoma 2014).

Prostate Cancer

Bauman et al. (2012) conducted a systematic review of 11 studies evaluating IMRT in the treatment of prostate cancer. The findings were in favor of recommending IMRT over 3D-CRT in the radical treatment of localized prostate cancer where doses greater than 70 Gy are required. There was insufficient data to recommend IMRT over 3D-CRT in the postoperative setting.

Alicikius et al. (2011) investigated long-term tumor control and toxicity outcomes after IMRT in 170 patients with clinically localized prostate cancer. Primary outcomes were freedom from biochemical relapse, distant metastases and cause-specific survival. The median follow-up was 99 months. The 10-year relapse-free survival rates were 81% for the low-risk group, 78% for the intermediate-risk group and 62% for the high-risk group. The 10-year distant metastases-free rates were 100%, 94% and 90%, respectively. The 10-year cause-specific mortality rates were 0%, 3% and 14%, respectively. The 10-year likelihood of developing grade 2 and 3 late genitourinary toxicity was 11% and 5%, respectively, and the 10-year likelihood of developing grade 2 and 3 late gastrointestinal toxicity was 2% and 1%, respectively. No grade 4 toxicities were observed. The authors concluded that high-dose IMRT is well tolerated and is associated with excellent long-term tumor-control outcomes in patients with localized prostate cancer.

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.

Hummel et al. (2010) conducted a systematic review evaluating the clinical effectiveness of IMRT for the radical treatment of prostate cancer. IMRT was compared to three-dimensional conformal radiotherapy (3DCRT) or radical prostatectomy. No randomized controlled trials (RCTs) of IMRT versus 3DCRT in prostate cancer were available, but 13 non-randomized studies were found, of which five were available only as abstracts. The comparative data seem to support the theory that higher doses, up to 81 Gy, can improve biochemical survival for patients with localized prostate cancer. The data also suggest that toxicity can be reduced by increasing conformality of treatment, particularly with regard to GI toxicity, which can be more easily achieved with IMRT than 3DCRT. The authors note that the strength of the conclusions of this review are limited by the lack of RCTs, and any comparative studies for some patient groups.

Al-Mamgani et al. (2009) compared the acute and late gastrointestinal (GI) and genitourinary (GU) toxicity in 78 prostate cancer patients treated with either a three-conformal radiotherapy technique with a sequential boost (SEQ) or a simultaneous integrated boost using intensity modulated radiotherapy

(SIB-IMRT). All patients were treated to a total dose of 78 Gy. A significantly lower incidence of acute Grade 2 or greater GI toxicity occurred in patients treated with SIB-IMRT compared with SEQ. For acute GU toxicity and late GI and GU toxicity, the incidence was lower after SIB-IMRT, but these differences were not statistically significant. The authors found that SIB-IMRT reduced the toxicity without compromising the outcome in patients with localized prostate cancer treated to 78 Gy radiation.

Several prospective studies by the same group of investigators reported excellent clinical outcomes with acceptable toxicity when using IMRT to treat prostate cancer (Zelefsy et al., 2001, 2002, 2006; Spratt et al., 2013).

Jani et al. (2007) compared acute genitourinary (GU) and gastrointestinal (GI) toxicity results of radiotherapy using IMRT versus conventional radiotherapy. The records of 481 consecutive prostate cancer patients receiving radiotherapy to localized fields at a single institution were reviewed; 108 received IMRT and 373 received conventional radiotherapy. The investigators found that IMRT was not associated with reduction of acute GU toxicity but was associated with a reduction of acute GI toxicity over conventional radiotherapy in the treatment of prostate cancer to localized fields.

ACR Appropriateness Criteria recommend that IMRT is usually appropriate for treating prostate cancer (ACR, 2011).

NCCN states that highly conformal radiation therapy, such as IMRT, should be used to treat prostate cancer. IMRT significantly reduces the risk of gastrointestinal toxicities and rates of salvage therapy without increasing side effects. Moderately hypofractionated image-guided IMRT regimens have been tested in randomized trials reporting similar efficacy and toxicity to conventionally fractionated IMRT. They can be considered as an alternative to conventionally fractionated regimens when clinically indicated. Daily prostate localization using IGRT is essential for target margin reduction and treatment accuracy. Imaging techniques, including ultrasound, implanted fiducials (an object placed in the field of view of an imaging system for use as a point of reference), electromagnetic targeting and tracking or endorectal balloon can be helpful in improving cure rates and minimizing complications (NCCN, Clinical Practice Guidelines in Oncology, Prostate Cancer 2014).

In a 2007 guideline for prostate cancer, the American Urological Association (AUA) stated that the advent of IMRT and image guidance radiotherapy either with transabdominal ultrasound or the intraprostatic placement of fiducial markers further refined radiation treatment delivery. The resulting dose accuracy and escalation provide proven improvements in local tumor elimination and reduction in late radiation-related complications (AUA, 2007; validity confirmed 2011).

Continuous Localization and Tracking

Noel et al. (2009) evaluated whether pre- and post-treatment imaging (immediately before and after a radiation therapy treatment fraction) and intermittent imaging (at intervals during a treatment fraction) are accurate predictors of prostate motion during the delivery of radiation. The Calypso 4D Localization System was used to continuously track the prostate during radiation delivery in 35 prostate cancer patients, for a total of 1,157 fractions (28-45 per patient). The results of the study suggested that pre- and post-treatment imaging is not a sensitive method of assessing intra-fraction prostate motion, and that intermittent imaging is sufficiently sensitive only at a high sampling rate.

According to the investigators, these findings support the value of continuous, real-time tracking in prostate cancer radiation therapy.

Quigley et al. (2009) evaluated the accuracy and usefulness of the Calypso 4D Localization System and Beacon transponders to continuously monitor tumor location and movement during external beam radiation therapy of the prostate. This clinical trial studied 43 patients at 5 sites. According to the study investigators, the Calypso System permits clinicians to intervene when the prostate moves outside the radiation isocenter, which should decrease adverse events and improve patient outcomes.

Combined Therapies
No evidence was identified in the clinical literature supporting the combined use of IMRT and proton beam radiation therapy in a single treatment plan.

Professional Societies
American College of Radiology (ACR)/ American Society for Radiation Oncology (ASTRO)
In a joint guideline, ACR and ASTRO state that IMRT has become widely used for a variety of clinical indications, such as tumors of the central nervous system, head and neck, breast, prostate, gastrointestinal tract and gynecologic system, as well as sites previously irradiated. In general, the ability of IMRT to deliver dose preferentially to target structures in close proximity to OAR and other non-target tissues makes it a valuable tool enabling the radiation oncologist to deliver dose to target volumes while minimizing dose to adjacent normal tissues. Successful IMRT programs involve integration of many processes: patient selection, patient positioning/immobilization, target definition, treatment plan development and accurate treatment delivery. Appropriate quality assurance (QA) procedures, including patient specific QA measures, are essential for maintaining the quality of an IMRT program and assuring patient safety (ACR/ASTRO, 2011; amended 2014).

American Society for Radiation Oncology (ASTRO)
ASTRO considers IMRT standard of care for the following sites: anus, central nervous system, nasopharynx, oropharynx, hypopharynx, larynx (except for early true vocal cord cancer) and prostate (ASTRO, 2013).

ASTRO considers IMRT reasonable in instances where sparing the surrounding normal tissue is of added clinical benefit to the patient (ASTRO, 2013). Examples of when IMRT might be advantageous include the following:

- The target volume is in close proximity to one or more critical structures and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).
- A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose “hotspot” within the treated volume to avoid excessive early or late normal tissue toxicity.
- A non-IMRT technique would substantially increase the probability of clinically meaningful normal tissue toxicity.
- The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

The FDA has approved a number of devices for use in IMRT, See the following website for more information (use product codes MUJ and IYE): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed August 2015.

The Calypso 4D Localization System is regulated by the FDA as a component of a medical linear accelerator. This device received FDA 510(k) approval on July 28, 2006 as an adjunct to radiation therapy in patients who have undergone permanent implantation of at least two Beacon transponders. See the following Web site for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf6/K060906.pdf. Accessed August 2015.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and/or 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; 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 (eg,3d positional tracking, gating, 3d surface tracking), each fraction of treatment

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PROTOCOL HISTORY/REVISION INFORMATION

Date	Action/Description
08/27/2015 02/26/2015 07/24/2014 12/19/2013 04/25/2013 01/24/2013 04/26/2012 10/27/2011 04/28/2011 10/28/2010 11/20/2009	Corporate Medical Affairs Committee

The foregoing Health Plan of Nevada/Sierra Health & Life Healthcare Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.

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JOURNAL OF CLINICAL ONCOLOGY

CORRESPONDENCE

Future of Protons Depends on Precision

TO THE EDITOR: In her editorial in *Journal of Clinical Oncology*, Kong[1] thoughtfully comments on our randomized phase II trial that compared protons (passively scattered proton therapy [PSPT]) with photons (intensity-modulated photon radiotherapy) for lung cancer.[2] Her closing remarks shed light on the prospects for future randomized studies to one day measure the clinical advantages of proton therapy, which have remained largely theoretical, although progress is being made.

Many clinical trialists have argued that the technologies used in our study limited the opportunity to take advantage of proton therapy's potential. When we initiated the study in 2009, proton therapy, especially for lung cancer, was in its infancy; the state of the art at that time involved the use of PSPT (as opposed to the current-day availability of intensity-modulated proton therapy [IMPT] delivered with scanning beams of protons). Moreover, greater sensitivity of protons to motion and anatomic changes, inherent uncertainty in the range of protons, and the lack of in-room volumetric image guidance to confirm that the treatments delivered matched the treatments planned required the use of relatively large margins. Other factors that undoubtedly influenced the outcomes were the use of a constant relative biologic effectiveness (RBE) value for protons, when in reality, the RBE is variable and considerably higher near the end of the range of protons[3-5]; the evolution of knowledge and its translation (the learning curve) over the course of the trial; and the frequent insurance denials for proton therapy.

Kong states that the trial results suggest that proton therapy has a dismal future for lung cancer. However, she also writes (and we agree), that there is ample reason to believe that the clinical advantages of proton therapy, which continues to evolve technologically, may one day be demonstrated through clinical trials that take advantage of these contemporary developments. With consideration of the challenges involved in conducting our trial, and the state of the technology and knowledge at the time it began, we find it encouraging that the rates of radiation pneumonitis and local failure were similar in both arms and to other reports. Intensity-modulated photon radiotherapy is a mature technology. The use of PSPT, on the other hand, is now known to result in inferior dose distributions compared with what is currently available. For readers who may be unfamiliar with recent milestones, most modern-day proton therapy no longer uses PSPT but rather scanning pencil beams of a range of energies that are manipulated electromagnetically, which allows more degrees of freedom for designing dose distributions than were possible with PSPT. Use of IMPT in which intensities of pencil beams are optimized by using sophisticated mathematical techniques allows tighter conformality of the radiation to the tumor, significant reduction in dose to nearby organs at risk, and minimization of the low-dose bath, which would reduce radiation-induced toxicity further.

The take-home message from our trial is that continuing improvements in technology and knowledge will enhance the clinical benefit of protons significantly. We now routinely evaluate the robustness of proton plans to test the resilience of proton dose distributions in the face of physical uncertainties. We and others have made significant strides in developing and implementing robust and variable RBE-weighted dose optimization for IMPT that render dose distributions more resilient and direct protons with higher biologic effectiveness to the target and away from critical normal tissues. Moreover, ongoing research in applying artificial intelligence techniques to treatment plan optimization will greatly diminish the effect of insufficient experience and expertise and maximize the potential of proton therapy.

The dosimetric advantages of proton therapy are real, but as Kong points out, clinicians, payers, and policymakers will continue to rely on successfully completed randomized clinical trials to know that the clinical benefits of proton therapy that are possible with ongoing research and development outweigh the costs. Only then will we know that the added burden of maintaining a proton therapy center is justified.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at jco.org.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Future of Protons Depends on Precision

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Status: Approved

RADIATION ONCOLOGY IMRT PLANNING NOTE

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Patient Name: **William G Eskew**
Medical Record #: **1195025**
Treatment Plan #:

Diagnosis / Tx Site: Squamous cell carcinoma, NOS Right Malignant neoplasm of upper lobe, unspecified bronchus or lung [C34.10

IMRT PLANNING is used for this patient since it achieves a better plan than with Conventional or Three-dimensional treatment planning. [Justification for IMRT must be based on at least one of the following conditions. Document all that apply and provide patient specific detail below]

✓ Dose limiting structures outside of the primary tumor volume are so close that they require IMRT to assure safety and morbidity reduction. (Include at least three critical structures)

Esophagus Heart Lung

✓ 4DCT Only

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 structure 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.

RADIATION ONCOLOGIST'S STATEMENT: "I reviewed the relevant data, studied various options for treatment and approved the final treatment plan."

* - ICD-9 Diagnosis

Patient Radiation Prescription
Tagged

Patient: Eskew, William G. **MR#: 1195025**

Diagnosis: 7/23/2015 Clinical Stage IV Right
Malignant neoplasm of upper lobe, unspecified bronchus or lung — Squamous cell carcinoma, NOS
Mets: BONE

Course: 1 Care Plan:

Rx Site: RUL Status: Pending
Technique: Protons
Modality: Proton
Dose Spec:

Start this site at fraction 1 of site RUL tumor and MD nod

Rx Dose	Rx BED	Fractional Dose	Fx BED	Number of Fractions	Fractionation Pattern
0 cGy	**0 CcGE**	**0 cGy**	**0 CcGE**		**Daily**

Pattern comment:

Comment: CT sim

Proton Plan

Status Date: N/A
Approved By: N/A
Status: Pending

RADIATION ONCOLOGY PROTON TREATMENT PLANNING NOTE

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center Proton Therapy

Patient Name: **William G Eskew**
Medical Record #: **1195025**
Treatment Plan #: **APD_ZXL**

Diagnosis / Tx Site: Squamous cell carcinoma, NOS Right Malignant neoplasm of upper lobe, unspecified bronchus or lung [C34.10

Proton Therapy is medically necessary for this patient since it achieves a better plan than with conventional photon 3D or IMRT treatment planning. [Justification for PROTON must be based on at least one of the following conditions. Document all that apply and provide patient specific detail below]

✓ The volume of interest is in such a location that its parameters cannot be clearly identified under conventional simulation techniques and can only be defined by MRI, CT, or other special diagnostic studies.

CT scan is required to delineate the target volumes

✓ The volume of interest is irregular and in close apposition to normal structures that must be protected. (Please list the normal structures)

Brachial Plexus Esophagus Heart

✓ 4DCT Only

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 structure 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.

RADIATION ONCOLOGIST'S STATEMENT: "I reviewed the relevant data, studied various options for treatment and approved the final treatment plan."

RADIATION ONCOLOGY IMRT PLANNING NOTE

THE UNIVERSITY OF TEXAS
MD Anderson ~~Cancer~~ Center

Patient Name: **William G Eskew**

Medical Record #: **1195025**

Treatment Plan #:

Diagnosis / Tx Site: Squamous cell carcinoma, NOS Right Malignant neoplasm of upper lobe, unspecified bronchus or lung [C34.10

IMRT PLANNING is used for this patient since it achieves a better plan than with Conventional or Three-dimensional treatment planning. [Justification for IMRT must be based on at least one of the following conditions. Document all that apply and provide patient specific detail below]

✓ Dose limiting structures outside of the primary tumor volume are so close that they require IMRT to assure safety and morbidity reduction. (Include at least three critical structures)

Esophagus Heart Lung

✓ 4DCT Only

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 structure 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.

RADIATION ONCOLOGIST'S STATEMENT: "I reviewed the relevant data, studied various options for treatment and approved the final treatment plan."

Radiotherapy and Oncology 86 (2008) 154—164
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Systematic review

Proton therapy in lung cancer: Clinical outcomes and technical issues. A systematic review

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ATreP — Provincial Agency for Proton Therapy, Trento, Italy

Abstract

***Background and purpose*. To determine whether, according to the currently available literature, proton therapy (PT) has a role in the treatment of non-small-cell lung cancer (NSCLC), to assess its safety and efficacy and to evaluate the main technical issues specifically related to this treatment technique. *Materials and methods*. During March 2007, two independent researchers conducted a systematic review of the current data on the treatment of NSCLC with PT. *Results*. In total, 113 reports were retrieved, 17 of which 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, with results comparable to those obtained with surgery, without significant toxicity. In addition, two papers were found that compared photon and proton dose distributions, which showed a potential for dose escalation and/or a sparing of the organ at risk with PT. Finally, six studies analyzed dosimetric and technical issues related with PT, mainly underlining the difficulties in designing dose distributions that are representative of the dose actually delivered during treatment. *Conclusions*. Although from a physical point of view PT is a good option for the treatment of NSCLC, 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 therefore not possible to draw definitive conclusions about the superiority of PT with respect to the photon techniques currently available for the treatment of NSCLC.**
 Radiotherapy and Oncology 86 (2008) 154—164.

Keywords: Systematic review; NSCLC; Proton therapy; Evidence-based-medicine

Lung cancer is estimated to be the primary cause of cancer-related death worldwide and the second most commonly diagnosed cancer in both men and women in 2006 [1]. The number of new cases (of which 75—85% are represented by non-small-cell lung cancers (NSCLC)) is increasing at an annual rate of about 3%. Despite the advances in detection and treatment, the overall 5-year survival still remains very poor, particularly in advanced stages [2,3].

Radiation therapy delivered with X-rays (XRT) plays a fundamental role in the treatment of NSCLC, either as a definitive treatment of medically inoperable or surgically unresectable disease or as part of a multimodality regimen (with chemotherapy and/or surgery) for locally advanced lesions [4—6]. A major problem for NSCLC patients treated with XRT continues to be local-regional failure, with the majority of patients still dying of the disease [5,7,8]. During the last 10 years there have been several technical advances in thoracic XRT that could allow radiation dose escalation [9—11]. Three-dimensional radiotherapy (3D-CRT), with or without chemotherapy, currently represents the most common therapeutic practice, while more sophisticated treatment techniques, such as intensity-modulated radiation therapy (IMRT) and hypofractionated stereotactic irradiation (with and without respiratory gating), are now under evaluation for selected patient subcategories [12—17].

Proton therapy (PT), i.e. radiotherapy delivered with high-energy proton beams, is now rapidly becoming a treatment option for more and more patients, after years of pioneering work carried out in a few centers around the world.

In principle, with PT it should be possible to design and deliver better dose distributions than with photons, thus allowing a possible improvement of the clinical results. The theoretical advantages offered by the physical properties of protons might make PT particularly useful for patients with limited residual pulmonary function, with large and irregular tumor shape, or for those who are treated with concurrent chemotherapy. However, it is worth to note that PT has some particular physical/technological factors that may compromise this theoretical gain at least in part [18—23]. For instance, the dose distributions achievable with protons are very sensitive to the changes in radiological depths along the beam path; in lung, due to respiration and the presence of different tissues density this issue must be carefully considered.

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The clinical benefit of PT in the treatment of NSCLC has not been assessed in depth so far: only very recently, after the data collection for our study, three systematic reviews on PT in clinical oncology considered this topic without reaching a clear conclusion about its efficacy in comparison to other irradiation modalities [24–26].

The aim of our study was to perform a systematic review of the scientific literature concerning the application of PT to NSCLC, giving a summary of the clinical experience gathered so far, and reporting treatment planning studies comparing protons with photons with technical considerations.

For a complete evaluation of their possible significance, it will be important to underline the quality, the external validity and the utility of the analyzed studies.

The systematic review of the results of other types of particle therapy (carbon ions) or recently available XRT modalities (e.g. tomotherapy, cyberknife, stereotactic irradiation) is beyond the scope of this paper.

