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(Submitted electronically)

RE: United Healthcare Proton Beam Radiation Therapy Policy

Dear Dr. Malin:

The American Society for Radiation Oncology (ASTRO)<sup>1</sup> appreciates United Healthcare's (UHC) recent update to its Proton Beam Radiation Therapy Policy to include coverage for hepatocellular carcinoma. Though we appreciate this addition, we are concerned the policy remains overly restrictive by excluding many other disease sites.

ASTRO publishes a distinct series of model policies to efficiently communicate correct coverage policies for radiation oncology services. We work to maintain updated information and inform payers of all changes to existing policies. ASTRO's Proton Beam Therapy (PBT) Model Policy was most recently revised in 2017 and is enclosed for your review. Below are the most significant differences between the ASTRO PBT Model Policy and the coverage proposed under United Healthcare's Proton Beam Radiation Therapy Policy.

Currently, UHC considers proton beam radiation therapy proven and medically necessary for the following indications:

- "Intracranial arteriovenous malformations (AVMs)
- Ocular tumors, including intraocular/uveal melanoma (includes the iris, ciliary body and choroid)
- Skull-based tumors (e.g., chordomas, chondrosarcomas or paranasal sinus tumors)
- 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."

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<sup>1</sup> ASTRO members are medical professionals, who practice at hospitals and cancer treatment centers in the United States and around the globe, and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.

ASTRO believes that based on published clinical data, several other disease sites meet the medical necessity requirements, including all malignant and benign primary CNS tumors, (UHC only lists arteriovenous malformations) and all primary liver tumors (UHC only lists localized, unresectable hepatocellular carcinomas). Additional disease sites that warrant the use of proton beam therapy are: advanced/unresectable head and neck cancers, non-metastatic retroperitoneal sarcomas, re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose), and for patients with genetic syndromes making total volume of radiation minimization crucial.

UHC also states,

**“Proton beam radiation therapy is unproven and not medically necessary for treating ALL other indications, including but not limited to:**

- Age-related macular degeneration (AMD)
- Bladder cancer
- Brain and spinal cord tumors
- Breast cancer
- Choroidal hemangioma
- Esophageal cancer
- Gynecologic cancers
- Head and neck cancers
- Lung cancer
- Lymphomas
- Pancreatic cancer
- Prostate cancer
- Vestibular tumors (e.g., acoustic neuroma or vestibular schwannoma)”

UHC’s policy does not allow coverage for any spinal cord tumors. ASTRO believes that all primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated should be covered.

Additionally, ASTRO believes that many of the disease sites that UHC considers “unproven and not medically necessary” are suitable for Coverage with Evidence Development (CED). ASTRO’s Proton Beam Therapy Model Policy clarifies that, “Radiation therapy for patients treated under the CED paradigm should be covered by the insurance carrier as long as the patient is enrolled in either an IRB-approved clinical trial or in a multi-institutional patient registry adhering to Medicare requirements for CED<sup>2</sup>.” These disease sites include, but are not limited to: bladder cancer, breast cancer, esophageal cancer, gynecologic cancers, head and neck cancers, lung cancer, lymphomas, pancreatic cancer, and non-metastatic prostate cancer. Additionally, there are currently two clinical trials regarding Proton Radiation Therapy for macular degeneration.<sup>34</sup>

The disease sites that should be eligible for Coverage with Evidence Development are further outlined below:

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<sup>2</sup> Coverage with Evidence Development Requirements Position Statement. American Society for Radiation Oncology Web site. [https://www.astro.org/ Practice-Management/Reimbursement/Coverage-Position-Statement](https://www.astro.org/Practice-Management/Reimbursement/Coverage-Position-Statement).

<sup>3</sup> <https://clinicaltrials.gov/ct2/show/NCT01833325>

<sup>4</sup> <https://clinicaltrials.gov/ct2/show/NCT01213082?term=Macular+degeneration&cond=Proton+therapy&rank=2>

UHC Policy	ASTRO PBT Model Policy
Bladder Cancer	Yes; Pelvic malignancies, including non-metastatic rectal, anal, <i>bladder</i> and cervical cancers
Breast Cancer	Yes; Breast cancer
Esophageal Cancer	Yes; Thoracic malignancies, including non-metastatic primary lung and esophageal cancers, and mediastinal lymphomas
Gynecologic Cancers	Yes; Pelvic malignancies, including non-metastatic rectal, anal, bladder and <i>cervical cancers</i>
Head and Neck Cancers	Yes; Non-T4 and resectable head and neck cancers including skin, melanoma, salivary gland, nasopharynx, oropharynx and thyroid
Lung Cancer	Yes; Thoracic malignancies, <i>including non-metastatic primary lung</i> and esophageal cancers, and mediastinal lymphomas
Lymphomas	Yes; Thoracic malignancies, including non-metastatic primary lung and esophageal cancers, and <i>mediastinal lymphomas</i>
Pancreatic Cancer	Yes; Abdominal malignancies, including <i>non-metastatic primary pancreatic</i> , biliary and adrenal cancers
Prostate Cancer	Yes; Non-metastatic prostate cancer

**We urge United Healthcare to update its Proton Beam Radiation Therapy coverage policy to include the aforementioned clinical indications, as well as cover those disease sites that are suitable for Coverage with Evidence Development.**

Thank you for your consideration of our comments. Should you have any questions or wish to discuss our recommendations further, please contact Jessica Adams, Health Policy Analyst (703) 839- 7396 or via email at [Jessica.adams@astro.org](mailto:Jessica.adams@astro.org).

Respectfully submitted,



Laura I. Thevenot  
Chief Executive Officer

Enclosed: ASTRO Proton Beam Therapy Model Policy