

April 18, 2018

Dr. Rajanish Singla
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(Submitted electronically)

RE: Stereotactic Radiosurgery for Brain Metastases and Proton Beam Therapy

Dear Dr. Singla:

The American Society for Radiation Oncology (ASTRO)¹ would like to provide input on eviCore's 2018 Radiation Therapy Clinical Guidelines. We are concerned that the revised policy relies on outdated and misinterpreted information, which will result in unwarranted denials and delays in care. 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. We urge eviCore to incorporate the recommended coverage as prescribed in ASTRO's model policies throughout the 2018 Radiation Therapy Clinical Guidelines policy. Below we highlight two key issues that warrant immediate reconsideration: 1) The coverage of stereotactic radiosurgery (SRS) for post-operative brain metastases, and 2) The use of proton beam therapy (PBT) for the treatment of cancer.

SRS for Brain Metastases

eviCore's 2018 Radiation Therapy Clinical Guidelines state under **Radiation Therapy for Brain Metastases** that, "post-operative SRS is considered not medically necessary." eviCore cites data published by Brown, et al. in 2017 stating, "The clinical relevance of this is unclear though there appears to be a higher rate of death due to brain metastases in the SRS group. As such, the use of SRS in the post-operative setting is considered not medically necessary." This statement is misleading, as there is no statistically significant difference in overall survival between the two arms of the study. The use of post-operative SRS is a compromise between neurocognitive preservation and intracranial control.

While ASTRO understands that post-operative SRS is not appropriate for every brain metastases patient, there are certain situations for which the treatment is indicated. Evidence released in 2017 shows that post-operative SRS is superior to observation alone in terms of local control, and superior to whole brain radiation therapy (WBRT) in terms of preservation of cognitive function. The National Cancer Institute study conducted by Brown, et al. concluded,

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.*

“Decline in cognitive function was more frequent with WBRT than with SRS and there was no difference in overall survival between the treatment groups. After resection of a brain metastasis, SRS radiosurgery should be considered one of the standards of care as a less toxic alternative to WBRT for this patient population.²”

The MD Anderson Cancer Center study conducted by Mahajan, et al. found,

“SRS of the surgical cavity in patients who have had complete resection of one, two, or three brain metastases significantly lowers local recurrence compared with that noted for observation alone. Thus, the use of SRS after brain metastasis resection could be an alternative to whole-brain radiotherapy³.”

Additionally, the National Comprehensive Cancer Network Central Nervous Systems cancer guidelines state,

“For patients with limited systemic disease or for whom reasonable systemic treatment options exist, aggressive management should be strongly considered. For surgical candidates, high-level evidence supports category 1 recommendations for surgical resection plus postoperative WBRT and for SRS plus WBRT if only one brain lesion is involved. Other options include SRS alone or SRS following resection (Category 2B)⁴.”

Since the classification of this NCCN guideline, the two additional post-operative SRS trials have been published. Based on the current literature, this guideline should have a NCCN Category of Evidence and Consensus listing as Category 1⁵.

Therefore, ASTRO recommends eviCore edit the Radiation Therapy Clinical Guidelines for brain metastases. There is strong evidence to support coverage for a combination of five resected and unresected post-operative lesions that are individually less than four centimeters in size. As it is written, the current policy limits providers and disrupts the process of care for brain metastases patients.

Proton Beam Therapy

eviCore’s 2018 Radiation Therapy Clinical Guidelines reference a 2012 ASTRO evidence-based review of PBT to support its position that the “the rationale for PBT is often associated with a low level of evidence,” and that “there is insufficient data clearly demonstrating its benefit over conventional forms of radiation therapy.” This analysis is not only over six years old but it has been replaced by a series of ASTRO PBT Model Policies that recognize multiple indications for the use of PBT. The first of which was issued in 2014, and a subsequent updated model policy was most recently issued in 2017.

PBT is neither a new nor an experimental technology for treating cancer with radiation. It utilizes proton radiation particles to deliver highly conformal radiation therapy to a specific tumor target area while

² [Lancet Oncol.](#) 2017 Aug;18(8):1049-1060. doi: 10.1016/S1470-2045(17)30441-2. Epub 2017 Jul 4.

³ [Lancet Oncol.](#) 2017 Aug;18(8):1040-1048. doi: 10.1016/S1470-2045(17)30414-X. Epub 2017 Jul 4.

⁴ https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

⁵ https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx

giving a much lower dose to the normal tissues in the proton beam's path of entry and exit. 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. Patients with genetic syndromes and those with tumors near the spinal cord with previous irradiation also benefit from the use of PBT.

ASTRO's most recently revised PBT Model Policy includes recommendations for coverage of several new disease sites on the basis of medical necessity requirements and published clinical data. The eviCore 2018 Radiation Therapy Clinical Guidelines neglect to include many of the clinical indications recognized in ASTRO's PBT Model Policy. Additionally, the eviCore 2018 Radiation Therapy Clinical Guidelines do not recognize the fact 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. A growing body of literature shows the late effects, quality of life, and cost effectiveness of proton beam therapy on pediatric patients.

ASTRO urges eviCore to revise the 2018 Radiation Therapy Clinical Guidelines to align with the ASTRO PBT Model Policy, including all Group 1 disease sites, and recognition for the need for coverage for pediatric patients. Additionally, we urge eviCore 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 IMRT and our recommendations further, please contact Anne Hubbard, Director of Health Policy (703) 839-7394 or via email at Anne.Hubbard@astro.org.

Respectfully submitted,



Laura I. Thevenot
Chief Executive Officer

Enclosed: ASTRO SRS Model Policy and PBT Model Policy