Materials and methods

Two independent researchers, plus one to settle the disputes as suggested by NHS report on systematic review [27], searched the PubMed database through March 2007 to identify studies about lung cancer and PT published in the last 10 years. Search terms used included, *proton, therapy*, and *lung*; the search was limited to articles in English. Reference lists of key articles were screened for additional articles. Studies were included if they reported clinical outcomes of patients treated with PT for NSCLC. Studies were also included if they reported results of treatment planning (dose-volume histograms, tumor control probabilities, etc.) or if they addressed technical issues related to PT treatment planning in lung. Review articles were excluded.

Results

In total 113 reports were retrieved from the initial PubMed and reference lists search. As a result of the abstracts reading, 92 studies were excluded because they did not fit with the inclusion criteria and four because they were review papers. There was no discrepancy between the two reviewers. Out of the remaining 17 studies complying with inclusion/exclusion criteria, four clinical trials were related to initial reports updated in the next publications; we are going to consider only the latest publication in our review.

As schematically reported in Fig. 1, in the end 13 articles were available: five were related to clinical results, two to treatment planning data, and six to technical/dosimetric considerations.

Clinical results

Clinical results about PT in NSCLC have been reported by three Institutions: the Loma Linda University Medical Center (LLUMC, Loma Linda, CA, USA) [28,29], the Proton Medical Research Center (PMRC, Tsukuba, Japan) [30,31], and the National Cancer Center Hospital East (NCCHE, Chiba, Japan) [32] updated in a series of further reports. Two reports, the first series of Tsukuba [30] and the first report of LLUMC [28], refer to a heterogeneous patient population (stage I–IV and recurrences), the others are restricted only to limited stage disease (stage IA–IB).

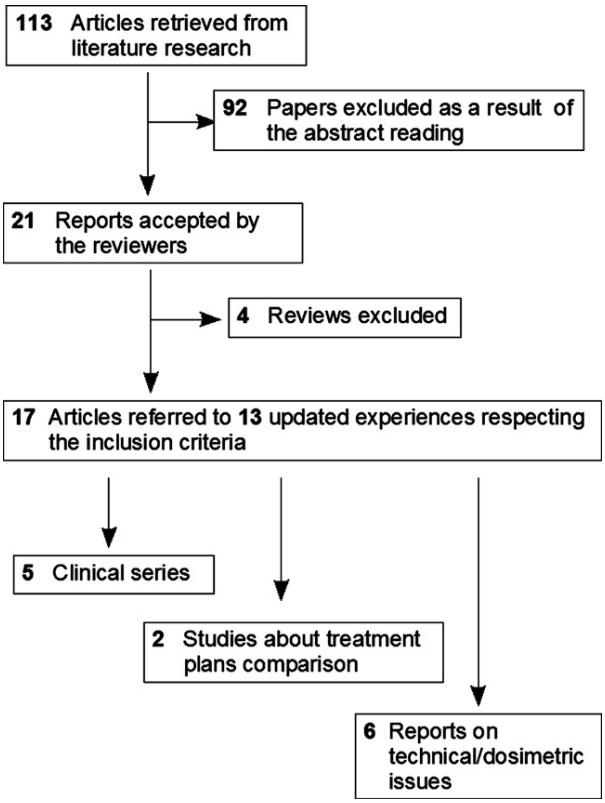

Fig. 1. Articles considered in the systematic review.

In total, 214 patients were treated: 181 with early-stage diseases and 33 with more advanced lesions with a median follow-up of 14–30 months.

Early stages

The patients with limited disease were not candidate for surgical resection, either because they were medically inoperable, or because they refused surgery. Three studies are completely devoted to patients in early stage [29,31,32]. In the study of Bush et al. [29] 68 patients with clinical stage I (T1 29, T2 39) were treated with two hypofractionated schemes of 51 CGE in 10 fractions or 60 CGE in 10 fractions, in 2 weeks (where CGE = proton Gy × 1.1). A 3-year local control of 74% with disease-specific survival of 72% was obtained, with a better control rate for T1 (87%) in comparison with T2 (49%). Acute toxicities were limited to mild fatigue and radiation dermatitis (mild-to-moderate erythema, not requiring treatment). No cases of radiation pneumonitis were observed. The study of Hata et al. [31] refers to 21 patients with stage IA (11 cases) or IB (10 cases) treated with a total dose of 50–60 Gy at a dose per fraction of 5–6 Gy (10-fractions) in a median of 15 days. A 2-year local control and cause-specific survival of 95% and 86%, respectively, was observed; no toxicities of grade 3–5 occurred (according to RTOG/EORTC morbidity scoring criteria). Nihei et al. [32]

treated 37 patients with stage IA (17 cases) and IB (20 cases) in a dose escalation study at total dose levels of 70–94 CGE with dose per fraction of 4–4.9 CGE obtaining a local control rate of 80%. Three cases of grade 3 late pulmonary toxicity (according to RTOG/EORTC radiation morbidity scoring scheme) were observed.

Advanced cases

The experience in patients with more advanced disease is more limited. In the study of Shioyama et al. [30] 14 patients with advanced stages (III, IV, recurrent disease) were treated. The short-term results (overall survival and cause-specific survival at 2 years) of the patients with stage III–IV (9 patients) were 62% and 70%, and of the recurrences (5 patients) were 80% and 100%, respectively. Long-term results (overall survival and cause-specific survival at 5 years) were both 0% for stage III/IV and 40% and 50%, respectively, for recurrences. In the initial experience of Bush et al. [28], 8 cases with stage IIIA were treated: 2-year overall survival and disease-free survival rates were 13% and 19%, respectively.

The details of the studies are reported in Tables 1 and 2.

Plan comparison studies

Two papers were analyzed comparing photon and proton dose distributions:

(1) Lee et al. [33] compared maximum prescription doses achievable with 3D-CRT vs. PT delivered with passive scattering, for a given set of constraints for the normal tissues. Neither dose-volume histograms (DVH) nor 2D dose distributions were shown in the article. For 5 out of 13 patients the proton technique was the only allowing dose escalation up to 90 Gy. However, 4 out of 13 patients could not be treated either with protons or with photons, even at a prescription dose of only 60 Gy.

(2) Chang et al. [34] compared the dose distributions obtained with photons (3D-CRT and IMRT) with those delivered with passive scattering PT at different dose levels in the PTV for 25 cases (10 stage I and 15 stage III).

For stage I lesions and a prescription dose of 66 Gy (66 CGE), PT did allow a 19%, 13% and 6% reduction in the mean values of lung V5, V10, and V20, respectively, compared to 3D-CRT. When, for the same patients, the prescribed dose was increased to 87.5 Gy (87.5 CGE) PT improved the same volume parameters by 21%, 16%, and 8% with respect to 3D-CRT.

For stage III tumors and a prescription dose of 63 Gy, the mean values of V5, V10, and V20 decreased by 15%, 11% and 5%, respectively, using PT. At a prescription dose of 74 Gy, the same values were reduced with PT by 18%, 14% and 8%, respectively (Table 3).

Finally, IMRT was used for a subgroup of 5 selected stage III patients with minimal tumor motion. For a prescribed dose of 60–63 Gy (60–63 CGE), the mean values of V5, V10, and V20 in the lung were reduced by 15%, 8% and 4%, respectively, with PT compared to IMRT. When the prescribed dose was set to 74 Gy (74 CGE), the same values decreased by 17%, 10% and 4% (Table 3).

Details were provided about the sparing for the other organs at risk (OARs) with PT, but no particulars were pro-

Table 1
Studies and patient characteristics

Reference	Country and period	Type of study	Selection criteria	No. of patients	Gender, median age (range)	P.S.	Stage	Histology	Median follow-up (range)
Shioyama et al. [30]	Japan 1983–2000	Single Institution	Medically inoperable or refusing surgery	51	M 43, F 8 74 years (25–87)	Swiss 0: 13, 1: 30, 2–3: 8	I: 28, II: 9, III: 8, IV: 1, recurrent disease: 5	SCC: 33, adenoca.: 17, large cell: 1	30 (18–153) months
Hata et al. [31]	Japan 2002–2005	Single Institution phase II study	Medically inoperable or refusing surgery	21	M 16, F 5 74 years (51–85)	ECOG 0–2	IA: 11, IB: 10	SCC: 6, adenoca.: 14, large cell: 1	25 (10–54) months
Bush et al. [28]	USA 1994–1998	Single Institution phase II study	Not candidate for surgical resection or patient refusal	37	M 15, F 22 72 years (54–87)	Karnofsky: 50–70: 17 80–100: 20	I: 27, II: 2, IIIa: 8	NSCLC	14 (3–45) months
Bush et al. [29]	USA nr	Single Institution phase II study	Medically inoperable or refusing surgery	68	M 30, F 38 72 years (52–87)	Karnofsky: mean 65 (50–90)	T1 29, T2 39	NSCLC	30 months
Nihei et al. [32]	Japan 1999–2003	Single Institution phase I dose escalation study + phase II	Medically inoperable or refusing surgery. Tumor size $\leqslant$ 5 cm; $pO_2 \geqslant 60$ torr	37	M 30, F 7 75 years (63–87)	Zubrod: 0–2	IA 17, IB 20	SCC: 15, adenoca: 15, others: 7	24 (3–62) months

Abbreviations: SCC, squamous cell carcinoma; adenoca, adenocarcinoma; NSCLC, non small cell lung cancer; M, male; F, female; P.S., performance status; OS, overall survival; LC, local control; nr, not reported.

Table 2
Treatment details

Reference	Treatment regimens	Proton beam delivery	Technical notes	Treatment effects/ outcome	Toxici
Shioyama et al. [30]	TD: 49–93 Gy (median 76) dpf: 2.0–6.0 Gy (median 3.0) Overall treatment time 10–76 days (median 43) 33 pts. PT only, 18 pts. XRT + PT	Passive scattering Energy: 250 MeV	CT slices every 5 mm CTV: GTV + 5–10 mm PTV: CTV + 5 mm + some mm caudally; resp. gating after 1992	5-year OS: 29%, 70% (st. IA), 16% (st. IB); 5-year CSS: 47% 5-year LC: 89% (st. IA), 39% (st. IB); in-field recurrence: 1/9 (st. IA), 6/19 (st. IB)	Acute 92% G 6% Gr 2% Gr
Hata et al. [31]	TD: 50 Gy (3 pts.) dpf: 5 Gy TD: 60 Gy (18 pts.) dpf: 6 Gy Overall treatment time 13–19 days (median 15)	Passive scattering Energy: 155–200 MeV	Body cast, resp. synchronized CT slices every 5 mm, CTV: GTV + 5 mm, PTV: CTV + 5 mm + 5 mm caudally for resp. movement, resp. gating	CR: 66% (14/21 pts.) 2-year OS: 74%, 2-year CSS: 86%, 2-year LC: 95%, 2-year DFS: 79%, In-field recurrence: 1 (st. IB)	Acute skin G lung G hemat Gr. 1– Late t Soft t 2: 2
Bush et al. [28]	First arm: TD: 51 CGE in 10 fr. over 2 weeks : (19 pts.); second arm: 73.8 CGE with 45 Gy in 25 fr. (XRT) + 23.8 CGE in 16 fr. (PT) over 3 weeks – concomitant boost: (22 pts.)	Passive scattering 250 MeV	Target: XRT: mediastinum, PT: GTV + margin for tumor motion evaluated during normal respiration with fluoroscopy, tipically 3 beams with PT	35 pts evaluable, 3-year LC: 74%, 2-year DFS: 63% 86% (st. I), 19% (st. III) 2-year LC 87% 2-year OS: 44% 39% (st. I), 13% (st. III)	2 pneu (photo proton Severa esoph (photo proton
Bush et al. [29]	TD: 51 CGE in 10 fr. over 2 weeks : (22 pts.); 60 CGE, in 10 fr. over 2 weeks: (46 pts.) No nodal irradiation	Passive scattering 250 MeV	Full body immobilization device, Fluoroscopy to evaluate target motion, Target: CTV (CT) + margin, 3–4 beams	68 pts evaluable, 3-year LC: 74%, T1:87%, T2: 49% DSS: 72%, 3-year OS: 44%	Mild f mild t moder erythe No pneum esoph cardia
Nihei et al. [32]	TD 70–94 CGE, phase I dose levels: 70/80/88/94, dpf: 4–4.9 CGE	Passive scattering Energy: 150–190 MeV	CT images exhalation free, CTV: GTV + 8 mm, PTV: CTV + 10 mm, resp. gating, 2–4 portals	2-year LC: 80% 2-year OS: 84% 2-year LRRFS 79% (st. IA), 60% (st. IB)	Late C 3 puln tox. ir each.

Abbreviations: TD, total dose; dpf, dose per fraction; fr., fraction; PT, proton therapy; XRT, X-ray radiation therapy; Gy, Gray; tox., toxicity; CGE, cobalt Gray equivalent computerized tomography; CTV, clinical tumor volume; GTV, gross tumor volume; PTV, planning tumor volume; resp., respiratory; DSS, disease-specific survival; st., stage; survival; DFS, disease-free survival; gr., grade; OS, overall survival; CSS, cause specific survival; pts., patients; LC, local control; CR, complete response.

Table 3
PT vs 3D-CRT and IMRT

	Prescription	V5 ± SE	V10 ± SE	V20 ± SE
Stage I (10 pts.)				
3D-CRT	66 Gy	31.8% ± 4.0	24.6% ± 3.5	15.8% ± 2.1
PT	66 CGE	13.0% ± 1.5	11.7% ± 1.4	9.8% ± 1.3
3D-CRT	87.5 Gy	34.5% ± 4.3	27.8% ± 3.7	19.3% ± 2.5
PT	87.5 CGE	13.4% ± 1.5	12.3% ± 1.4	10.9% ± 1.4
Stage III (10 pts.)				
3D-CRT	63 Gy	54.1% ± 3.3	46.9% ± 2.6	34.8% ± 1.5
PT	63 CGE	39.1% ± 1.4	35.6% ± 1.2	30.0% ± 1.3
3D-CRT	74 Gy	58.1% ± 5.0	50.9% ± 4.3	39.9% ± 1.9
PT	74 CGE	39.7% ± 1.4	36.6% ± 1.2	31.6% ± 1.2
Stage III (5 pts.)				
IMRT	60-63 Gy	58.5% ± 2.9	45.3% ± 2.1	34.5% ± 2.2
PT	60-63 CGE	43.1% ± 4.0	37.0% ± 1.8	30.8% ± 1.5
IMRT	74 Gy	61.5% ± 3.4	49.0% ± 2.3	37.1% ± 2.3
PT	74 CGE	44.0% ± 4.1	39.3% ± 2.5	33.3% ± 1.5

Abbreviations: 3D-CRT, three-dimensional conformal radiation therapy; IMRT, intensity-modulated radiotherapy; PT, proton therapy; CGE, cobalt Gray equivalent; SE, standard error; pts., patients [34].

vided about the PTV coverage (e.g. minimum dose). Only in Chang's paper, a 4D-CT study was performed for all patients to allow consideration of tumor motion in planning.

Technical issues

Six articles were found dealing with physical and/or technological issues related to the use of PT for NSCLC [18—23].

Moyers et al. [18] evaluated three planning strategies with different aperture and distal margin definitions to determine which method could best provide adequate tumor coverage. They proposed that inclusion of target motion, range and set-up uncertainties into a plan should be performed separately for each beam direction. Instead of creating one single PTV, a 'beam-direction-based' protocol should be considered, in order to take correctly into account the effect of proton range uncertainty. In other words, for every beam direction specific 'safety volume' must be created, that takes into account the possible dosimetric effect of geometric uncertainties for that specific beam direction. As a consequence, they argued that the PTV concept (as specified in ICRU 62 [35]) can be used only to determine the lateral margins of beams and in general is of limited usefulness in proton therapy.

Similarly, Engelsman et al. [21,22] showed the inappropriateness of a purely geometric PTV definition, also underlining the need of a time-resolved density information, because of the pronounced density differences between tumor and surrounding lung tissue. They studied the effect of the so-called 'smearing' and aperture sizes on several combinations of systematic errors and breathing motions. Smearing (i.e. the procedure by which the range compensator is modified in such a way that target coverage is ensured also in presence of small range uncertainties) has the potential to compensate for respiration-induced density variation, but after smearing, the dose distribution is not as conformal as expected, leading to increased dose in healthy lung.

Paganetti et al. [19] applied 4D Monte Carlo simulation (based on 4D CT data sets) to analyze the impact of a 2-cm amplitude breathing motion on the GTV and CTV dose distributions, when PT was delivered with passive scattering. Unexpectedly, for the case analyzed, breathing motion actually reduced the heterogeneity in target dose, resulting in a dose distribution within the GTV and CTV more homogeneous than in the planned ('static') dose distribution. The 4D Monte Carlo was then used by the same authors [20] to evaluate the benefit of 're-painting' (i.e. delivering a fraction dose by rescanning the target several times) a beam in intensity-modulated PT (IMPT). In scanning, because of the delivery technique, interplay effects may occur with respiration that are non-existent in treatments with scattered beams. They simulated different respiratory amplitude and reported that a four times repainting can compensate at least in part the effects of a 1.5 cm GTV motion.

Like Engelsman et al. [22], also Kang et al. [23] studied four alternative proton planning strategies using a single CT dataset derived from a set of 4D-CT images of ten patients, to evaluate the 'actual' (cumulative) dose distributions compared to the 'apparent' dose distribution designed on a single CT dataset. Free breathing (FB), average (AVE) CT, maximum intensity projection (MIP) and average replacement of the internal gross tumor volume (AVE_RIGTV) strategies were considered. For each strategy, the resulting cumulative dose distribution in a respiratory cycle (10 phases) was evaluated using a deformable image registration method.

The MIP approach was rejected because it showed unacceptably poor 4D target coverage and less sparing of normal tissues than the other planning strategies. The FB and AVE plans generally needed a larger smearing parameter (2.5 cm), which resulted in improved target coverage, but the dose to normal tissues increased as well. Only the AVE_RIGTV plans obtained better 4D dose coverage than apparent dose coverage for the PTV, and critical structures sparing, for all patients involved with a moderate smearing parameter (1 cm).

Discussion

Owing to very limited clinical data available and to the fast technical evolution in PT, we analyzed all the evidences that can be found in the literature concerning the use of PT in lung tumors. This includes studies dealing with planning comparisons and with technical issues that must be addressed to translate in clinical practice the theoretical gain available with PT.

On a general point, we embrace Lodge's et al. proposal [24] to introduce an International Hadron Therapy Register, which would also render more uniform and comparable the results obtained from the various participating centers. This also recalls Olsen et al.'s ''concerted effort'' idea [25].

Nevertheless, it is important to stress the different 'weight' of the studies reported and to clearly distinguish between reasonable hypothesis and clinical evidence. As showed in the clinical results, no randomized clinical trials involving PT in lung cancer are available. Direct clinical comparison between PT and other modern irradiation modalities (such as stereotactic body radiation therapy (SBRT), for early-stage tumors) or between PT and IMRT (for more advanced lesions) is missing. Moreover, plan comparisons and technical studies surely provide useful information, but by nature they cannot provide solid information about the actual clinical gain.

Clinical outcome

Clinical results with PT in NSCLC have been reported by three institutions only (LLUMC, PMRC, and NCCHE) [28–32,36] with patient characteristics, treatment modalities, and results updated in subsequent reports.

