ASTRO
TARGETING CANCER CARE

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Submitted electronically: tfenter@bcbsms.com

RE: BCBS Mississippi Medical SBRT Policy

Dear Dr. Fenter,

The American Society for Radiation Oncology (ASTRO)[1] appreciates the opportunity to comment on BCBS Mississippi policy number A.6.01.10 *Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT)*. ASTRO offers comments on this policy as outlined below.

**Stereotactic Body Radiation Therapy (SBRT) Indications**

Although the disease sites listed as medically necessary for SBRT are appropriate, ASTRO disagrees with the policy statement that SBRT is investigational for prostate cancer and pancreatic adenocarcinomas. This does not represent the extensive body of evidence proving the effectiveness of this therapeutic treatment option. ASTRO's SBRT Model Policy, updated in 2020, and enclosed for you review, includes evidence supporting coverage of these disease sites. Below are evidence summaries associated with each disease site:

Prostate Cancer

A published analysis of 1,100 patients enrolled on prospective trials of SBRT for prostate cancer demonstrates biochemical relapse-free survival rates and quality of life outcomes that compare favorably with other definitive treatments for prostate cancer[2,3]. After a median dose of 36.25 Gy in 4-5 fractions, the 5-year biochemical relapse free survival rate was 93% for all patients; 95%, 83% and 78% for GS $\leqslant$6, 7 and $\geqslant$8, respectively; and 95%, 84% and 81% for low-, intermediate- and high-risk patients, respectively. A transient decline in the urinary and bowel

[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.*

domains were observed within the first 3 months after SBRT, which returned to baseline status or better within 6 months and remained so beyond 5 years. In addition, SBRT's cost effectiveness relative to other forms of radiation therapy of prostate cancer[4,5] is appealing in this setting.

Additional publications of clinical studies, particularly those presenting long term outcome data, demonstrate the efficacy and safety of treating prostate cancer with SBRT. An abstract from the SHARP (Stereotactic Hypofractionated Accurate Radiotherapy of the Prostate) trial provides an update on the original feasibility and toxicity. Pham and colleagues found an overall 5-year (nadir + 2ng/ML) biochemical relapse free survival rate of 93% and only 2.5% grade three late genitourinary toxicity for a total of forty patients[6].

Freeman also reported a 93% rate of biochemical progression-free survival at a medium follow-up of five years [7]. The following table summarizes findings from this and other studies that show excellent biochemical control rates with very low rates of serious toxicity. **Thus, we believe that SBRT is an appropriate alternative for select patients with low to intermediate risk prostate cancer and recommend adding ICD-10 code C61 indicated for SBRT.**

| | N | Selection | SBRT dose | Grade 3+ late toxicity | Biochemical progression-free survival | Median Follow-up |
|---|---|---|---|---|---|---|
| **Freeman** [7] | 41 | Low-risk | 35-36.26 Gy x 5 | 0% | 93% | 60 months |
| **King** [8] | 67 | Low-risk | 36.25 Gy x 5 | 3% | 94% (PSA relapse-free) | 32 months |
| **Madsen** [9] | 40 | Low-risk | 33.5 Gy x 5 | 0% | 90% | 41 months |
| **Katz** [10] | 50; 254 | Low, intermediate and high-risk | 35 Gy x 5; 36.25 Gy x 5 | 0%; 0.5% | Low (99%), Int (100%), High (83%) | 30; 17 months |

Pancreatic Cancer

A study of 20 patients with unresectable pancreatic adenocarcinomas and a neuroendocrine tumor found that, "in addition to the increase in overall survival obtained with SBRT in the treatment of pancreatic adenocarcinoma, the importance of achieving local control should not be undermined. Preventing or delaying local recurrence with SBRT not only decreases tumor burden but may also offer palliative benefit. Untreated local disease can lead to significant pain, gastric outlet obstruction, biliary obstruction, and other morbidities that decrease quality of life. Thus, SBRT should also be considered as a palliative option for unresectable pancreatic adenocarcinoma".[11]

The following table includes a summary of four peer-reviewed studies in which SBRT, either single or multiple fractions, have been used to treat patients with unresectable pancreas cancer. The use of SBRT did not appear to compromise the administration of systemic chemotherapy. Furthermore, the overall survival results achieved for this extremely challenging clinical situation are as good or better than what is commonly achieved in studies involving conventionally fractionated radiotherapy. This evidence demonstrates that SBRT is "First-line therapy" for locally advanced disease patients, according to the latest NCCN Clinical Practice Guidelines for Pancreas. **Thus, we believe that SBRT as used in these studies is medically necessary therapy for non-metastatic, unresectable pancreas cancer and recommend adding ICD-10 codes C25.0- C25.9 to list of diagnoses**:

| | N | Selection | SBRT dose to PTV | Chemo | Grade 3+ late toxicity | 1 yr OS |
|---|---|---|---|---|---|---|
| **Chang** [12] | 77 | Unresectable Med. Inoperable Locally recurrent Max 7.5 cm | 25 Gy x 1 | GEM-based | 10% | 21% |
| **Rwigema** [13] | 71 | Unresectable | 24 Gy x 1 | GEM +/- erlotinib | 4% | 41% |
| **Mahadevan** [14] | 36 | Unresectable | 8-12 Gy x 3 | GEM x 6 mos | 14% | 61% |
| **Polistina** [15] | 23 | Unresectable | 10 Gy x 3 | GEM pre- and post | 0% | 39% |

ASTRO urges Blue Cross Blue Shield of Mississippi to include both prostate and pancreatic cancer as indications for its SBRT policy based on the growing clinical data and to align with the ASTRO SBRT Model Policy and NCCN guidelines. The BCBS policies of neighboring states, Louisiana, and Alabama, include both prostate and pancreas as indications for SBRT treatment, as do most of the BCBS policies across the country. ASTRO encourages BCBS of Mississippi to view our Payer Education webinar, designed to provide information to federal and private insurance payers on appropriate coverage of radiation therapy services, at https://academy.astro.org/content/astro%E2%80%99s-payer-education-webinar-demand#group-tabs-node-course-default1. ASTRO appreciates the opportunity to offer comments and recommendations for updating the current policy. If you have any questions and/or feedback, please feel free to contact Emilio Beatley, ASTRO's Health Policy Coordinator, at 703-839-7360 or via email at Emilio.Beatley@astro.org.

Sincerely,

Laura I. Thevenot
Chief Executive Officer

CC:

Enclosed: ASTRO SBRT Model Policy

References:

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