

June 8, 2018

Thomas Ebert, MD
Chief Medical Officer
Fallon Health Plan of Massachusetts
20 Boston Turnpike
Shrewsbury, MA 01545
Thomas.ebert@fchp.org
(Submitted electronically)

RE: Fallon Health Proton Beam Therapy Clinical Coverage Criteria

Dear Dr. Thomas Ebert:

The American Society for Radiation Oncology (ASTRO)¹ would like to take this opportunity to provide input on the Fallon Health Proton Beam Radiation Therapy Clinical Coverage Criteria. ASTRO publishes a distinct series of model policies to efficiently communicate correct coverage policies for radiation oncology services. We 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.

Proton beam therapy (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. We encourage Fallon Health to consult ASTRO's Proton Beam Therapy Model Policy, a copy of which is attached to this letter. Below please find the most significant differences between the ASTRO PBT Model Policy and the coverage proposed under the Fallon Health PBT Clinical Coverage Criteria:

The Fallon Health PBT Clinical Coverage Criteria does not include re-irradiation cases (where cumulative critical structure dose would exceed tolerance dose). ASTRO's most recently revised PBT Model Policy recommends coverage of several additional disease sites, including re-irradiation cases, on the basis of medical necessity requirements and published clinical data.

We urge Fallon Health to provide coverage for re-irradiation cases and other Group 1 indications listed in ASTRO's PBT Model Policy.

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.*

Outside of indications listed in “Group 1” of the model policy, 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 effectiveness of PBT to inform appropriate utilization. Therefore, ASTRO considers all Group 2 indications appropriate for CED. **We encourage Fallon Health to provide coverage for those patients receiving PBT as part of an IRB-approved clinical trial or multi-institutional patient registry.**

In addition, while proton beam therapy is not a new technology, its use in the treatment of prostate cancer is evolving. **ASTRO strongly supports allowing for coverage with evidence development for prostate cancer patients treated on clinical trials or within prospective registries.** ASTRO believes that collecting data in these settings is essential to informing consensus on the role of proton therapy for prostate cancer, especially insofar as it is important to understand how the effectiveness of proton therapy compares to other radiation therapy modalities such as IMRT and brachytherapy.

ASTRO urges Fallon Health to align with the ASTRO PBT Model Policy for re-irradiation and other indications covered in Group 1, and to recognize that all other indications not listed in Group 1 are suitable for Coverage with Evidence Development (CED). Radiation therapy for patients treated under the CED paradigm should be covered 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.

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,



Laura I. Thevenot
Chief Executive Officer

Enclosed:
ASTRO 2017 Proton Beam Therapy Model Policy