All the clinical reports are phase I or I–II studies using escalated/accelerated PT including a limited number of patients treated in a period of time of some years with different techniques and schedules. The articles of the Tsukuba group [30,31] were preceded by a short report regarding the first 14 patients treated as a feasibility test [36]. The reports of LLUMC [28,29] are also corroborated by some studies related to the effects of protons as assessed with radiologic imaging [37], pulmonary function tests [38] and biologic values [39].

Early stages

Surgery (lobectomy or pneumonectomy) continues to provide the best chance for cure in early-stage patients producing the best reported survival outcomes with a 5-year survival rate of about 60% for stage I [40–42].

Patients not suitable for surgical procedures because of comorbid conditions such as chronic obstructive pulmonary and heart disease, advanced age, poor general status or refusing surgical intervention are usually referred for consideration for radiotherapy. XRT alone with different dose levels and fractionations has been widely employed delivering usually doses up to 60–70 Gy to the primary tumor [40,43].

The clinical results of XRT are reported as poorer than those obtained with surgery with median survival rate of 30 months and overall 5-year survival rates up to 30% [3,44–46]. These data indicate that conventional XRT is largely inadequate for a large fraction of the patients. The lack of local control is the main cause of failure, occurring in approximately 40% of patients (range 6.4–70%) using total doses of 55–80 Gy [3,44,45]. The most likely cause of excessive recurrence rate is poor targeting and/or administration of inadequate doses [44].

Only recently, stereotactic XRT with photon beams has been used to treat stage I NSCLC in many institutions, and is more and more common to deliver doses that are biologically higher than those used in 3D-CRT. Even though results from randomized clinical trials are not available also for this modality, and although a systematic review of SBRT results is beyond the scope of this report, it is to underline that several publications have documented the efficacy and safety of the treatment of early-stage primary NSCLC with SBRT. The series (obtained from Pubmed) with at least 20 cases treated and a minimum follow-up of 12 months published after the 2000 [47–59] are reported in Table 4. The rates of local control are high (67–95% at 2 years) and they compare favorably with those of conventional treatment. Despite the use of higher biological doses than typically given in XRT, SBRT has rarely been associated with an increased rate of complications and the reported incidence of grade 3 toxicities is generally less than 5%, being radiation pneumonitis the most frequently observed. It is to note that median follow-up durations are short (15–43 months).

For the same early-stage lesions, encouraging results have been recently reported with the use of carbon ions [60]. Given the limited amount of patients treated, the experimental characteristic of this technique and the experience coming from a single institution, we decided to not consider these data for a comparison with the other irradiation modalities.

PT in lung cancer has been used primarily in the treatment of early stages. Whereas at the Chiba Institution [32] only limited stage disease (stage IA–IB) was treated, the reports of the series of Tsukuba [30] and of LLUMC [28] referred to a heterogeneous patient population and only more recently their attention has been focused on early-stage patients [29,31].

The results in limited stages are reported to be very encouraging with local control rates at 2 years of 80–95% and overall survival of 74–84%, obtained with very few acute and late toxicity: only in one study [32] a pulmonary toxicity of grade 3 was observed. These results compare favorably with the data of surgery where surgical resections (lobectomy or pneumonectomy) have been found to produce a 60–70% 5-year survival rate [40,61]. As observed also in conventional radiotherapy studies or surgical series [4,40,62–65], better results are reported for stage IA, 100% local control at 2 years [30,31], in comparison to stage IB, suggesting the usefulness to further increase the dose [29], even though the risk of toxicity could be substantial [32]. It is to note that in the study of Nihei et al. [32] a large pulmonary volume was treated and that, according to the linear quadratic model, the biological equivalent doses used were high (95–138 Gy equivalent, with $\alpha/\beta = 10$).

The best would be to evaluate these results in a randomized clinical trial that directly compares protons vs. SBRT, with the same fractionation. We believe that if the encouraging results of SBRT in early stage will be confirmed through sound studies, PT might not be able to sig-

Table 4
Studies of SBRT in lung cancer with at least 20 cases treated and a minimum of 1 year of follow-up published after 2000

Author	year	pts.	T1	T2	mDose [Gy]	fr.	% Survival					MS [months]	% LC (years)	% CR	% PR	% F-up	LR [months]	Toxicity
							1 year	2 year	3 year	4 year	5 year							
Beitler et al. [50]	2006	75	nr	nr	40	5	63	45	–	–	17	17.2	nr	8	33	24	nr	2 pneum effusion pneumot
Nyman et al. [51]	2006	45	18	27	45	3	80	71	55	–	30	39	80 (3)	9	63	43	9	3 atelec fracture mild tox
Uematsu et al. [47]	2001	50	24	26	50–60	5–10 5–12 boost	–	–	66	–	–	nr	94 (3)	nr	nr	36	3	10% mar and poo function
Onishi et al. [59]	2007	257	164	93	18–75	1–22	– –	– –	– –	– –	70.8* 30.2**	nr	80 (3)	23	61	38	36	5.4% >G
Nagata et al. [49]	2005	45	32	13	48	4	IA 93 IB 82	90 72	83 72	– –	83 72	nr	IA 95 (5) IB 100 (5)	16	84	30	–	2 Grade no Grad
Hoyer et al. [58]	2006	40	22	18	45	3	–	48	–	–	–	nr	85 (2)	20	38	28	3	48% Gra
Xia et al. [52]	2006	43	25	18	70	10	I 100 II 93	91 64	91 64	– –	– –	nr	IA 95 (5) IB 100 (5)	68 56	32 33	30 54	– 2	2 Grade 18% Gra 2% Grad 16% Gra
Timmermann et al. [53]	2006	70	35	35	60–66	3	–	54.7	–	–	–	32.6	95 (2)	nr	nr	17	3	14% Gra
Hof et al. [57]	2007	42	17	21	19–30	1	74.5	65.4	37.4	–	–	nr	67.9 (3)	nr	nr	15	6	no Grad
Zimmermann et al. [56]	2006	68	22	18	24–40	3–5	–	–	53	–	–	nr	88 (3)	64.7	29.4	17	4	6.4% Gra 5% rib fr
Fritz et al. [55]	2006	33	nr	nr	30	1	83	63	53	39	–	20.4	94 (1)	nr	nr	18	2	24% pne without
Yoon et al. [54]	2006	21	13	8	30–48	3–4	89	–	51	–	–	nr	81 (2)	nr	nr	13	3	no Grad
Fukumoto et al. [48]	2002	22	13	9	48–60	8	94	73	–	–	–	nr	67 (2)	29	65	24	1	no Grad

Abbreviations: mDose, median dose; pts., patients; fr., number of fractions; yrs, years; MS, median survival; C, local control; CR, complete response; gr, grade; PR, partial resp
recurrence; tox., toxicity; pneum, pneumonitis; esop., esophagitis; mPTV, mean planning target volume; mTD, median tumor diameter; TV, median tumor volume; nr, not repo
pulmonary disease.

* BED > 100 Gy.

** BED < 100 Gy.

nificantly improve the clinical outcome in this patients category.

Advanced stages

The treatment of patients with tumors in advanced stages is even more challenging, being local control a major problem. The role of surgery in advanced stage is more limited. In operable tumors the overall 5-year survival is declining from the 63% in stage IA to 19% in stage IIIA [40]. Patients with completely resected stage III disease have 5-year survival rates of 7–24% [6] and with unresectable disease of 3–13% [61]. Radiotherapy alone is able to control only a minority of these lesions [66]. The limitations of irradiation in these stages are mainly due to the size of the lesions, often irregularly shaped or located next to critical normal tissues which determine dosimetric solutions that cannot be proposed to the patients because of the high risk of complications.

In order to improve these results, more aggressive treatments have been suggested escalating the dose [8,67], combining radiotherapy and chemotherapy [68–71] and using altered fractionations [72,73]. Such approaches are associated with significant toxicity [74–76].

In cases of advanced stages, SBRT is not applied due the excessive toxicity. For these advanced cases, the current irradiation standard is still represented by 3D-CRT delivered with conventional fractionation, usually combined with chemotherapy. IMRT is in theory a promising technique for patients with nodal involvement [10,11], but no clinical series are currently available on the benefit of IMRT on advanced stage NSCLC.

Thanks to its peculiar ballistic properties, PT could be a possible solution for the technical difficulties in irradiating advanced cases enabling high-dose delivery to the tumor while minimizing the irradiated volume and dose given to normal tissues. Unfortunately, the clinical data on the use of PT in advanced disease are very limited with 33 patients only available in the literature (11 stage II, 16 stage III, 1 stage IV and 5 recurrences) [28,30].

In the study of Shioyama et al. [30] 14 patients with advanced stages (III, IV, recurrence) were treated. Even though the short-term results of these few patients were very promising, with 70% and 100% cause-specific survival at 2 years, respectively, the long-term causing specific survival was disappointing for stage III–IV patients (0%) and more favorable for patients suffering from a recurrence (50%).

In the initial experience of Bush et al. [28], 8 cases with stage IIIA were treated: 2-year overall survival was only 13%, but it is to note that only one patient had an in-field failure.

Being no other reports on the treatment of advanced NSCLC with PT available in the literature at this moment, it is impossible to draw any significant conclusion in this setting of patients due to the limited number of patients treated. For these patients, protons could allow a better therapeutic ratio than IMRT [34], thus allowing to escalate the dose and/or to reduce the treatment toxicity. It is therefore important to carry out phase I–II studies in patients with advanced stage disease, where conventional photon techniques are not capable of delivering sufficiently high doses and where proton therapy is not necessarily more challenging than IMRT from a technical point of view. It would be also interesting to evaluate the impact of several fractionations and chemotherapy protocols on PT treatments, that nowadays are delivered with 2–6 CGE dose per fraction.

Plan comparison studies and technical issues

The main difference of protons with respect to photons, i.e. their finite range in tissue, on the one hand makes proton irradiation very appealing, because of the dose distributions that can be produced; on the other hand, it makes it also quite problematic, because extreme care should be devoted to make sure that the differences between treatment planning and treatment delivery do not translate in tumor under-dosage or OARs over-dosage.

This is particularly true for lung tumors, where the need for compensating for breathing motion and for the changes in lung density due to respiration must be balanced against unnecessary irradiation of the healthy lung.

The study by Lee et al. [33] provided information on the minimum dose to PTVs, but no data are presented about target/OARs DVH, TCP or NTCP; moreover, as with for the majority of the cases studied by Chang et al. [34], the comparisons were made between 3D-CRT and PT. When IMRT was taken into account in the study by Chang et al. [34], the differences with respect to PT with regard to normal tissue doses were smaller than for 3D-CRT. It is interesting to note that in Chang's article the 'smearing parameter' was selected on the basis of the formula suggested by Moyers [18], and therefore the results could have been different if they had followed the margin 'recipe' proposed by Engelsman [21].

Furthermore, in order to extract useful information from the treatment planning studies we analyzed, we had to accept some implicit assumption of these studies, such as that:

– Proton and photon dose distributions in the target volume can be compared by PTV dose parameters. This is not obvious, as with protons the dose distribution is in general not invariant even for small displacements, making the use of the PTV difficult. Using different PTV definitions for photons and protons (e.g. defining field-specific PTVs for PT) is a step forward, though it might make the comparison more complex. In general, we think that future studies comparing photon and proton therapy, in particular for lung cancer, should move to different approaches of planning and reporting the dose, either including geometrical uncertainties in the planning procedure [77–79] and/or reporting the dose in terms of probability level [80,81]. In this context, the availability of 4D information is going to be crucial.

– The dose parameters chosen by the authors were the most appropriate to compare the dose distributions in the target. In some studies, protons and photons plans were compared in term of prescribed dose in the target, i.e. an implicit assumption was made that the same prescription dose does translate in the same quality of the dose distribution in the target, e.g. in terms of tumor control probability. This is not obvious, either for the problem of how the geometrical uncertainties are handled (see previous points), or because the prescribed dose unequivocally translates in a

TCP estimate only if the dose is perfectly homogeneous throughout the target volume.

Furthermore, it is also very difficult to extrapolate general considerations from the study by Moyers et al. [18] because their results were obtained on a single patient, with very specific characteristics, field arrangements and PTV definition.

The results by Engelsman et al. [21] show that smearing has the potential to compensate for systematic errors and respiration-induced density variation, but high degree of smearing and large margins will obviously lead to an increase in lung dose.

Beam gating techniques might be a solution in the case of large breathing motion (e.g. >1 cm), provided that a reliable surrogate of the actual target position is used to trigger the beam. Moreover, for protons, it could be of major importance to reproduce not only the target position but also the internal density changes along the path of proton beams. In this respect, Engelsman et al. [22] concluded that CT data extracted from 4D datasets representing an average target position plus patient-specific planning margins should be used to plan and deliver the prescribed dose to the target.

Using a different approach, Paganetti et al. [19,20] developed a technique, based on Monte Carlo simulations, that could be very useful for a pre-treatment uncertainty analysis, where the effect of motion is simulated on 'static' dose distributions.

In the Kang et al. study [23] the AVE_RIGTV strategy achieved the best overall 4D tumor dose coverage and critical structure sparing. In addition, the study underlined that radiation oncologists should determine the combined volume of the GTVs at all respiratory phases from the 4D-CT dataset to explicitly include target motion and deformation. In agreement with Engelsman et al. [22] Kang et al. found that the smearing margin was not necessarily as large as the range of tumor motion. Differently from Engelsman et al., Kang et al. did not optimize multiple plans for 4D-CT volumes at end-inhalation, mid-exhalation, and end-exhalation, but they only designed one treatment plan and can predict target coverage.

When it comes to advanced techniques of handling the geometrical uncertainties due to respiration, to date, there are no prospective evaluations on the clinical impact of the implementation of gating techniques or volume definitions that take movement into account. It is thus very difficult, if not impossible, to provide a quantitative evaluation of the clinical benefits produced by such technologies. Nevertheless, as already mentioned, because the PT is very sensitive to displacements in the lung region, it can be expected that a careful study on the definition of the volumes to irradiate and the adoption of gating techniques could be crucial in treatment with protons, especially if mobile and advanced stage lesions are to be treated.

Therefore, one could start treating patients with small respiratory movements, who by the way represent the majority of lung cancer patient.

Finally, no data are available on the potential benefit of PT delivered with spot scanning, where the dosimetric advantages potentially achievable with this technique have to be balanced against its sensitivity with respect to intrafraction motion.

Conclusions

The use of PT in NSCLC is mainly based on the theoretical advantages in dose distribution. Little clinical data are available, in terms of number of institutions involved, number of treated patients and quality of studies conducted (i.e. lack of randomized controlled trials), making it impossible to draw definitive conclusions about its efficacy.

Current data suggest that PT is a promising modality of irradiation in the treatment of early-stage disease, producing favorable results and low toxicity (both acute and late).

Indications for PT in advanced stages are based mainly on planning studies, that should be followed up by further clinical investigations.

Well-designed clinical trials and prospective studies will allow to better evaluate the benefits of PT with respect to other high-precision radiotherapy treatments (e.g. tomotherapy, stereotactic RT, cyberknife and IMRT), provided that the technical peculiarities of PT in lung treatment will be adequately taken into account.

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DISTRICT COURT

CLARK COUNTY, NEVADA

SANDRA L. ESKEW, individually and as special administrator of the Estate of William George Eskew; TYLER ESKEW; AND WILLIAM G. ESKEW, JR., Plaintiffs, vs. SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.; DOES I through XXX, inclusive, Defendants.	Case No.: A-19-788630-C Dept. No.: 4 **NOTICE OF ENTRY OF ORDER REGARDING DEFENDANTS' MOTIONS IN LIMINE**

PLEASE TAKE NOTICE that an Order Regarding Defendants' Motions In Limine was filed March 16, 2022, in the above-captioned matter.

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A copy of the Order is attached hereto.

Dated this 17th day of March, 2022.

WEINBERG, WHEELER, HUDGINS,
GUNN & DIAL, LLC

/s/ Ryan T. Gormley

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CERTIFICATE OF SERVICE

I hereby certify that on the 17th day of March, 2022, a true and correct copy of the foregoing **NOTICE OF ENTRY OF ORDER REGARDING DEFENDANTS' MOTIONS IN LIMINE** was electronically filed and served on counsel through the Court's electronic service system pursuant to Administrative Order 14-2 and N.E.F.C.R. 9, via the electronic mail addresses noted below, unless service by another method is stated or noted:

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SANDRA L. ESKEW, individually and as special administrator of the Estate of William George Eskew; TYLER ESKEW; AND WILLIAM G. ESKEW, JR., Plaintiffs, vs. SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.; UNITED HEALTHCARE, INC.; and DOES I through XXX, inclusive, Defendants.	Case No.: A-19-788630-C Dept. No.: 4 **ORDER REGARDING DEFENDANTS' MOTIONS IN LIMINE**

Defendants filed Motion in Limine Nos. 1-21. The Court, having considered the pleadings and papers on file, including each motion and related briefing, and argument of counsel on February 10-11, 2022, hereby orders as follows:

1. Defendants' Motion in Limine No. 1:

Defendants filed Motion in Limine No. 1: Limit the Testimony Of Plaintiffs' 'Bad Faith' Expert Stephen Prater ("MIL 1"), seeking to limit the anticipated testimony of Plaintiff's 'Bad Faith' Expert Stephen Prater to testifying regarding insurance standards, practices, and procedures and whether Defendants' conduct was inconsistent with those standards, practices, and procedures.

The Court grants in part MIL 1. MIL 1 is granted as (1) the opinions in section 2 of the motion regarding "Bad Faith" opinions, (2) Mr. Prater will not reference the California Supreme Court case at page 7 paragraph 22 of his report on direct examination, and (3) as to the statement in paragraph 25 of Mr. Prater's report, Mr. Prater cannot offer an opinion that the agreement of coverage is a contract of adhesion because the Court concludes that the opinion of that agreement of coverage is a contract of adhesion is a legal conclusion. MIL 1 is denied as to the remainder of the motion.

2. Defendants' Motion in Limine No. 2:

The Court defers a ruling on Defendants' Motion in Limine No. 2: Exclude Evidence, Argument, and/or Testimony Relating to the Financial Condition of Non-Party UnitedHealth Group until and in the event that trial proceeds to a punitive damages phase.

3. Defendants' Motion in Limine No. 3:

Defendants filed Motion in Limine No. 3: Exclude Evidence, Argument and/or Testimony Relating to Pre-Contract Communications Concerning Coverage ("MIL 3"), seeking to exclude evidence, argument, and/or testimony relating to pre-contract communications concerning insurance coverage, such as interactions between Mr. Eskew's wife, Sandra Eskew, and the Eskews' insurance broker, Janet Holland-Williams, that occurred prior to Mr. Eskew entering into his health plan with SHL.

The Court grants MIL 3 pursuant to the parol evidence rule; however, nothing prohibits Mrs. Eskew from discussing her belief, based upon the reading of the policy and the steps that she took to secure coverage. However, the conversations she had with Mrs. Holland-Williams

will not come in at trial, but she can testify to what she believed coverage would be and what she was seeking. (2/10/22 Trans. at 30:9-17).

4. Defendants' Motion in Limine No. 4:

Defendants filed Motion in Limine No. 4: Exclude Evidence, Argument and/or Testimony Relating to The Preparation of The Denial Letter ("MIL 4"), seeking to exclude evidence, argument, and/or testimony relating to the preparation of the letter sent by SHL to Mr. Eskew, Dr. Liao, and the Proton Center setting forth the reasons for denying the prior authorization at issue.

The Court denies MIL 4.

5. Defendants' Motion in Limine No. 5:

Defendants filed Motion in Limine No. 5: Exclude Evidence, Argument and/or Testimony Relating to Opinions from Judge Scola ("MIL 5"), seeking to exclude evidence, argument, and/or testimony relating to a recusal order issued by a judge in Florida, the Honorable Robert N. Scola, Jr., where he referred to the denial of proton therapy as "immoral and barbaric."

