



June 8, 2018

Charles Deshazer, MD
Chief Medical Officer
Highmark Inc.
120 Fifth Ave
Pittsburgh, PA 15222
Charles.Deshazer@highmark.com
(Submitted electronically)

RE: Highmark BCBS Delaware, Highmark Pennsylvania, Highmark West Virginia: Proton Beam Therapy

Dear Dr. Charles Deshazer:

The American Society for Radiation Oncology (ASTRO)¹ would like to provide input on the Highmark BCBS Proton Beam Radiation Therapy Policy. In reviewing the updates to the policy, we have concerns regarding the coverage limitations and interpretation of medical necessity for Proton Beam Therapy (PBT). We appreciate the opportunity to bring these issues to your attention.

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 Policy was most recently revised in June 2017 and is enclosed for your review. PBT is considered reasonable in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient. Below are the most significant differences between the ASTRO PBT Model Policy and the coverage proposed under the Highmark Proton Beam Radiation Therapy Policy.

The Highmark proton beam radiation therapy treatment policy provides coverage for a limited range of indications, including: Spinal/Cranial, Optical, Liver and Testicular tumors. ASTRO's most recently revised PBT Model Policy includes recommendations for coverage of several additional disease sites based on medical necessity requirements and published clinical data.

¹ *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.*

The Highmark Proton Beam Therapy Policy neglects to include many of the clinical indications recognized in ‘Group 1’ of ASTRO’s PBT Model Policy, including:

- Malignant and benign primary CNS tumors,
- Advanced and/or unresectable head and neck cancers,
- Cancers of the paranasal sinuses and other accessory sinuses and non-metastatic retroperitoneal sarcomas,
- Patients with genetic syndromes making total volume of radiation minimization crucial such as, but not limited to, NF-1 patients and retinoblastoma patients, and
- Re-irradiation cases where cumulative critical structure dose would exceed tolerance dose.

Additionally, the Highmark Proton Beam Therapy Policy does not recognize that PBT is an important treatment option for certain pediatric tumors, since damage to the surrounding normal tissues of children can produce serious long-term side effects on the growth and development of vital organs and tissues. PBT’s reduced radiation dose to healthy tissues can reduce side effects for patients with demonstrated effectiveness and increased quality of life. To date, scientific evidence exists confirming that PBT is particularly useful in a number of pediatric cancers, particularly those in the brain, as well as for certain adult cancers, such as ocular melanoma, chordoma, chondrosarcoma, and primary hepatocellular carcinoma.

Outside of indications listed in “Group 1,” ASTRO also supports coverage for PBT for all patients enrolled in either an IRB-approved clinical trial or in a multi-institutional patient registry adhering to Medicare requirements for Coverage with Evidence Development (CED). ASTRO recognizes the importance of collecting sufficient data to compare the effectiveness of PBT to inform appropriate utilization. Therefore, ASTRO considers all indications appropriate for CED. We encourage Highmark to provide coverage for those patients receiving PBT as part of an IRB-approved clinical trial or multi-institutional patient registry.

The ASTRO PBT Model Policy includes an extensive list of references supporting all of the above-listed recommendations. The model policy also includes a complete list ICD-10 codes supporting the indications of coverage listed in Group 1. We encourage Highmark to utilize the ASTRO PBT Model Policy as a reference when updating their Proton Beam Radiation Therapy Treatment Delivery policy.

ASTRO urges Highmark to align with the ASTRO PBT Model Policy, including all Group 1 disease sites, and provide coverage for pediatric patients. Additionally, we urge Highmark to recognize that all other indications not listed in Group 1 are suitable for Coverage with Evidence Development (CED), 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.

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Thank you for your consideration of our comments. Should you have any questions or wish to discuss our recommendations further, please contact Kimberly Case, Health Policy Coordinator (703) 839-7360 or via email at Kimberly.Case@astro.org.

Sincerely,

A handwritten signature in black ink that reads "Laura Thevenot". The signature is written in a cursive, flowing style.

Laura I. Thevenot
Chief Executive Officer

Enclosed:
ASTRO 2017 Proton Beam Therapy Model Policy