The Court grants MIL 5.

6. Defendants' Motion in Limine No. 6:

Defendants filed Motion in Limine No. 6: Exclude Evidence, Argument and/or Testimony Relating to The New York Proton Center ("MIL 6"), seeking to exclude evidence, argument, and/or testimony related to the New York Proton Center.

The Court denies MIL 6.

7. Defendants' Motion in Limine No. 7:

Defendants filed Motion in Limine No. 7: Exclude Certain Photos ("MIL 7"), seeking to exclude photos labeled as bates numbers Eskew-000064-71.

The Court grants in part MIL 7. While Plaintiff is permitted to use photos of Mr. Eskew, Plaintiff may not use photos with other people or animals in it.

8. Defendants' Motion in Limine No. 8:

Defendants filed Motion in Limine No. 8: Preclude Argument or Questioning Relating to Comparing Testimony Preparation Time with Prior Authorization Review Time ("MIL 8"), seeking to exclude argument or questioning relating to comparing the time witnesses spent preparing to testify at trial to the amount of time the medical director, Dr. Ahmad, spent reviewing the prior authorization request at issue.

The Court denies MIL 8.

9. Defendants' Motion in Limine No. 9:

Defendants filed Motion in Limine No. 9: Exclude Evidence, Argument and/or Testimony Relating to Generalized Patient Numbers or Studies ("MIL 9"), seeking to exclude evidence, argument, and/or testimony relating to generalized numbers, not specific to lung cancer, concerning the amount of patients treated with proton therapy and/or the amount of studies discussing proton therapy.

The Court denies MIL 9.

10. Defendants' Motion in Limine No. 10:

Defendants filed Motion in Limine No. 10: Exclude Evidence, Argument and/or Testimony Relating to Medicare Coverage ("MIL 10"), seeking to exclude evidence, argument and/or testimony relating to the extent that Medicare provides coverage for proton therapy.

The Court denies MIL 10.

11. Defendants' Motion in Limine No. 11:

Defendants filed Motion in Limine No. 11: Exclude Evidence, Argument and/or Testimony Relating to Unqualified Opinions Regarding Medical Causation ("MIL 11"), seeking to exclude evidence, argument and/or testimony relating to unqualified opinions regarding medical causation, such as the theory offered by Mr. Eskew's wife, Sandra Eskew, that Mr. Eskew starved to death.

The Court grants MIL 11. While Ms. Eskew may testify as to her observations of Mr. Eskew, she cannot offer opinions related to causation such as her husband starved to death.

12. Defendants' Motion in Limine No. 12:

Defendants filed Motion in Limine No. 12: Exclude Testimony from Dr. Liao Regarding Matters Outside the Course and Scope of Her Treatment of Mr. Eskew ("MIL 12"), seeking to exclude testimony from Mr. Eskew's radiation oncologist at MD Anderson, Dr. Liao, regarding matters outside the course and scope of her treatment of Mr. Eskew, such as her opinion that Mr. Eskew suffered from grade 3 esophagitis following the conclusion of his treatment at MD Anderson.

The Court denies MIL 12.

13. Defendants' Motion in Limine No. 13:

Defendants filed Motion in Limine No. 13: Exclude Evidence, Argument and/or Testimony Relating to Questioning Attempting to Alter the Scope of the Jury's Inquiry ("MIL 13"), seeking to exclude evidence, argument and/or testimony relating to questions that attempt to alter the scope of the jury's inquiry, such as Plaintiffs' counsel's questioning of Dr. Ahmad as to whether he had a "good reason" to deny the prior authorization request at issue.

The Court grants MIL 13. Plaintiffs will not be allowed to ask at trial regarding a good reason; however, they will be allowed to ask Dr. Ahmad reasonable basis questions regarding the denial of the claim. (2/10/22 Trans. at 64:17-20).

14. Defendants' Motion in Limine No. 14:

Defendants filed Motion in Limine No. 14: Exclude Evidence, Argument and/or Testimony Relating to Inflammatory Questioning Regarding Personal Opinions ("MIL 14"), seeking to exclude evidence, argument and/or testimony relating to inflammatory questioning regarding personal opinions, such as Plaintiffs' counsel's questioning of Dr. Ahmad as to whether he is "proud" of his handling of the prior authorization at issue.

The Court grants in part MIL 14. The motion is granted as to whether or not a witness was proud of the denial or his feelings towards Mr. Eskew or his family. Whether or not Mr. Eskew was treated fairly is a relevant inquiry. (2/10/22 Trans. 67:9-20).

15. Defendants' Motion in Limine No. 15:

Defendants filed Motion in Limine No. 15: Exclude Evidence, Argument and/or Testimony Relating to Hypothetical Questioning Regarding What Would Be Fairer ("MIL 15"), seeking to exclude evidence, argument and/or testimony relating to hypothetical questions regarding what would be "fairer," such as Plaintiff's counsel's questioning of Ms. Sweet as to her opinions on how the prior authorization review at issue could have been "fairer."

The Court grants MIL 15. The parties may not ask questions regarding what is fairer. Plaintiff's counsel has agreed not to ask the precise questions at pages two and three of the motion..

16. Defendants' Motion in Limine No. 16:

Defendants filed Motion in Limine No. 16: Exclude Evidence, Argument and/or Testimony Relating to Misleading Questioning Regarding The Nature Of Insurance and Personal Experience With Insurance ("MIL 16"), seeking to exclude evidence, argument and/or testimony relating to misleading questioning regarding the nature of insurance and certain witness's personal experience with insurance, such as Plaintiff's counsel's questioning of Dr. Ahmad characterizing insurance as a "promise" and inquiring into Dr. Ahmad's personal experience with insurance coverage.

The Court grants MIL 16 in that Plaintiff's counsel has agreed not to ask Dr. Ahmad if he believes insurance is a promise. (3:17-25).

17. Defendants' Motion in Limine No. 17:

Defendants filed Motion in Limine No. 17: Exclude Evidence, Argument and/or Testimony Relating to Litigation Conduct ("MIL 17"), seeking to exclude evidence, argument and/or testimony exclude evidence, argument and/or testimony relating to litigation conduct in this case, such as Defendants' handling of the pleadings, discovery, and pre-trial motions.

The Court grants in part MIL 17. The parties may not comment on the litigation conduct of the lawyers. (7:8-16, 8:16-20).

18. Defendants' Motion in Limine No. 18:

Defendants filed Motion in Limine No. 18: Exclude Evidence, Argument and/or Testimony Relating to Other Cases ("MIL 18"), seeking to exclude evidence, argument, and/or testimony relating to other cases concerning proton therapy.

The Court grants in part MIL 18. Evidence, argument, and/or testimony relating to other cases concerning proton therapy will be excluded, so long as the defense does not open the door.

19. Defendants' Motion in Limine No. 19:

Defendants filed Motion in Limine No. 19: Exclude Evidence, Argument and/or Testimony Relating to "Finally Day in Court" Assertions ("MIL 19"), seeking to exclude evidence, argument, and/or testimony relating to assertions, such as Plaintiffs will "finally have their day in court" and others like it.

The Court denies MIL 19.

20. Defendants' Motion in Limine No. 20:

Defendants filed Motion in Limine No. 20: Exclude Evidence, Argument and/or Testimony Relating to Need for Industry Change Assertions ("MIL 20"), seeking to exclude evidence, argument, and/or testimony relating to industry change assertions, such as this case could prompt change in the insurance industry as it relates to proton therapy or prior authorization reviews generally.

The Court denies MIL 20. The parties are instructed to read and comply with *Lioce*.

21. Defendants' Motion in Limine No. 21:

Defendants filed Motion in Limine No. 21: Preclude Improper and Inflammatory "Reptile" Tactics and Arguments ("MIL 21"), seeking to exclude argument or trial tactics derived from Don Keenan's "Reptile Theory," such as "golden rule," "send a message," "safety," and "conscience of the community" type arguments.

The Court denies MIL 21. The parties are instructed to read and comply with *Lioce*.

IT IS ORDERED.

Dated this 16th day of March, 2022

HON. NADIA KRALL
DISTRICT COURT JUDGE
Nadia Krall
District Court Judge

Submitted by:

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CSERV

DISTRICT COURT
CLARK COUNTY, NEVADA

Sandra Eskew, Plaintiff(s) vs. Sierra Health and Life Insurance Company Inc, Defendant(s)	CASE NO: A-19-788630-C DEPT. NO. Department 4

AUTOMATED CERTIFICATE OF SERVICE

This automated certificate of service was generated by the Eighth Judicial District Court. The foregoing Order was served via the court's electronic eFile system to all recipients registered for e-Service on the above entitled case as listed below:

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DISTRICT COURT

CLARK COUNTY, NEVADA

SANDRA L. ESKEW, as special administrator of the Estate of William George Eskew, Plaintiff, vs. SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC., Defendant.	Case No.: A-19-788630-C Dept. No.: 4 **HEARING REQUESTED** **DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW**

Defendant Sierra Health and Life Insurance Company, Inc. ("SHL") submits this Motion for Judgment as a Matter of Law pursuant to NRCP 50(a), the following Memorandum of Points and Authorities, and any argument allowed on this matter.

MEMORANDUM OF POINTS AND AUTHORITIES

SHL seeks judgment as a matter of law on Plaintiff's (1) sole claim for insurance bad faith and (2) demand for punitive damages. Even viewing the evidence and inferences in favor of Plaintiff, Plaintiff has failed to prove a sufficient issue for the jury on these claims.

LEGAL STANDARD

The Court may grant judgment as a matter of law where "a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a *legally sufficient evidentiary basis* to find for the party on that issue." NRCP 50(a)(1) (emphasis added). Said another way, "the district court may grant a motion for judgment as a matter of law if the opposing party has failed to prove a sufficient issue for the jury, so that his claim cannot be maintained under the controlling law." *Nelson v. Heer*, 123 Nev. 217, 223, 163 P.3d 420, 425 (2007). In deciding such a motion, the Court "must view all the evidence and inferences in favor of the nonmoving party." *D&D Tire v. Ouellette*, 131 Nev. 462, 466, 353 P.3d 32, 35 (2015).

ARGUMENT

A. BAD FAITH CLAIM

To prevail on her claim for insurance bad faith, Plaintiff must prove the following elements by clear and convincing evidence: (1) the proton therapy was a covered service under the terms of Mr. Eskew's Agreement of Coverage ("AOC"); (2) SHL had no reasonable basis for its denial of the prior authorization claim; (3) SHL knew, or recklessly disregarded, the fact that there was no reasonable basis for the denial; and (4) SHL's denial was a legal cause of harm to Mr. Eskew. *Powers v. United Servs. Auto. Ass'n*, 114 Nev. 690, 703, 962 P.2d 596, 604 (1998).

Plaintiff's claim for insurance bad faith should not reach the jury because (1) Plaintiff has failed to show that proton therapy was a covered service under the AOC; (2) Plaintiff failed to show that SHL had no reasonable basis for the denial of Mr. Eskew's prior authorization request; (3) Plaintiff failed to show that SHL knew, or recklessly disregarded, the fact that there was no reasonable basis for the denial; and (4) Plaintiff's claimed compensatory damages under NRS 41.100 are unrecoverable.

1. Plaintiff has failed to show that proton therapy was a covered service under the AOC.

Proton therapy was not a covered service under the AOC because (1) the AOC is plain and unambiguous and (2) the conclusion that proton therapy was not a covered service was consistent with the AOC's plain and unambiguous terms.

a. The AOC is plain and unambiguous.

The interpretation of an insurance policy, like all contracts, presents a question of law. *Fed. Ins. Co. v. Coast Converters*, 130 Nev. 960, 965, 339 P.3d 1281, 1285 (2014). A policy or plan, if unambiguous, must be considered "as a whole," and enforced "according to the plain and ordinary meaning of its terms." *Id.* Whether a policy or plan is ambiguous "turns on whether it creates reasonable expectations of coverage as drafted." *Id.* Courts should take caution not to "rewrite contract provisions that are otherwise unambiguous . . . [or] increase an obligation to the insured where such was intentionally and unambiguously limited by the parties." *Id.*

Here, Mr. Eskew's AOC, regardless of whether Plaintiff wants to look at Admitted Exhibit ("AEx") 2, 3, or 4, is not ambiguous "as drafted." Section 4.1 of the AOC, entitled Availability of Covered Services, provides that "Covered Services are available only if and to the extent that they are . . . Medically Necessary as defined in this AOC." The contract further provides in Section 5 that "Only Medically Necessary services are considered to be Covered Services." In addition, Section 6.1 excludes coverage for any "services which are not Medically Necessary, whether or not recommended or provided by a Provider." Section 13.21 defines "Covered Services" as "the health services, supplies and accommodations for which SHL pays benefits under this Plan." Section 13.66 defines "Medically Necessary" as follows:

> [A] service or supply needed to improve . . . 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.

Under these terms, it is clear that the only services that are "Covered Services" are those services determined to be "Medically Necessary" by SHL. Even Mrs. Eskew recognized this during her testimony. In exercising its discretion to make this determination, SHL can consider any or all of the items in the set of six bullet points above. As drafted, that is what the AOC provides for according to its plain and ordinary terms.

b. SHL's conclusion that proton therapy was not a covered service was consistent with the AOC's plain and unambiguous terms.

"The insured . . . bears the burden of proving that its alleged loss falls within the terms of the various provisions under which it seeks coverage." *Cty. of Clark v. Factory Mut. Ins. Co.*, No. CV-S-02-1258-KJD-RJJ, 2005 WL 6720917, at *2 (D. Nev. Mar. 28, 2005) (citing *Lucini-Par. Ins., Inc. v. Buck*, 108 Nev. 617, 620, 836 P.2d 627, 629 (1992)).

The evidence at trial confirms the two pertinent facts in SHL's favor. First, SHL determined that proton therapy was not a "Covered Service" because it was not "Medically Necessary." This is shown by the claim file (AEx. 5) and Dr. Ahmad's testimony. Second, SHL reached this conclusion by relying on "reports in peer-review literature" and "evidence based reports and guidelines published by nationally recognized professional organizations that include supporting scientific data," consistent with Section 13.66 of the AOC. This fact is readily apparent from the claim file (AEx. 5), Dr. Ahmad's testimony, and the UHC Proton Policy (AEx. 24).

Moreover, Dr. Chang confirmed as much when he agreed that the UHC Proton Policy (AEx. 24), which was relied on, among other things, by Dr. Ahmad, contained "peer-review literature" and "evidence based reports and guidelines published by nationally recognized professional organizations." Thus, SHL did not deviate from the AOC's plain and unambiguous terms in deciding that proton therapy was not a "Covered Service."

To hold otherwise would constitute a rewriting of the AOC's plain terms. None of Plaintiff's side theories—attachment B, typos in the claim file, preparation of the denial letter, or the so-called "rigged" system—change this outcome. The AOC should be enforced according to its plain and unambiguous terms and judgment entered in SHL's favor on Plaintiff's claim for insurance bad faith.

2. Plaintiff failed to show that SHL had no reasonable basis for the denial of Mr. Eskew's prior authorization request.

The reasonable basis inquiry is subject to a high standard. To meet this standard, the insurer's denial of benefits must have been both "objectively and subjectively unreasonable." *Rivas v. Gov't Employees Ins. Co*., No. 2:20-cv-306-JCM-NJK, 2020 WL 3128596, at *2 (D. Nev. June 12, 2020) (applying Nevada law). An insurer's "honest mistake, bad judgment, or negligence" is not enough. *See Allstate Ins. Co. v. Miller*, 125 Nev. 300, 317, 212 P.3d 318, 330 (2009). Likewise, an insurer "is not liable for bad faith for being incorrect about policy coverage as long as the insurer had a reasonable basis to take the position that it did." *Pioneer Chlor Alkali Co. v. Nat'l Union Fire Ins. Co. of Pittsburgh, Pennsylvania*, 863 F. Supp. 1237, 1242 (D. Nev. 1994) (citing *American Excess Ins. Co. v. MGM Grand Hotels, Inc.*, 102 Nev. 601, 729 P.2d 1352, 1355 (1986)).

Here, the evidence presented shows that SHL had a reasonable basis for its denial of Mr. Eskew's prior authorization request. First, SHL had a reasonable basis by acting consistently with the plain terms of the AOC, as detailed above.

Second, SHL had a reasonable basis consistent with the UHC Proton Policy (AEx. 24). While the extent of what Dr. Ahmad relied on is disputed, even Mr. Prater agreed that Dr. Ahmad relied on the UHC Proton Policy (AEx. 24). When it comes to the UHC Proton Policy, Dr. Chang

confirmed the following as true: (1) it contained references to peer-review literature; (2) it contained references to evidence based reports and guidelines published by nationally recognized professional organizations; (3) he did not offer the opinion that the policy was missing any material clinical evidence; (4) he did not offer the opinion that the policy failed to cite to any literature or clinical evidence that it should have cited; and (5), perhaps most important of all, he did not contend that any of the summaries of evidence in the policy regarding lung cancer were not accurate.

Against that backdrop, there is no question that the UHC Proton Policy provided a reasonable basis for the denial. The issue is not a matter of weighing Dr. Liao's opinion and Dr. Chang's opinion (or Stephen Prater's opinion) on "Medically Necessary" against the policy's conclusion. Nor does it matter that Dr. Chang opined that certain pieces of literature in the UHC Proton Policy weighed in favor of approving the request. The issue is whether any reasonable basis existed for the denial. The accuracy and credibility of the following references in the policy, among others, are unchallenged:

- "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 . . . ." (Dr. Chang confirmed, as do the MD Anderson records, that Mr. Eskew was not part of a clinical trial).
- "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)."
- "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."

Given this evidence, it is uncontested that SHL acted consistent with the guidance from ASTRO (the American Society for Radiation Oncology) and AHRQ (the Agency for Healthcare Research and Quality, a federal government agency charged with improving the safety and quality of healthcare). Acting consistent with these sources cannot be equivalent to acting without a reasonable basis.

Third, if there is any question as to SHL's ability to retain discretion to determine medical necessity, that is an open question of law. *See Brewington v. State Farm Mut. Auto. Ins. Co.*, 96 F. Supp. 3d 1105, 1109 (D. Nev. 2015) ("A reasonable, or good faith, dispute over an open question of law affecting insurance coverage cannot constitute an insurance bad faith claim as a matter of law."). No Nevada court has determined that an insurer's contractual reservation of authority to determine medical necessity under a health plan's definition of the same is unenforceable.

3. Plaintiff failed to show that SHL knew, or recklessly disregarded, the fact that there was no reasonable basis for the denial.

To establish knowledge or reckless disregard, "[i]t is not enough to show that, in hindsight, an insurer acted unreasonably; the plaintiff must show that the insurer knew or recklessly disregarded" that there was no reasonable basis for its denial. *Fernandez v. State Farm Mut. Auto. Ins. Co.*, 338 F. Supp. 3d 1193, 1200 (D. Nev. 2018) (citing *Guar. Nat. Ins. Co. v. Potter*, 112 Nev. 199, 912 P.2d 267, 272 (1996)).

Here, assuming *arguendo* that no reasonable basis existed for the denial, Plaintiff failed to present sufficient evidence of any person acting with knowledge or reckless disregard with respect to the issue at hand—the basis for the denial. When it comes to the records provided by MD Anderson, the very comparative study relied on by Dr. Liao to recommend proton therapy was not included in the clinical records. When it comes to the UHC Proton Policy, Dr. Chang did not opine that the UHC Proton Policy was missing any evidence or misrepresented any evidence. Lastly, Shelean Sweet confirmed that the denial was processed according to the procedures in place.

Plaintiff has attempted to vilify the entire system of utilization management. But Plaintiff's arguments and questions regarding a "rigged" system are not evidence. Further, Mr. Prater's speculation and credibility judgments should not change the fact that there is insufficient evidence to satisfy the knowledge element for insurance bad faith.

4. Plaintiff's claimed compensatory damages under NRS 41.100 are unrecoverable.

Plaintiff claims that the alleged bad faith denial was a legal cause of harm to Mr. Eskew with respect to (1) emotional distress damages from the alleged bad faith denial and (2) pain and

suffering damages because of the alleged Grade 3 chronic esophagitis. Neither allegation should reach the jury for separate reasons, as shown below.

a. Plaintiff failed to show that the alleged bad faith denial was the legal cause of harm to Mr. Eskew with respect to his pain and suffering damages.

"[T]here is a proximate cause requirement for recovery of emotional distress damages in bad faith actions." *Major v. W. Home Ins. Co.*, 87 Cal. Rptr. 3d 556, 572 (Cal. Ct. App. 2009), as modified on denial of reh'g (Jan. 30, 2009). When the record is devoid of evidence that a wrongful act proximately caused the damages, a judgment as a matter of law is appropriate. *Nelson v. Heer*, 123 Nev. 217, 225, 163 P.3d 420, 426 (2007). "Mere correlation…is insufficient as a matter of law to establish causation." *Wilson v. Circus Circus Hotels, Inc.*, 101 Nev. 751, 754, 710 P.2d 77, 79 (1985). "For an act to be the proximate cause of an injury, it must appear that the injury was the natural and probable consequence of the negligence or wrongful act, and that it ought to have been foreseen in the light of the attending circumstances." *Van Cleave v. Kietz-Mill Minit Mart*, 97 Nev. 414, 416, 633 P.2d 1220, 1221 (1981) (internal quotation marks omitted). In other words, proximate cause limits liability to foreseeable consequences. *Nelson*, 123 Nev. at 225, 163 P.3d at 426. It encompasses "any cause which in natural and continuous sequence, unbroken by any efficient intervening cause, produces the injury complained of and without which the result would not have occurred." *Taylor v. Silva*, 96 Nev. 738, 741, 615 P.2d 970, 971 (1980).

Here, when it comes to Plaintiff's claim for Mr. Eskew's alleged pain and suffering damages because of the alleged Grade 3 chronic esophagitis, Plaintiff has not met her burden to establish causation. Dr. Chang admitted that the Grade 1 or Grade 2 esophagitis that was diagnosed at MD Anderson was not attributable to the use of the IMRT instead of proton therapy. In addition, Dr. Chang recognized that when it came to the alleged Grade 3 chronic esophagitis, even in his view, the use of IMRT instead of proton beam increased the odds of such a result from 3% to 15%. That 12% difference cannot be enough to equate to a "natural and probable consequence," particularly where there were the intervening acts of deciding not to appeal and deciding not to pay for the proton therapy directly and proceeding with the IMRT instead. The causal relationship

does not rise above a mere correlation. Thus, Plaintiff's claim for pain and suffering damages related to the alleged chronic Grade 3 esophagitis should not reach the jury.[1]

b. Plaintiff's failure to introduce evidence of economic loss forecloses her claim for Mr. Eskew's alleged emotional distress damages.

Over the past 40 years, the Nevada Supreme Court has consistently looked to California law to define the parameters of bad faith law in Nevada. *See Avila v. Century Nat. Ins. Co.*, 473 F. App'x 554, 556 (9th Cir. 2012) ("We presume that Nevada would look to California law in determining whether the bad faith claim would be viable"). In fact, Nevada's bad faith law derives from California law. *See U.S. Fid. & Guar. Co. v. Peterson*, 91 Nev. 617, 540 P.2d 1070, 1071 (1975).

In California, courts have long held that to state a claim for bad faith, the insured must have suffered economic loss. *Cont'l Ins. Co. v. Superior Court*, 37 Cal. App. 4th 69, 86–87, 43 Cal. Rptr. 2d 374, 384 (Cal. App. 1995) ("In the absence of any economic loss there is no invasion of [the insureds'] property rights to which their alleged emotional distress over [the insurer's] denial and delay could be incidentally attached. In short, there would be no legal basis for an action for bad faith."). The economic loss "must be tied to actual, not merely potential, economic loss." *Major v. W. Home Ins. Co.*, 169 Cal. App. 4th 1197, 1214, 87 Cal. Rptr. 3d 556, 571 (Cal. App. 2009), as modified on denial of reh'g (Jan. 30, 2009). While emotional distress damages are recoverable from a bad faith claim, they must derive from the emotional distress associated with the financial loss. *Continental Insurance*, 37 Cal. App. 4th at 85-86, 43 Cal. Rptr. 2d at 383-84 (providing that "a claim for emotional distress in a bad faith action cannot stand alone, but must be accompanied by some showing of economic loss") (citing *Gruenberg v. Aetna Ins. Co.* 9 Cal.3d 566, 108 Rptr. 48, 510 (Cal. 1973)); *Blake v. Aetna Life Ins. Co.*, 99 Cal. App. 3d 901, 925, 160 Cal. Rptr. 528 (Cal. App. 1979) ("In the customary 'bad faith' case, the essence of the plaintiffs'

[1] Similarly, Dr. Chang's opinion as to "medical causation" with respect to chronic Grade 3 esophagitis is not stated to a reasonable degree of medical probability because it is based on a 3% to 15% difference. Further, Dr. Liao's opinion as to "medical causation" with respect to Grade 3 esophagitis was not within the course and scope of her treatment of Mr. Eskew, as it is not referenced in a medical record and there is no evidence that Dr. Liao communicated with Mr. Eskew or his family after July 2016, when his treatment with MD Anderson stopped and he was doing well, pursuant to his MD Anderson medical records (AEx. 154).

emotional distress is the anxiety arising from the financial deprivation traceable directly to nonpayment of the claim.").[2]

Here, Plaintiff did not present sufficient evidence of any economic losses suffered by Mr. Eskew because of the alleged bad faith denial. Plaintiff presented only evidence related to emotional distress and pain and suffering. Without evidence of economic loss, following the approach from California law that the Nevada Supreme Court would likely adopt, there can be no emotional distress damages.

B. PUNITIVE DAMAGES

Plaintiff did not present sufficient evidence to obtain punitive damages. In Nevada, "proof of bad faith, by itself, does not establish liability for punitive damages." *United Fire Ins. Co. v. McClelland*, 105 Nev. 504, 512, 780 P.2d 193, 198 (1989). Something more is required, specifically "clear and convincing evidence that the defendant has been guilty of oppression, fraud or malice, express or implied." NRS 42.005(1); *see U.S. Fid. & Guar. Co. v. Peterson*, 91 Nev. 617, 621, 540 P.2d 1070, 1072 (1975) (concluding that while the record supported a finding of bad faith, "the necessary requisites to support punitive damages [were] not present"). When faced with a claim for punitive damages, a trial court must first make a threshold determination that the plaintiff has presented sufficient evidence to satisfy the high evidentiary burden for punitive damages before submitting the question to the jury. *See Countrywide Home Loans, Inc. v. Thitchener*, 124 Nev. 725, 740, 192 P.3d 243, 253 (2008).

In bad faith suits, the common law definitions of oppression, fraud, and malice apply. NRS 42.005(5). Oppression occurs when the plaintiff is subjected to "cruel and unjust hardship in conscious disregard of his rights." *Ainsworth v. Combined Ins. Co. of America*, 105 Nev. 237, 774 P.2d 1003, 1012 (Nev. 1989) (internal quotation marks and citations omitted), abrogated on other grounds by *Powers*, 114 Nev. 690, 962 P.2d 596. Malice refers to conduct which is intended to injure a person or conduct with a conscious or deliberate disregard of the rights or safety of others. *Granite Construction Co. v. Rhyne*, 107 Nev. 651, 817 P.2d 711, 713 (1991); *see also Coughlin v.*

[2] This issue was previously briefed by the parties with respect to Defendants' Motion to Dismiss (previously filed in this matter), which is incorporated herein by reference.

Tailhook Ass'n, 112 F.3d 1052, 1055–56 (9th Cir. 1997). Fraud is found where a party intentionally makes a false representation to a plaintiff who relies upon that false statement to his detriment. *J.A. Jones Constr. Co. v. Lehrer McGovern Bovis, Inc.*, 120 Nev. 277, 89 P.3d 1009, 1017 (2004).

Here, Plaintiff has failed to present sufficient evidence to make a showing of oppression, fraud, or malice by clear and convincing evidence. First, there is no evidence of fraud. There is no evidence of a false representation or detrimental reliance.

Second, there is insufficient evidence of oppression or malice. The denial of the prior authorization request based on ASTRO and AHRQ guidance cannot support a finding of "cruel and unjust hardship." Likewise, it also cannot support a finding of "conduct which is intended to injure a person or conduct with a conscious or deliberate disregard of the rights or safety of others."

Revisiting Plaintiff's argument from summary judgment, there, Plaintiff relied on *Powers v. United Servs., Auto. Ass'n*, 114 Nev. 690, 704, 962 P.2d 596, 604-05 (1998), attempting to draw the comparison between the facts here and the "intentional course of conduct" in *Powers* that supported an award of punitive damages. In *Powers*, however, the evidence showed that the investigation at issue was done "in violation of [the insurer's] own procedures." 114 Nev. at 703, 962 P.2d at 604. Thus, the "intentional course of conduct" that supported an award of punitive damages arose out of the insurer's one-off deviation from their standard procedures in order to harm the insured. That simply did not happen here.

This case is much more akin to *Peterson*, where the Nevada Supreme Court concluded that while there was sufficient evidence of bad faith, there was insufficient evidence to support an award of punitive damages because although the insurer wrongfully denied benefits, it did so in accordance with its normal procedures without any specific malice or oppression as to the insured. *U.S. Fid & Guar. Co. v. Peterson*, 91 Nev. 617, 620, 540 P.2d 1070, 1072 (1975).

Plaintiff tries to distance her case from this precedent by raising side issues related to the preparation of the denial letter, typos in the claim file, and loaded rhetoric. But, at bottom, there is insufficient evidence for Plaintiff's demand for punitive damages to reach the jury.

CONCLUSION

Based on the foregoing, SHL respectfully requests that the Court grant the Motion and enter judgment as a matter of law against Plaintiff on her claim for insurance bad faith and demand for punitive damages.

DATED: March 25, 2022.

WEINBERG, WHEELER, HUDGINS,
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CERTIFICATE OF SERVICE

I hereby certify that on March 25, 2022 a true and correct copy of the foregoing **DEFENDANT'S MOTION FOR JUDGMENT AS A MATTER OF LAW** was electronically filed and served on counsel through the Court's electronic service system pursuant to Administrative Order 14-2 and N.E.F.C.R. 9, via the electronic mail addresses noted below, unless service by another method is stated or noted:

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CLERK OF THE COURT

JI

EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

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

Plaintiff,

vs.

SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.,

Defendant.

Case No.: A-19-788630-C
Dept. No.: 4

DEFENDANT'S PROPOSED JURY INSTRUCTIONS (DISPUTED)

(Updated to remove UHC)

Case Number: A-19-788630-C

Jury Instruction No. _____

The purpose of trial is to ascertain the truth.

Your purpose as jurors is to find and determine the facts. Under our system of civil procedure, you are the sole judge of the facts. You determine the facts from the testimony you hear and the other evidence, including exhibits introduced in court. It is up to you to determine the inferences which you feel may be properly drawn from the evidence. It is especially important that you perform your duty of determining the facts diligently and conscientiously, for ordinarily, there is no means of correcting an erroneous determination of facts by the jury.

Source/Authority:

Nevada Jury Instructions 1GI.1 and 1GI.5 (2011) (modified).

Jury Instruction No. _____

In this action, Plaintiff Sandra L. Eskew, as special administrator of the Estate of William G. Eskew, seeks to establish liability for breach of the implied covenant of good faith and fair dealing, otherwise known as bad faith, against Sierra Health and Life Insurance Company, Inc. I will now instruct you on the law pertaining to this claim.

Source/Authority:

NEV.J.I. 2.1 (2018) (modified).

Jury Instruction No. _____

In order to establish a breach of the implied covenant of good faith and fair dealing, Plaintiff Sandra Eskew, as the Special Administrator of the Estate of William George Eskew, must prove the following elements by clear and convincing evidence:

1. The proton beam therapy was a covered service under the terms of Mr. Eskew's Agreement of Coverage.
2. Sierra Health and Life had no reasonable basis for its denial of the prior authorization claim.
3. Sierra Health and Life knew, or recklessly disregarded, the fact that there was no reasonable basis for the denial of the prior authorization claim; and
4. Sierra Health and Life's denial was a legal cause of harm to William G. Eskew.

Source/Authority:

NEV.J.I. 11.5 (2018) (modified); NEV.J.I. 11.6 (2018) (modified); *Powers v. United Serv. Auto. Ass'n*, 114 Nev. 690, 962 P.2d 596, 604 (1998) ("To establish a prima facie case of bad-faith refusal to pay an insurance claim, the plaintiff must establish that the insurer had no reasonable basis for disputing coverage, and that the insurer knew or recklessly disregarded the fact that there was no reasonable basis for disputing coverage."); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc.*, 526 F. Supp. 3d 789, 802 (D. Nev. 2021) ("However, evidence that an insurer failed to properly investigate is only probative insofar as it supports the ultimate conclusion that an insurer denied a claim without a reasonable basis to do so."); *Molfetta v. Time Ins. Co.*, No. 207CV01240JCMLRL, 2010 WL 2041703, at *2 (D. Nev. May 17, 2010) (explaining that whether an insurer does not breach its contract with an insured, the insurer "could not, as a matter of law, have breached the implied covenant of good faith and fair dealing"); *Pioneer Chlor Alkali Co. v. Nat'l Union Fire Ins. Co. of Pittsburgh, Pennsylvania*, 863 F. Supp. 1237, 1244 (D. Nev. 1994) ("Nevada's Supreme Court has consistently announced and ruled that bad faith involves the denial of an insured's claim without any reasonable basis."); *Benavides v. State Farm General Ins. Co.*, 136 Cal.App.4th 1241, 1250 (2006) ("[A]n insured

cannot maintain a claim for tortious breach of the implied covenant of good faith and fair dealing absent a covered loss. If the insurer's investigation – adequate or not – results in a correct conclusion of no coverage, no tort liability arises for breach of the implied covenant.");

§ 204:41. Standard of proof, 14A Couch on Ins. § 204:41 ("Even in jurisdictions which recognize that bad-faith breach of the covenant of good faith may be remedied in tort, or at least remedied with damages typical of recovery in tort, there is concern that insurers should not be lightly held to such a new form of action. Accordingly, in some jurisdictions, the standard of proof for bad faith is elevated to a "clear and convincing" standard."); *Wolfe v. Allstate Prop. & Cas. Ins. Co.*, 790 F.3d 487, 497 (3d Cir. 2015) (providing that on a common law bad faith action under Pennsylvania law, an insurer's bad faith must be proven by clear and convincing evidence); *Freidline v. Shelby Ins. Co.*, 774 N.E.2d 37, 40 (Ind. 2002) ("To prove bad faith, the plaintiff must establish, with clear and convincing evidence, that the insurer had knowledge that there was no legitimate basis for denying liability."); *Maroney v. Allstate Ins. Co.*, 12 Wis. 2d 197, 201, 107 N.W.2d 261, 263 (1961) ("Considering all the undisputed facts presented in this case, it may be that the insurer acted negligently, exercising poor judgment, but it is not enough to show that it acted negligently in deciding to litigate rather than settle the case. 'Bad faith is a ***species of fraud***, and the evidence to sustain a finding thereof must be clear, satisfactory, and convincing.'"); *Allied Prop. & Cas. Ins. Co. v. Zenith Aviation Inc.*, No. 118CV264AJTIDD, 2019 WL 10960569, at *6 (E.D. Va. July 2, 2019) ("Dispositive to both of Zenith's claims—its claim for consequential damages arising from Allied's alleged breach of the implied contractual duty of good faith and fair dealing and its claims for costs and attorneys' fees pursuant to Va. Code § 38.2-209—is whether Allied acted in bad faith in denying Zenith's claim. However, under Virginia law, the standard of proof differs as to "common law breach of contract action[s]" premised on an insurer's alleged bad faith versus bad faith claims for attorneys' fees and costs under § 38.2-209. (citation omitted). Because "'bad faith' runs counter to the presumption that contracting parties have acted in good faith," the insured must prove bad faith by clear and convincing evidence in order to establish a breach of contract based on an insurer's bad faith.")

Chachas v. City of Ely, Nev., 615 F. Supp. 2d 1193, 1209 (D. Nev. 2009) ("Where a defamation action involves a public official, a plaintiff must allege and prove by clear and convincing evidence "actual malice." Id. (citing New York Times Co. v. Sullivan, 376 U.S. 254, 279–80, 84 S.Ct. 710, 11 L.Ed.2d 686 (1964)). Actual malice is "knowledge that [the statement] was false or with reckless disregard of whether it was false." Id. (citing Sullivan, 376 U.S. at 280, 84 S.Ct. 710)."); *Posadas v. City of Reno*, 109 Nev. 448, 454, 851 P.2d 438, 443 (1993) ("Actual malice is defined as knowledge of the falsity of a statement or a reckless disregard for its truth.").

Jury Instruction No. _____

An insurance policy is a contract. The contract should be considered as a whole and given a reasonable and harmonious reading. If the language in the policy is clear and unambiguous, the language is enforced as written in order to accomplish the intent of the parties.

The language of the contract should be viewed from the perspective of one not trained in the law and plain and ordinary meaning of the terms should be used.

Source/Authority:

NEV.J.I. 11.17 (2018) (modified); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc.*, 526 F. Supp. 3d 789, 797 (D. Nev. 2021) (laying out Nevada law when it comes to interpretation of an insurance contract*); Century Sur. Co. v. Casino W., Inc*., 130 Nev. 395, 398, 329 P.3d 614, 616 (2014) ("And we consider the policy as a whole to give reasonable and harmonious meaning to the entire policy.").

Jury Instruction No. _____

To preclude coverage under an insurance policy's exclusion provision, an insurer must (1) draft the exclusion in obvious and unambiguous language, (2) demonstrate that the interpretation excluding coverage is the only reasonable interpretation of the exclusionary provision, and (3) establish that the exclusion plainly applies to the particular case.

Source/Authority:

Century Sur. Co. v. Casino W., Inc., 130 Nev. 395, 398–99, 329 P.3d 614, 616 (2014) ("To preclude coverage under an insurance *399 policy's exclusion provision, an insurer must (1) draft the exclusion in "obvious and unambiguous language," (2) demonstrate that the interpretation excluding coverage is the only reasonable interpretation of the exclusionary provision, and (3) establish that the exclusion plainly applies to the particular case before the court.").

Jury Instruction No. _____

A defendant is entitled to deny a prior authorization request on the basis of debatable law or facts and will not be liable for bad faith for denying a claim if its position has any reasonable basis.

Source/Authority:

Powers v. United Servs. Auto. Ass'n, 114 Nev. 690, 728, 962 P.2d 596, 620 (1998), opinion modified on denial of reh'g, 115 Nev. 38, 979 P.2d 1286 (1999) ("A mere incorrect or "improper" denial of a claim is not tortious. A company may, in the utmost of good faith and propriety, deny a claim, only to have it proven later, in court, that its denial of the claim was improper and that the claimant was, indeed, entitled to indemnity."); *Brewington v. State Farm Mut. Auto. Ins. Co.*, 96 F. Supp. 3d 1105, 1109 (D. Nev. 2015) ("In other words, if a coverage position by an insurer with respect to a legal interpretation of a policy provision is fairly debatable, a denial of coverage cannot constitute bad faith where there is no contrary, controlling authority in the jurisdiction.").

Jury Instruction No. _____

There are no hard and fast rules for what constitutes a reasonable basis. Whether a defendant had a reasonable basis depends on the circumstances of each case.

Source/Authority:

Albert H. Wohlers & Co. v. Bartgis, 114 Nev. 1249, 1260, 969 P.2d 949, 957 (1998), as amended (Feb. 19, 1999) ("Based on these facts, we conclude that Allianz's [actions] were unreasonable."); *U. S. Fid. & Guar. Co. v. Peterson*, 91 Nev. 617, 620, 540 P.2d 1070, 1071 (1975) (holding that "[t]he record supports a finding that the insurance company exercised bad faith in its dealings" and further specifying individual facts from the record supporting that decision); *James River Ins. Co. v. Hebert Schenk, P.C.*, 523 F.3d 915, 923 (9th Cir. 2008) ("The first element of this test [which is whether an insurer "act[ed] unreasonably toward the insured"] is objective and asks whether the insurer acted in a "manner consistent with the way a reasonable insurer would be expected to act under the circumstances."); *Amadeo v. Principal Mut. Life Ins. Co.*, 290 F.3d 1152, 1161 (9th Cir. 2002) (citations and quotation marks omitted) ("[T]he reasonableness of an insurer's claims-handling conduct is ordinarily a question of fact."); *Phillips v. Clark Cty. Sch. Dist.*, 903 F. Supp. 2d 1094, 1104 (D. Nev. 2012) (holding that "the Court concludes that Defendant's denial was, at least, reasonable in light of the facts and circumstances of this particular claim and the injury incurred").

Jury Instruction No. _____

Evidence of conformance with industry standards goes to show that an insurer acted with a reasonable basis.

Source/Authority:

Hangarter v. Provident Life & Acc. Ins. Co., 373 F.3d 998, 1016 (9th Cir. 2004) ("While Caliri's testimony that Defendants deviated from industry standards supported a finding that they acted in bad faith . . ."); *RSUI Indem. Co. v. Vision One, LLC*, No. C08-1386RSL, 2009 WL 5125420, at *2 (W.D. Wash. Dec. 18, 2009) (explaining that a expert could testify as to the reasonableness of the insurer's actions in terms of whether or not insurer complied with or deviated from industry standards).

Jury Instruction No. _____

An insurer has a duty to investigate a claim filed by its insured. When investigating a claim, an insurer has a duty to diligently search for and consider evidence that supports an insured's claimed loss.

However, evidence that an insurer failed to properly investigate is only probative to the extent that it supports the ultimate conclusion that an insurer denied a claim without a reasonable basis to do so.

Source/Authority:

NEV.J.I. 11.8 (2018) (modified); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc.*, 526 F. Supp. 3d 789, 802 (D. Nev. 2021) ("However, evidence that an insurer failed to properly investigate is only probative insofar as it supports the ultimate conclusion that an insurer denied a claim without a reasonable basis to do so.").

Jury Instruction No. _____

An incorrect or improper denial of coverage does not amount to breach of the implied covenant of good faith or fair dealing as long as the defendant had a reasonable basis to take the position that it did.

Source/Authority:

Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc., 526 F. Supp. 3d 789, 801 (D. Nev. 2021) ("Poor judgment or negligence on the part of an insurer does not amount to bad faith."); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc*., 526 F. Supp. 3d 789, 801 (D. Nev. 2021) ("The insurer is not liable for bad faith for being incorrect about policy coverage as long as the insurer had a reasonable basis to take the position that it did."); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc.*, 526 F. Supp. 3d 789, 801 (D. Nev. 2021) ("Instead, bad faith involves something more than an unreasonable action, a negligent action, by the insurer."); *Allstate Ins. Co. v. Miller*, 125 Nev. 300, 317, 212 P.3d 318, 330 (2009) ("Thus, if the insurer's actions resulted from an honest mistake, bad judgment or negligence, then the insurer is not liable under a bad-faith theory."); *Pioneer Chlor Alkali Co. v. Nat'l Union Fire Ins. Co. of Pittsburgh, Pennsylvania*, 863 F. Supp. 1237, 1243 (D. Nev. 1994) ("While bad faith involves the absence of any reasonable basis to deny coverage, bad faith is not a reasonableness of conduct standard. (citation omitted). Thus, bad faith involves something more than an unreasonable action, a negligent action, by the insurer. That is, bad faith does not directly address the manner in which an insurer processes a claim as does NRS 686A.310. Bad faith requires an awareness that no reasonable basis exists to deny the insured's claim.").

Jury Instruction No. _____

An honest mistake, poor judgment, or negligence on the part of the defendant does not amount to breach of the implied covenant of good faith or fair dealing. Breach of the implied covenant of good faith or fair dealing involves something more than an unreasonable or negligent action by the defendant.

Source/Authority:

Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc., 526 F. Supp. 3d 789, 801 (D. Nev. 2021) ("Poor judgment or negligence on the part of an insurer does not amount to bad faith."); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc*., 526 F. Supp. 3d 789, 801 (D. Nev. 2021) ("The insurer is not liable for bad faith for being incorrect about policy coverage as long as the insurer had a reasonable basis to take the position that it did."); *Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc.*, 526 F. Supp. 3d 789, 801 (D. Nev. 2021) ("Instead, bad faith involves something more than an unreasonable action, a negligent action, by the insurer."); *Allstate Ins. Co. v. Miller*, 125 Nev. 300, 317, 212 P.3d 318, 330 (2009) ("Thus, if the insurer's actions resulted from an honest mistake, bad judgment or negligence, then the insurer is not liable under a bad-faith theory."); *Pioneer Chlor Alkali Co. v. Nat'l Union Fire Ins. Co. of Pittsburgh, Pennsylvania*, 863 F. Supp. 1237, 1243 (D. Nev. 1994) ("While bad faith involves the absence of any reasonable basis to deny coverage, bad faith is not a reasonableness of conduct standard. (citation omitted). Thus, bad faith involves something more than an unreasonable action, a negligent action, by the insurer. That is, bad faith does not directly address the manner in which an insurer processes a claim as does NRS 686A.310. Bad faith requires an awareness that no reasonable basis exists to deny the insured's claim.").

Jury Instruction No. _____

A defendant's speed in handling a claim could indicate that it had not adequately investigated, but efficiency does not prove inadequacy.

Source/Authority:

Goodrich v. Garrison Prop. & Cas. Ins. Co., Inc., 526 F. Supp. 3d 789, 802 (D. Nev. 2021) ("[A]n insurer's speed in handling a claim could indicate that it had not adequately investigated, but efficiency does not necessarily prove inadequacy.").

Jury Instruction No. _____

In determining whether a defendant acted with no reasonable basis, you may consider whether the defendant did any of the following:

(a) Misrepresenting to insureds or claimants pertinent facts or insurance policy provisions relating to any coverage at issue.

(b) Failing to acknowledge and act reasonably promptly upon communications with respect to claims arising under insurance policies.

(c) Failing to adopt and implement reasonable standards for the prompt investigation and processing of claims arising under insurance policies.

(d) Failing to affirm or deny coverage of claims within a reasonable time after proof of loss requirements have been completed and submitted by the insured.

(e) Failing to effectuate prompt, fair, and equitable settlements of claims in which liability of the insurer has become reasonably clear.

(f) Compelling insureds to institute litigation to recover amounts due under an insurance policy by offering substantially less than the amounts ultimately recovered in actions brought by such insureds, when the insureds have made claims for amounts reasonably similar to the amounts ultimately recovered.

(g) Attempting to settle a claim by an insured for less than the amount to which a reasonable person would have believed he or she was entitled by reference to written or printed advertising material accompanying or made part of an application.

(h) Attempting to settle claims on the basis of an application which was altered without notice to, or knowledge or consent of, the insured, or the representative, agent or broker of the insured.

(i) Failing, upon payment of a claim, to inform insureds or beneficiaries of the coverage under which payment is made.

(j) Making known to insureds or claimants a practice of the insurer of appealing from arbitration awards in favor of insureds or claimants for the purpose of compelling

them to accept settlements or compromises less than the amount awarded in arbitration.

(k) Delaying the investigation or payment of claims by requiring an insured or a claimant, or the physician of either, to submit a preliminary claim report, and then requiring the subsequent submission of formal proof of loss forms, both of which submissions contain substantially the same information.

(m) Failing to provide promptly to an insured a reasonable explanation of the basis in the insurance policy, with respect to the facts of the insured's claim and the applicable law, for the denial of the claim or for an offer to settle or compromise the claim.

(n) Advising an insured or claimant not to seek legal counsel.

(o) Misleading an insured or claimant concerning any applicable statute of limitations.

The presence or absence of any of these factors alone is not enough to determine whether the defendant's conduct was or was not in bad faith. You must consider the defendant's conduct as a whole in making this determination.

Source/Authority:

NEV.J.I. 11.21 (2018) (used list of unfair practice); California Civil Jury Instructions 2337 (2020) (used language for opening and closing paragraph).

Jury Instruction No. _____

It is not enough to show that, in hindsight, a defendant acted with no reasonable basis; the plaintiff must show that the defendant knew or recklessly disregarded that there was no reasonable basis for its conduct.

Source/Authority:

Igartua v. Mid-Century Ins. Co., 262 F. Supp. 3d 1050, 1053 (D. Nev. 2017) ("It is not enough to show that, in hindsight, an insurer acted unreasonably; the plaintiff must show that the insurer knew or recklessly disregarded that it was acting unreasonably.").

Jury Instruction No. _____

An insurer has a reasonable basis to deny coverage if the insured's claim is fairly debatable either on a matter of fact or law. A claim is fairly debatable when it is open to dispute on any logical basis. And so, if reasonable minds can differ on the coverage-determining facts or law, then the claim is fairly debatable.

Source/Authority:

Sloan v. Country Preferred Ins. Co., No. 212CV01085APGPAL, 2014 WL 12788197, at *6 (D. Nev. May 15, 2014), adhered to on reconsideration, No. 212CV01085APGPAL, 2015 WL 13674185 (D. Nev. Mar. 5, 2015) ("An insurer's belief that the validity of an insured's claim is 'fairly debatable' is a defense to a bad faith claim. The existence of that subjective belief, however, is a question of fact for the jury.") (citing *Albert H. Wohlers & Co. v. Bartgis*, 114 Nev. 1249, 1259, 969 P.2d 949, 957 (1998), as amended (Feb. 19, 1999)); *Telligen, Inc. v. Atl. Specialty Ins. Co.*, 454 F. Supp. 3d 843, 845-46 (S.D. Iowa 2020) ("An insurer has a reasonable basis to deny coverage if the insured's claim is fairly debatable either on a matter of fact or law. A claim is fairly debatable when it is open to dispute on any logical basis. And so, if reasonable minds can differ on the coverage-determining facts or law, then the claim is fairly debatable.").

Jury Instruction No. _____

A legal cause of injury, damage, loss, or harm is a cause which is a substantial factor in bringing about the injury, damage, loss, or harm.

Source/Authority:

NEV.J.I. 4.5 (2018).

Jury Instruction No. _____

A substantial factor is a factor that a reasonable person would consider to have contributed to harm. It must be more than a remote or trivial factor. It does not have to be the only cause of the harm.

Conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct.

Source/Authority:

NEV.J.I. 4.5 (2018); California Civil Jury Instructions 430 (2020).

Jury Instruction No. _____

A mere possibility of causation does not satisfy the requirement of legal cause.

Source/Authority:

Bergman v. United States, 579 F. Supp. 911, 921 (W.D. Mich. 1984 ("A 'mere possibility' of causation does not satisfy the requirement of proximate cause.") (citing *Brown Mechanical Contractors, Inc. v. Centennial Insurance Company*, 431 So.2d 932, 942 (Ala. 1983); *Ex Parte Travis*, 414 So.2d 956 (Ala. 1982)).

Jury Instruction No. _____

If you find that Sierra Health and Life breached the implied covenant of good faith and fair dealing, also known as bad faith, then Plaintiff Sandra L. Eskew, as the Special Administrator of the Estate of William G. Eskew, can recover all consequential damages that William G. Eskew incurred or sustained before his death that were caused by Sierra Health and Life's breach of the implied covenant of good faith and fair dealing. In determining this award of damages, if any, from the evidence presented, you will take into consideration the nature, extent, and duration of the damages that you believe William G. Eskew incurred or sustained.

Source/Authority:

NRS 41.100(3) ("Except as otherwise provided in this subsection, when a person who has a cause of action dies before judgment, the damages recoverable by the decedent's executor or administrator include all losses or damages which the decedent incurred or sustained before the decedent's death, including any penalties or punitive and exemplary damages which the decedent would have recovered if the decedent had lived, and damages for pain, suffering or disfigurement and loss of probable support, companionship, society, comfort and consortium. This subsection does not apply to the cause of action of a decedent brought by the decedent's personal representatives for the decedent's wrongful death.").

U. S. Fid. & Guar. Co. v. Peterson, 91 Nev. 617, 619–20, 540 P.2d 1070, 1071 (1975) ("We approve and adopt the rule that allows recovery of consequential damages where there has been a showing of bad faith by the insurer.").

NEV.J.I. 5.1 (2018) (modified opening sentence from model instruction is reflected in last sentence).

Jury Instruction No. _____

"Consequential damages" are damages that can fairly and reasonably be considered to arise naturally from a breach of the implied covenant of good faith and fair dealing.

Source/Authority:

Century Sur. Co. v. Andrew, 134 Nev. 819, 825, 432 P.3d 180, 186 (2018) ("Consequential damages 'should be such as may fairly and reasonably be considered as arising naturally, or were reasonably contemplated by both parties at the time they made the contract.'").

Jury Instruction No. _____

Plaintiff seeks to recover damages for the physical and mental pain, suffering, emotional distress, and anxiety that William G. Eskew allegedly incurred from the date of the breach of the implied covenant of good faith and fair dealing to the date of his death caused by the breach.

Plaintiff does not allege that Sierra Health and Life caused or contributed to William G. Eskew's death.

Source/Authority:

NEV.J.I. 5.1 (2018); Plaintiff's Fifth Supplement to NRCP 16.1(a) Disclosures (identifying categories of damages sought).

Jury Instruction No. _____

No fixed standard exists for deciding the amount of physical and mental pain, suffering, emotional distress, and anxiety damages. Nor is the opinion of any witness required as to the amount of such reasonable compensation. You must use your judgment to decide upon a reasonable amount based on the evidence and your common sense.

Source/Authority:

NEV.J.I. 5.2 (2018); Plaintiff's Fifth Supplement to NRCP 16.1(a) Disclosures (identifying categories of damages sought).

Jury Instruction No. _____

A party cannot recover damages for losses it could have avoided by reasonable efforts. The burden is on the party whose wrongful acts resulted in the damages to prove that the damages might have been lessened by reasonable diligence and expenditures on the part of the party seeking damages. Reasonable diligence does not require that the party seeking damages ask the party whose wrongful conduct resulted in the damages to remedy the injury, detriment, harm or loss resulting from the alleged wrongful act.

Source/Authority:

NEV.J.I. 13.49 (2018) (modified); *Cordova v. Am. Fam. Mut. Ins. Co*., No. 2:13-CV-1111-KJD-VCF, 2016 WL 4060304, at *2 (D. Nev. July 28, 2016) (explaining that a plaintiff had a duty to mitigate consequential damages arising from a bad faith claim).

Jury Instruction No. _____

Plaintiff seeks punitive damages against Sierra Health and Life. Therefore, if you find that Sierra Health and Life is liable for breach of the implied covenant of good faith and fair dealing you may then consider whether you should award punitive or exemplary damages against it.

Punitive or exemplary damages are used to make an example of or punish wrongful conduct. You have discretion to award such damages, only if you find by clear and convincing evidence that Sierra Health and Life was guilty of oppression, fraud or malice in that its conduct breached the implied covenant of good faith and fair dealing.

"Malice" means conduct which is intended to injure a person or despicable conduct which is engaged in with a conscious disregard of the rights or safety of others.

"Oppression" means despicable conduct that subjects a person to cruel and unjust hardship with conscious disregard of the rights of that person.

"Fraud" means an intentional misrepresentation, deception or concealment of a material fact known to Sierra Health and Life to which William G. Eskew relied upon to his detriment.

"Conscious disregard" means knowledge of the probable harmful consequences of a wrongful act and a willful and deliberate failure to avoid these consequences.

At this time, you are to decide only whether an award of punitive damages is justified. If you decide an award of punitive damages is justified, you will later decide the amount of punitive damages to be awarded, after you have heard additional evidence and instruction.

Source/Authority:

NEV.J.I. 12.1 (2018) (modified); Nevada Jury Instructions 12PD.1 (2011) (modified); NRS 42.005; *Wyeth v. Rowatt*, 126 Nev. Adv. Op. 44, 244 P.3d 765 (2010); *Countrywide Home Loans, Inc. v. Thitchener*, 124 Nev. 725, 192 P.3d 243 (2008); *Evans v. Dean Witter Reynolds, Inc.*, 116 Nev. 598, 5 P.3d 1043 (2000); *Clark v. Lubritz*, 113 Nev. 1089, 944 P.2d 861 (1997); *see also State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 123 S.Ct. 1513 (2003); *White v. Ford Motor Co.*, 312 F.3d 998 (9th Cir. 2002); *Betsinger v. D.R. Horton, Inc.*, 126 Nev. Adv. Op. 17, 232 P.3d 433 (2010); *Bongiovi v. Sullivan*, 122 Nev. 556, 138 P.3d 433 (2006); *Dillard*

Dep't. Stores, Inc. v. Beckwith, 115 Nev. 372, 989 P.2d 882 (1999), *cert. denied*, 530 U.S. 1276 (2000); *Albert H. Wohlers & Co. v. Bartgis*, 114 Nev. 1249, 969 P.2d 949 (1999), *cert. denied*, 527 U.S. 1038 (1999); *Guaranty Nat'l Ins. Co. v. Potter*, 112 Nev. 199, 912 P.2d 267 (1996); *Ace Truck & Equip. Rentals, Inc. v. Kahn*, 103 Nev. 503, 746 P.2d 132 (1987); *Phillip Morris USA v. Williams*, 549 U.S. 346 (2007); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408 (2003); *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996).

NRS 42.005(5) ("For the purposes of an action brought against an insurer who acts in bad faith regarding its obligations to provide insurance coverage, the definitions set forth in NRS 42.001 are not applicable and the corresponding provisions of the common law apply."); *Ainsworth v. Combined Ins. Co. of America*, 105 Nev. 237, 774 P.2d 1003, 1012 (Nev.1989) (internal quotation marks and citations omitted), abrogated on other grounds by *Powers*, 114 Nev. 690, 962 P.2d 596 (providing that oppression occurs when the plaintiff is subjected to "cruel and unjust hardship in conscious disregard of his rights"); *Granite Construction Co. v. Rhyne*, 107 Nev. 651, 817 P.2d 711, 713 (1991) (providing that malice refers to conduct which is intended to injure a person or conduct with a conscious or deliberate disregard of the rights or safety of others); *see also Coughlin v. Tailhook Ass'n*, 112 F.3d 1052, 1055–56 (9th Cir. 1997); *J.A. Jones Constr. Co. v. Lehrer McGovern Bovis, Inc*., 120 Nev. 277, 89 P.3d 1009, 1017 (2004) (providing that fraud is found where a party intentionally makes a false representation to a plaintiff who relies upon that false statement to his detriment).

Jury Instruction No. _____

A breach of the implied covenant of good faith and fair dealing alone does not mean that a defendant acted with oppression, fraud, or malice. Instead, you must separately find oppression, fraud or malice by clear and convincing evidence.

Source/Authority:

United Fire Ins. Co. v. McClelland, 105 Nev. 504, 512, 780 P.2d 193, 198 (1989) (providing that "proof of bad faith, by itself, does not establish liability for punitive damages"); *U. S. Fid. & Guar. Co. v. Peterson*, 91 Nev. 617, 621, 540 P.2d 1070, 1072 (1975) (concluding that while the record supported a finding of bad faith, "the necessary requisites to support punitive damages [were] not present").

Jury Instruction No. _____

Acts or conduct by Sierra Health and Life that took place outside the state of Nevada, whether lawful or unlawful, cannot be relied on to award punitive damages.

Source/Authority:

Nevada Jury Instructions 12PD.2 (2011) ("Evidence has been presented concerning a defendant's conduct outside Nevada and/or conduct injuring others are who not parties to this litigation. You cannot use such evidence to award plaintiff punitive damages for conduct outside Nevada, or conduct injuring others who are not parties tot his litigation, or conduct that does not bear a reasonable relationship to the conduct injuring plaintiff that warrants punitive damages in this case."); California Civil Jury Instructions 3945; BAJI 14.71.1; *Philip Morris USA v. Williams*, 549 U.S. 346, 353–354 (2007) (holding the United States Constitution requires an instruction that punitive damages may not be awarded for a party's conduct related to non-parties); *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 422 (2003) (holding the United States Constitution requires an instruction that punitive damages may not be awarded for a party's conduct that occurred in another State); *White v. Ford Motor Co.*, 312 F.3d 998 (9th Cir. 2002) (holding Nevada jury was required to be instructed that a defendant cannot be punished for conduct, lawful or unlawful, that occurred in another state).

Jury Instruction No. _____

Acts or conduct by persons or entities that are not parties to this lawsuit cannot be relied on to award punitive damages.

Source/Authority:

Nevada Jury Instructions 12PD.2 (2011) ("Evidence has been presented concerning a defendant's conduct outside Nevada and/or conduct injuring others are who not parties to this litigation. You cannot use such evidence to award plaintiff punitive damages for conduct outside Nevada, or conduct injuring others who are not parties tot his litigation, or conduct that does not bear a reasonable relationship to the conduct injuring plaintiff that warrants punitive damages in this case."); California Civil Jury Instructions 3945; BAJI 14.71.1; *Philip Morris USA v. Williams*, 549 U.S. 346, 353–354 (2007) (holding the United States Constitution requires an instruction that punitive damages may not be awarded for a party's conduct related to non-parties); *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408, 422 (2003) (holding the United States Constitution requires an instruction that punitive damages may not be awarded for a party's conduct that occurred in another State); *White v. Ford Motor Co.*, 312 F.3d 998 (9th Cir. 2002) (holding Nevada jury was required to be instructed that a defendant cannot be punished for conduct, lawful or unlawful, that occurred in another state).

PHASE 2 INSTRUCTIONS REGARDING PUNITIVE DAMAGES AWARD

Jury Instruction No. _____

There are no fixed standards for determining the amount of a punitive damage award; the amount, if any, is left to your sound discretion, to be exercised without passion or prejudice and in accordance with the following governing principles.

The amount of a punitive damage award is not to compensate the plaintiff for harm suffered but what is reasonably necessary and fairly deserved (in light of the blameworthiness and harmfulness inherent in the defendant's conduct) to punish and deter the defendant and others from engaging in conduct such as that warranting punitive damages in this case. Your award cannot be more than otherwise warranted by the evidence in this case merely because of the wealth of the defendant. Your award cannot either punish the defendant for conduct injuring others who are not parties to this litigation.

In determining the amount of your punitive damage award, you should consider the following guideposts:

1. The degree of reprehensibility of the defendant's conduct, in light of (a) the culpability and blameworthiness of the defendant's fraudulent, oppressive and/or malicious misconduct under the circumstances of this case; (b) whether the conduct injuring plaintiffs that warrants punitive damages in this case was part of a pattern of similar conduct by the defendant; and (c) any mitigating conduct by the defendant, including any efforts to settle the dispute.

2. The ratio of your punitive damage award to the actual harm inflicted on William G. Eskew by the conduct warranting punitive damages in this case, since the measure of punishment must be both reasonable and proportionate to the amount of harm to William G. Eskew and to the compensatory damages recovered by the plaintiff in this case.

3. How your punitive damages award compares to other civil or criminal penalties that could be imposed for comparable misconduct, since punitive damages are to provide a means by which the community can express its outrage or distaste for the misconduct of a fraudulent, oppressive or malicious defendant and deter and warn others that such conduct will not be tolerated.

Source/Authority:

Nevada Jury Instructions 12PD.2 (2011) (modified to remove affirmative defense of annihilation and financial condition, which Defendants are not asserting).

Jury Instruction No. _____

There is no right to punitive damages. Accordingly, you need not award punitive damages even if you find that the standard for imposing punitive damages has been satisfied.

Source/Authority:

Smith v. Wade, 461 U.S. 30, 52 (1983) (punitive damages "are never awarded as of right, no matter how egregious the defendant's conduct. 'If the plaintiff proves sufficiently serious misconduct on the defendant's part, the question whether to award punitive damages is left to the jury, which may or may not make such an award.'"); *Smith Food & Drug Centers, Inc. v. Bellegarde*, 114 Nev. 602, 958 P.2d 1208 (1998).

Jury Instruction No. _____

Any individuals other than William G. Eskew who might claim to have been harmed by the defendant have the right to bring their own lawsuit seeking compensatory and punitive damages for the wrong, if any done to them. Therefore, in determining the amount of punitive damages, if any, that is necessary for punishment and deterrence, you may consider only the wrong done to William G. Eskew in this case. You may not award any punitive damages for the purpose of punishing or deterring defendant's conduct toward anyone else or any conduct outside the State of Nevada.

Source/Authority:

Philip Morris USA v. Williams, 549 U.S. 346, 354 (2007) ("the Due Process Clause forbids a state to use a punitive damage award to punish a defendant for injury that it inflicts upon non parties or those whom they directly represent i.e. injury that it inflicts upon those who are essentially, strangers to the litigation"); *State Farm Ins. Co. v. Campbell*, 538 U.S. 408, 426 (2003) ("Due process does not permit courts, in the calculation of punitive damages, to adjudicate the merits of other parties' hypothetical claims against a defendant under the guise of the reprehensibility analysis.... Punishment on these bases creates the possibility of multiple punitive damages awards for the same conduct; for in the usual case nonparties are not bound by the judgment some other plaintiff obtains."); *id.* at 421-22 (2003) ("Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction" * * * out of state conduct "must have a nexus to the specific harm suffered by the plaintiff").

Jury Instruction No. _____

A defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages. A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business.

Source/Authority:

State Farm Mut. Auto. Ins. Co. v. Campbell, 123 S.Ct. 1513, 1523 (2003).

Jury Instruction No. _____

Your award of punitive damages must be based solely on the conduct that by clear and convincing evidence was shown to constitute fraud, oppression, or malice.

Source/Authority:

14A STEVEN PLITT ET AL., COUCH ON INSURANCE § 207:73 (3d ed. June 2021 update) ("In most instances, unless the insured would be entitled to a directed verdict on the underlying insurance claim, an arguable reason to deny the claim exists, precluding the imposition of punitive damages."); *Pioneer Chlor Alkali Co. v. Nat'l Union Fire Ins. Co.*, 863 F. Supp. 1237, 1250–51 (D. Nev. 1994) (acknowledging "difficulty constructing a factual situation where an insurer who violated [NRS 686A.310] could have done so with an oppressive or malicious intent yet not denied, or refused to pay, the claim").

Jury Instruction No. _____

A defendant's conduct in litigation before trial may not be used to impose punitive damages.

Source/Authority:

Bahena v. Goodyear Tire & Rubber Co., 126 Nev. 243, 259 n.1, 235 P.3d 592, 603 n.1 (2010) (Pickering, J., dissenting) (explaining that the district court's discovery sanction extended only to striking Goodyear's answer as to liability; Goodyear was allowed to defend on punitive damages without the presumption of liability: "Goodyear avoided punitive damages in this case by arguing that a road hazard, rather than design or manufacturing defect, caused the tire failure from which this accident resulted."); *see also* Nev. J.I. 2.5 (2018); NRS 47.250(3); *Bass-Davis v. Davis*, 122 Nev. 442, 448, 134 P.3d 103, 106-07 (2006); *Bosack v. Soward*, 586 F.3d 1096, 1105 (9th Cir. 2009) ("Absent an abuse of process or malicious prosecution, 'a defendants trial tactics and litigation conduct may not be used to impose punitive damages in a tort action.'" (quoting *De Anza Santa Cruz Mobile Estates Homeowners Assn. v. De Anza Santa Cruz Mobile Estates*, 114 Cal. Rptr. 2d 708, 730 (App. Ct. 2001)); *Palmer v. Ted Stevens Honda, Inc.*, 238 Cal. Rptr. 363, 369 (App. Ct. 1987) ("Not only was admission of this evidence of defendant's litigation conduct . . . error, we conclude it undermines the integrity of the punitive damage award" because it "inflamed the jury so as to disregard the court's admonitions about its limited purpose"); *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003) (restricting punitive damages to punish the defendant for "the acts upon which liability was premised," not independent or subsequent misconduct); *Simmons v. Southern Pac. Transportation Co.*, 133 Cal. Rptr. 42, 58 (Cal. App. 1976) (citing *Noe v. Kaiser Foundation Hospitals*, 435 P.2d 306 (Cal. 1967)) (refusing to allow punitive damages based upon railroad's willful destruction of evidence because "[e]ven assuming that the railroad engaged in file-stripping, evidence suppression, and willful refusal to file accident reports, these matters occurred long after the accident and could not have had any bearing on the accident itself"; thus, "[i]nconsistencies, evasions and untruths made subsequent to the occasion have been considered by this court to be only evidence of an attempt to avoid responsibility for past actions rather than evidence of previous disregard for

consequences"); *Brito v. Gomez Law Group, LLC*, 658 S.E. 2d 178, 184-85 (Ga. App. 2008) (no authority supports punitive damages "as a sanction for spoliation of evidence, and the record contains no evidence of intentional actions by [defendant] going beyond mere spoliation"); *Schenk v. HNA Holdings, Inc.*, 613 S.E.2d 503, 24 A.L.R.6th 919 (N.C. App. 2005) (that engineer directed asbestos specialist to destroy memorandum and provide only verbal reports of asbestos removal was insufficient to establish that corporate owner's officer, director, or manager participated in willful or wanton conduct that resulted in third-party maintenance workers' asbestos-related injuries; no evidence that destruction of memorandum resulted in workers' injuries); *cf. also Reeves v. Alyeska Pipeline Service Co.*, 56 P.3d 660 (Alaska 2002) (destruction of evidence was not presented to the jury as separate tort theory, "and it would be improper to speculate that the jury found that these torts were established, much less that they warranted an award of punitive damages").

[NOTE: Defendants object to the introduction of its financial condition at trial.]

Jury Instruction No. _____

The wealth of a defendant does not diminish its entitlement to all the protections of the law on which you have been instructed. A defendant's financial resources do not justify a large punishment, or even any punishment. Moreover, you may not punish a defendant simply on the basis of its size.

Source/Authority:

Nevada Jury Instructions 12 PD.2 (2011) (modified) ("Your award cannot be more than otherwise warranted by the evidence in this case merely because of the wealth of the defendant."); *State Farm Ins. Co. v. Campbell*, 123 S. Ct. 1513, 1525 (2003) (the wealth of the defendant cannot justify an otherwise unconstitutional punitive damages award); *BMW of N. Am. v. Gore*, 517 U.S. 559, 585 (1996) ("the fact that BMW is a large corporation rather than an impecunious individual does not diminish its entitlement to fair notice of the demands that the several states impose on the conduct of its business"); *see also Bongiovi v. Sullivan*, 122 Nev. 556, 582-83, 138 P.3d 433, 452 (2006) (adopting federal guideposts set forth in *State Farm* and *BMW of N. Am.*).

Jury Instruction No. _____

In contrast to compensatory damages, punitive damages rest on justifications similar to those for criminal punishment. Because exemplary damages resemble criminal punishment, they require appropriate substantive and procedural safeguards to minimize the risk of unjust punishment.

One of these safeguards is that, in contrast to your verdict on compensatory damages, your verdict as to the amount of punitive damages must be unanimous.

Source/Authority:

State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 417 (2003) (stating that punitive damages "serve the same purposes as criminal penalties"); *Austin v. Stokes-Craven Holding Corp*., 691 S.E.2d 135, 150 (S.C. 2010) ("[P]unitive damages are quasi-criminal in nature."); *George Grubbs Enters., Inc. v. Bien*, 900 S.W.2d 337, 339 (Tex. 1995) ("In contrast to compensatory damages, exemplary damages rest on justifications similar to those for criminal punishment."); *Grisham v. Philip Morris, Inc*., 670 F. Supp. 2d 1014, 1036 (C.D. Cal. 2009) (there are "heightened due process considerations surrounding punitive damages awards" under the Fourteenth Amendment); *see Campbell*, 538 U.S. at 417 (basing the Court's decision on the fact that "defendants subjected to punitive damages in civil cases have not been accorded the protections applicable in a criminal proceeding[, which] increases our concerns over the imprecise manner in which punitive damages systems are administered"); *George Grubbs*, 900 S.W.2d at 339 ("Because exemplary damages resemble criminal punishment, they require appropriate substantive and procedural safeguards to minimize the risk of unjust punishment."); *Austin*, 691 S.E.2d at 150 ("Because punitive damages are quasi-criminal in nature, the process of assessing punitive damages is subject to the protections of the Due Process Clause of the Fourteenth Amendment of the United States Constitution."). *See generally, e.g., Philip Morris USA v. Williams*, 549 U.S. 346 (2007); *BMW of N. Am., Inc. v. Gore*, 517 U. S. 559 (1996); *TXO Prod. Corp. v. Alliance Res. Corp*., 509 U.S. 443 (1993); *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991); KIRCHER, PUNITIVE DAMAGES: LAW AND PRACTICE 2D § 3.03 (2000); *Ramos v. Louisiana*, 140 S. Ct. 1390, 1397 (2020) (requiring a unanimous verdict in state-court criminal

trials); NRS 175.481 ("The verdict shall be unanimous. It shall be returned by the jury to the judge in open court."); NRS 175.191 ("A defendant in a criminal action is presumed to be innocent until the contrary is proved; and in case of a reasonable doubt whether the defendant's guilt is satisfactorily shown, the defendant is entitled to be acquitted."); NRS 175.211 ("1. A reasonable doubt is one based on reason. It is not mere possible doubt, but is such a doubt as would govern or control a person in the more weighty affairs of life. If the minds of the jurors, after the entire comparison and consideration of all the evidence, are in such a condition that they can say they feel an abiding conviction of the truth of the charge, there is not a reasonable doubt. Doubt to be reasonable must be actual, not mere possibility or speculation. 2. No other definition of reasonable doubt may be given by the court to juries in criminal actions in this State.").

FILED IN OPEN COURT
04-04-2022 4:57 PM
STEVEN D. GRIERSON
CLERK OF THE COURT
BY PHARAN BURCHFIELD, DEPUTY

VER

IN THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF CLARK

SANDRA L. ESKEW, as Special Administrator of the Estate of William George Eskew, Plaintiff, vs. SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC. Defendant.	Case No. A-19-788630-C Dept. No. 4

A-19-788630-C
VER
Verdict
4987916

VERDICT

We, the empaneled jury in the above-entitled case, return the following special verdict on the questions submitted to us:

1. Do you find that Sierra Health and Life breached the implied covenant of good faith and fair dealing?

YES ✓ NO _____

If you answered "yes" to question 1, please proceed to question 2. If you answered "no" to question 1, you have completed this verdict form. The foreperson should sign it and inform the marshal that you have reached a verdict.

2. What amount of money do you find for the damages to William Eskew caused by the breach of the implied covenant of good faith and fair dealing?

$ 40,000,000.00

If you answered "yes" to question 2, please proceed to question 3. If you answered "no" to question 2, you have completed this verdict form. The foreperson should sign it and inform the marshal that you have reached a verdict.

3. Do you find, by clear and convincing evidence, that Sierra Health and Life acted with malice and/or oppression to justify an award of punitive damages?

YES ✓ NO _____

DATED this 4 day of April 2022.

FOREPERSON

INST

FILED IN OPEN COURT
04-04-2022
STEVEN D. GRIERSON
CLERK OF THE COURT
BY PHARAN BREHFIELD, DEPUTY

DISTRICT COURT

CLARK COUNTY, NEVADA

SANDRA ESKEW, as the Special Administrator of the Estate of William George Eskew, Plaintiff, vs. SIERRA HEALTH AND LIFE INSURANCE, INC., Defendant.	Case No. A-19-788630-C Dept. No. 4 **JURY INSTRUCTIONS**

A-19-788630-C
JI
Jury Instructions
4987918

INSTRUCTION NO. 1

MEMBERS OF THE JURY:

It is my duty as judge to instruct you in the law that applies to this case. It is your duty as jurors to follow these instructions and to apply the rules of law to the facts as you find them from the evidence.

You must not be concerned with the wisdom of any rule of law stated in these instructions. Regardless of any opinion you may have as to what the law ought to be, it would be a violation of your oath to base a verdict upon any other view of the law than that given in the instructions of the court.

INSTRUCTION NO. 2

The purpose of trial is to ascertain the truth.

Your purpose as jurors is to find and determine the facts. Under our system of civil procedure, you are the sole judge of the facts. You determine the facts from the testimony you hear and the other evidence, including exhibits introduced in court. It is up to you to determine the inferences which you feel may be properly drawn from the evidence. It is especially important that you perform your duty of determining the facts diligently and conscientiously, for ordinarily, there is no means of correcting an erroneous determination of facts by the jury.

INSTRUCTION NO. 3

If, in these instructions, any rule, direction or idea is repeated or stated in different ways, no emphasis thereon is intended by me and none may be inferred by you. For that reason, you are not to single out any certain sentence or any individual point or instruction and ignore the others, but you are to consider all the instructions as a whole and regard each in the light of all the others.

The order in which the instructions are given has no significance as to their relative importance.

INSTRUCTION NO. 4

Although you are to consider only the evidence in the case in reaching a verdict, you must bring to the consideration of the evidence your everyday common sense and judgment as reasonable men and women. Thus, you are not limited solely to what you see and hear as the witnesses testify. You may draw reasonable inferences from the evidence which you feel are justified in the light of common experience, keeping in mind that such inferences should not be based on speculation or guess.

A verdict may never be influenced by sympathy, prejudice or public opinion. Your decision should be the product of sincere judgment and sound discretion in accordance with these rules of law.

INSTRUCTION NO. 5

If during trial, I have said or done anything which has suggested to you that I am inclined to favor the claims or position of any party, you will not be influenced by any such suggestion.

I have not expressed, nor intended to express, nor have I intended to intimate, any opinion as to which witnesses are or are not worthy of belief, what facts are or are not established, or what inference should be drawn from the evidence. If any expression of mine has seemed to indicate an opinion relating to these matters, I instruct you to disregard it.

INSTRUCTION NO. 6

The defendant in this case is a corporation. A corporation is entitled to the same fair and unprejudiced treatment as an individual would be under like circumstances, and you should decide the case with the same impartiality you would use in deciding a case between individuals.

INSTRUCTION NO. 7

Throughout the following instructions, I instruct that a party must prove certain claims or allegations by either a preponderance of the evidence or by clear and convincing evidence. The meaning of these terms is as follows.

"Preponderance of the evidence" means such evidence as, when considered and weighed against that opposed to it, has more convincing force and produces in your mind a belief that what is sought to be proved is more probably true than not true.

"Clear and convincing evidence" means such evidence that will produce in your mind a firm belief or conviction as to the allegations sought to be established. It is an intermediate degree of proof, being more than a mere preponderance but not to the extent of such certainty as is required to prove an issue beyond a reasonable doubt. Proof by clear and convincing evidence is proof which persuades you that the truth of the contentions is highly likely.

In determining whether a party has met either burden, you must consider all the evidence, whether introduced by the plaintiff or defendant.

INSTRUCTION NO. 8

The evidence which you are to consider in this case consists of the testimony of the witnesses, the exhibits, and any facts admitted or agreed to by counsel.

There are two types of evidence: direct and circumstantial. Direct evidence is direct proof of a fact, such as testimony by a witness about what the witness personally saw or heard or did. Circumstantial evidence is the proof of one or more facts from which you could find another fact. The law makes no distinction between the weight to be given either direct or circumstantial evidence. Therefore, all of the evidence in the case, including the circumstantial evidence, should be considered by you in arriving at your verdict.

Statements, arguments and opinions of counsel are not evidence in the case. However, if the attorneys stipulate (meaning to agree) to the existence of a fact, you must accept the stipulation of evidence and regard that fact as proved.

Questions are not evidence. Only the answer is evidence. You should consider a question only if it helps you understand the witness's answer. Do not assume that something is true just because a question suggests that it is.

You must also disregard any evidence to which an objection was sustained by the court and any evidence ordered stricken by the court. Anything you may have seen or heard outside the courtroom is not evidence and must also be disregarded.

INSTRUCTION NO. 9

You must decide all questions of fact in this case from the evidence received in this trial and not from any other authority. You must not make any independent investigation of the facts or the law or consider or discuss facts as to which there is no evidence. This means, for example, that you must not on your own visit the scene, conduct experiments or consult reference works for additional information.

INSTRUCTION NO. 10

The credibility or "believability" of a witness should be determined by his or her manner upon the stand, his or her relationship to the parties, his or her fears, motives, interests or feelings, his or her opportunity to have observed the matter to which he or she testified, the reasonableness of his or her statements and the strength or weakness of his or her recollections.

If you believe that a witness has lied about any material fact in the case, you may disregard the entire testimony of that witness or any portion of this testimony which is not proved by other evidence.

INSTRUCTION NO. 11

Discrepancies in a witness's testimony or between his testimony and that of others, if there were any discrepancies, do not necessarily mean that the witness should be discredited. Failure of recollection is a common experience, and innocent misrecollection is not uncommon. It is a fact, also, that two persons witnessing an incident or transaction often will see or hear it differently. Whether a discrepancy pertains to a fact of importance or only to a trivial detail should be considered in weighing its significance.

INSTRUCTION NO. 12

During the trial, deposition testimony was provided to you. A deposition is the testimony of a person taken before trial. At a deposition, the person took the same oath to tell the truth that would be taken in court and is questioned by the attorneys. You must consider the deposition testimony that was presented to you in the same way as you consider testimony given in court.

INSTRUCTION NO. 13

Certain evidence was admitted for a limited purpose. At the time this evidence was admitted it was explained to you that it could not be considered by you for any purpose other than the limited purpose for which it was admitted. You may only consider that evidence for the limited purpose that I described and not for any other purpose.

INSTRUCTION NO. 14

The parties may have shown you charts and summaries to help explain the facts. The charts or summaries themselves, however, are not evidence or proof of any facts. Charts and summaries are only as good as the underlying evidence that supports them. You should therefore give them only such weight as you think the underlying evidence deserves.

INSTRUCTION NO. 15

An attorney has a right to interview a witness for the purpose of learning what testimony the witness will give. The fact that the witness has talked to an attorney and told that attorney what he or she would testify to does not reflect adversely on the truth of the testimony of the witness.

INSTRUCTION NO. 16

A witness who has special knowledge, skill, experience, training or education in a particular science, profession or occupation is an expert witness. An expert witness may give his or her opinion as to any matter in which he or she is skilled.

You should consider such expert opinion and weigh the reasons, if any, given for it. You are not bound, however, by such opinion. Give it the weight to which you deem it entitled, whether that be great or slight, and you may reject it, if, in your judgment, the reasons for it are unsound.

INSTRUCTION NO. 17

An expert witness has testified about his or her reliance upon information that have not been admitted into evidence. Reference by the expert witness to this material is allowed so that the expert witness may tell you what he or she relied upon to form his or her opinions. You may not consider the material as evidence in this case. Rather, you may only consider the material to determine what weight, if any, you will give to the expert's opinions.

INSTRUCTION NO. 18

A hypothetical question has been asked of an expert witness. In a hypothetical question, the expert witness is told to assume the truth of certain facts, and the expert witness is asked to give an opinion based upon those assumed facts. You must decide if all of the facts assumed in the hypothetical question have been established by the evidence. You can determine the effect of that assumption upon the value of the opinion.

INSTRUCTION NO. 19

In this action, Plaintiff Sandra L. Eskew, as special administrator of the Estate of William G. Eskew, seeks to establish liability for breach of the implied covenant of good faith and fair dealing, otherwise known as bad faith, against Sierra Health and Life Insurance Company, Inc. I will now instruct you on the law pertaining to this claim.

INSTRUCTION NO. 20

In every insurance contract there is an implied covenant of good faith and fair dealing that neither the insurance company nor the insured will do anything to injure the rights of the other party to receive the benefits of the agreement.

The relationship of an insured to an insurer is one of special confidence and akin to that of a fiduciary. A fiduciary relationship exists when one has the right to expect trust and confidence in the integrity and fidelity of another. This special relationship exists in part because, as insurance companies are well aware, consumers contract for insurance to gain protection, peace of mind, and security against calamity. To fulfill its implied covenant of good faith and fair dealing, an insurance company must give at least as much consideration to the interests of the insured as it gives to its own interests.

INSTRUCTION NO. 21

In order to establish a breach of the implied covenant of good faith and fair dealing, Plaintiff, Sandra Eskew, as the Special Administrator of the Estate of William George Eskew, must prove the following by a preponderance of the evidence:

1. The proton beam therapy was a covered service under the terms of the agreement of coverage.
2. Sierra Health and Life had no reasonable basis for its February 5, 2016 denial of the prior authorization claim.
3. Sierra Health and Life knew, or recklessly disregarded, the fact that there was no reasonable basis for the February 5, 2016 denial of the prior authorization claim; and
4. Sierra Health and Life's denial was a legal cause of harm to William Eskew.

INSTRUCTION NO. 22

The agreement of coverage is an insurance contract. The interpretation of an insurance contract is subject to legal standards:

1. The terms of the insurance contract are construed in their plain, ordinary and popular meaning.
2. Any clause within the insurance contract that provides coverage is interpreted broadly to afford the greatest possible coverage to the insured.
3. An exclusion or restriction to coverage in the insurance contract must be interpreted narrowly against the insurer.
4. If it is unambiguous, the insurance contract is construed as written and you may not increase the obligations of the parties if the contract intentionally and unambiguously limited such obligations.
5. If the insurance contract is ambiguous, any ambiguity must be construed in favor of the insured and to effectuate the insured's reasonable expectations.

The insurance contract is ambiguous if a provision at issue, as drafted, is subject to more than one reasonable interpretation.

INSTRUCTION NO. 23

An insurer has a duty to investigate a claim filed by its insureds. When investigating a claim, an insurer has a duty to diligently search for, and to consider, evidence that supports an insured's claimed loss. An insurer may not reasonably and in good faith deny a prior authorization claim without thoroughly investigating the claim.

INSTRUCTION NO. 24

The insurer is not liable for bad faith for being incorrect about policy coverage as long as the insurer had a reasonable basis to take the position that it did. Bad faith requires an awareness that no reasonable basis exists to deny the insurance claims.

INSTRUCTION NO. 25

There is a law in the State of Nevada called the Nevada Unfair Insurance Practice Act which prohibited Sierra Health and Life from doing any one of the following:

1. Misrepresenting to an insured pertinent facts or insurance policy provisions relating to any coverage at issue.

2. Failing to provide promptly to an insured a reasonable explanation of the basis in the insurance policy, with respect to the facts of an insured's claim and the applicable law, for the denial of the claim.

The violations of any provision of the Nevada Unfair Insurance Practice Act may be evidence of a breach of the implied covenant of good faith and fair dealing. The presence or absence of any of these factors alone is not enough to determine whether the defendant's conduct was or was not in bad faith. You must consider the defendant's conduct as a whole in making this determination.

INSTRUCTION NO. 26

At all relevant times, there existed insurance regulations in Nevada that provided as follows:

1. Each insurer shall fully disclose to a first-party claimants all pertinent benefits, coverages or other provisions under which a claim is presented. A first-party claimant includes a person asserting a right to payment under an insurance contract.
2. Within 30 working days after receipt by the insurer of a properly executed proof of loss, the first-party claimant must be advised of the acceptance or denial of the claim by the insurer. No insurer may deny a claim on the grounds of a specific policy provision, condition or exclusion unless reference to that provision, condition or provision is included in the denial. The denial must be given to the first-party claimant in writing and filed and retained in the insurer's claim file. If the claim of the first-party claimant is accepted, the insurer shall pay the claim within 30 days after accepted.

The failure to comply with a regulation may be evidence of a breach of the implied covenant of good faith and fair dealing.

INSTRUCTION NO. 27

A legal cause of injury, damage, loss, or harm is a cause which is a substantial factor in bringing about the injury, damage, loss, or harm.

INSTRUCTION NO. 28

A substantial factor is a factor that a reasonable person would consider to have contributed to harm. It must be more than a remote or trivial factor. It does not have to be the only cause of the harm.

Conduct is not a substantial factor in causing harm if the same harm would have occurred without that conduct.

INSTRUCTION NO. 29

In determining the amount of losses, if any, suffered by William Eskew as a legal result of the breach of the implied covenant of good faith and fair dealing, you will take into consideration the nature, extent and duration of the damage Mr. Eskew sustained, and you will decide upon a sum of money sufficient to reasonably and fairly compensate for the physical pain, mental suffering, anguish, disability, loss of enjoyment of life and emotional distress to Mr. Eskew.

Plaintiff does not claim Sierra Health and Life caused or contributed to Mr. Eskew's death.

INSTRUCTION NO. 30

No definite standard is prescribed by law by which to fix reasonable compensation for physical pain, mental suffering, anguish, disability, loss of enjoyment of life and emotional distress. Nor is the opinion of any witness required as to the amount of such reasonable compensation. You must use your judgment to decide upon a reasonable amount based on the evidence and your common sense.

INSTRUCTION NO. 31

A party cannot recover damages for losses it could have avoided by reasonable efforts. The burden is on the party whose wrongful acts resulted in the damages to prove that the damages might have been lessened by reasonable diligence and expenditures on the part of the party seeking damages. Reasonable diligence does not require that the party seeking damages ask the party whose wrongful conduct resulted in the damages to remedy the injury, detriment, harm or loss resulting from the alleged wrongful act.

INSTRUCTION NO. 32

If you find that Plaintiff Sandra Eskew as the Special Administrator for the Estate of William George Eskew, has proved that Sierra Health and Life breached the implied covenant of good faith and fair dealing, you may then consider whether you should award punitive damages against the defendant, for the sake of example and by way of punishment. You may in your discretion award such damages if, but only if, you find by clear and convincing evidence that either defendant acted with fraud, malice, or oppression in the conduct upon which you base your finding of liability.

"Malice" means conduct which is carried on by Sierra Health and Life with a conscious disregard of the rights of William Eskew.

"Oppression" means subjecting William Eskew to cruel and unjust hardship in conscious disregard of his rights.

"Conscious disregard" means knowledge of the probable harmful consequences of a wrongful act and a willful and deliberate failure to act to avoid those consequences.

The purposes of punitive damages are to punish a wrongdoer that acts with fraud, oppression and/or malice in harming a plaintiff and deter similar conduct in the future, not make the plaintiff whole for her injuries. Consequently, a plaintiff is never entitled to punitive damages as a matter of right and whether to award punitive damages against a defendant is entirely within your discretion.

At this time, you are to decide only whether defendant engaged in wrongful conduct causing actual harm to the plaintiff with the requisite state of mind to permit an award of punitive damages against the defendant, and if so, whether an award of punitive damages against the defendant is justified by the punishment and deterrent purposes of punitive damages under the circumstances of this case. If you decide an award of punitive damages is justified, you will later decide the

amount of punitive damages to be awarded, after you have heard additional evidence and instruction.

INSTRUCTION NO. 33

A breach of the implied covenant of good faith and fair dealing by itself does not mean that a defendant acted with malice or oppression.

INSTRUCTION NO. 34

I have given you instructions embodying various rules of law to help guide you to a just and lawful verdict. Whether some of these instructions will apply will depend upon what you find to be the facts. The fact that I have instructed you on various subjects in this case including that of damages must not be taken as indicating an opinion of the court as to what you should find to be the facts or as to which party is entitled to your verdict.

INSTRUCTION NO. 35

It is your duty as jurors to consult with one another and to deliberate with a view toward reaching an agreement, if you can do so without violence to your individual judgment. Each of you must decide the case for yourself, but should do so only after a consideration of the case with your fellow jurors, and you should not hesitate to change an opinion when convinced that it is erroneous. However, you should not be influenced to vote in any way on any question submitted to you by the single fact that a majority of the jurors, or any of them, favor such a decision. In other words, you should not surrender your honest convictions concerning the effect or weight of evidence for the mere purpose of returning a verdict or solely because of the opinion of the other jurors. Whatever your verdict is, it must be the product of a careful and impartial consideration of all the evidence in the case under the rules of law as given you by the court.

INSTRUCTION NO. 36

If, during your deliberations, you should desire to be further informed on any point of law or hear again portions of the testimony, you must reduce your request to writing signed by the foreperson. The officer will then return you to court where the information sought will be given you in the presence of the parties or their attorneys. Remember, the court is not at liberty to supplement the evidence.

INSTRUCTION NO. 37

When you retire to consider your verdict, you must select one of your number to act as foreperson, who will preside over your deliberation and will be your spokesman here in court.

During your deliberation, you will have all the exhibits which were admitted into evidence, these written instructions and a special verdict form which has been prepared for your convenience.

In civil actions, three-fourths of the total number of jurors may find and return a verdict. This is a civil action. As soon as six or more of you have agreed upon each answer required by the directions in the special verdict form, you must have the verdict signed and dated by your foreperson, and then return with it to this room.

INSTRUCTION NO. 38

Now you will listen to the arguments of counsel who will endeavor to aid you to reach a proper verdict by refreshing in your minds the evidence and by showing the application thereof to the law; but, whatever counsel may say, you will bear in mind that it is your duty to be governed in your deliberation by the evidence, as you understand it and remember it to be, and by the law as given you in these instructions, and return a verdict which, according to your reason and candid judgment, is just and proper.

Dated 4th, April, 2022

GIVEN: _____

DISTRICT COURT JUDGE

FILED IN OPEN COURT 4:07PM
04-05-2022
STEVEN D. GRIERSON
CLERK OF THE COURT
BY PHARAN BURCHFIELD, DEPUTY

VER

IN THE EIGHTH JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR THE COUNTY OF CLARK

SANDRA L. ESKEW, as Special Administrator of the Estate of William George Eskew, Plaintiff, vs. SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC. Defendants.	Case No. A-19-788630-C Dept. No. 4

A-19-788630-C
VER
Verdict
4988066

VERDICT

We, the empaneled jury in the above-entitled case, return the following special verdict on the questions submitted to us:

1. What amount of money do you find for punitive damages?

$ 160,000,000

DATED this 5th day of April 2022.

FOREPERSON

FILED IN OPEN COURT
04/05/2022
STEVEN D. GRIERSON
CLERK OF THE COURT
BY PHARAN BURCHFIELD, DEPUTY

INST

EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

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

Plaintiff,

vs.

SIERRA HEALTH AND LIFE INSURANCE COMPANY, INC.,

Defendant.

Case No.: A-19-788630-C
Dept. No.: 4

JURY INSTRUCTIONS FOR PHASE 2

A-19-788630-C
JI
Jury Instructions
4988067

INSTRUCTION NO. 1

The law provides no fixed standards as to the amount of a punitive damage award, but leaves the amount to the jury's sound discretion, exercised without passion or prejudice and in accordance with the following governing principles.

The amount of a punitive damage award is not to compensate William Eskew for harm suffered but what is reasonably necessary in light of the defendants' financial condition and fairly deserved in light of the blameworthiness and harmfulness inherent in the defendants' conduct to punish and deter the defendants and others from engaging in conduct such as that warranting punitive damages in this case. Your award cannot be more than otherwise warranted by the evidence in this case merely because of the wealth of the defendants. Your award cannot either punish defendants for conduct injuring others who are not parties to this litigation or financially annihilate or destroy the defendants in light of the defendants' financial condition.

In determining the amount of your punitive damage award, you should consider the following guideposts:

1. The degree of reprehensibility of the defendants' conduct, in light of (a) the culpability and blameworthiness of the defendants' fraudulent, oppressive and/or malicious misconduct under the circumstances of this case; (b) whether the conduct injuring William Eskew that warrants punitive damages in this case was part of a pattern of similar conduct by the defendants; and (c) any mitigating conduct by the defendants.

2. The ratio of your punitive damage award to the actual harm inflicted on William Eskew by the conduct warranting punitive damages in this case, since the measure of punishment must be both reasonable and proportionate to the amount of harm to William Eskew and to the compensatory damages recovered by William Eskew in this case.

3. How your punitive damages award compares to other civil or criminal penalties that could be imposed for comparable misconduct, since punitive damages are to provide a means by which the community can express its outrage or distaste for the misconduct of a fraudulent, oppressive or malicious defendant and deter and warn others that such conduct will not be tolerated.

Evidence has been presented concerning a defendant's conduct outside Nevada and/or conduct injuring others who are not parties to this litigation. You cannot use such evidence to award punitive damages for conduct outside Nevada, or conduct injuring others who are not parties to this litigation, or conduct that does not bear a reasonable relationship to the conduct injuring plaintiffs that warrants punitive damages in this case. You may consider such evidence only with respect to the reprehensibility of the defendant's conduct and only to the extent the conduct is similar and bears a reasonable relationship to the defendant's conduct injuring William Eskews that warrants punitive damages in this case.

INSTRUCTION NO. 2

There is no right to punitive damages. Accordingly, you need not award punitive damages even though you have found that the standard for imposing punitive damages has been satisfied.

INSTRUCTION NO. 3

If you have already awarded punitive damages within your $40,000,000.00 award, no further award should be made.

INSTRUCTION NO. 4

Your award of punitive damages must be based on the conduct that by clear and convincing evidence was shown to constitute oppression or malice.

INSTRUCTION NO. 5

A defendant's conduct in litigation during trial may not be used to impose punitive damages.

INSTRUCTION NO. 6

In contrast to compensatory damages, punitive damages rest on justifications similar to those for criminal punishment. Because exemplary damages resemble criminal punishment, they require appropriate substantive and procedural safeguards to minimize the risk of unjust punishment.

One of these safeguards is that, in contrast to your verdict on compensatory damages, your verdict as to the amount of punitive damages must be unanimous.

Dated 5th, April, 2022

GIVEN: [signature]

DISTRICT COURT JUDGE