September 12, 2017

Craig Samitt, MD
Executive Vice President and Chief Clinical Officer
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(Submitted electronically)

Re: Stereotactic Body Radiotherapy for Pancreatic Cancer

Dear Dr. Samitt,

The American Society for Radiation Oncology (ASTRO)\(^1\) would like to provide input on Anthem’s Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT) policy. We are concerned by Anthem’s decision to classify SBRT for primary or metastatic cancers of the pancreas as “investigational and not medically necessary.” We believe this decision is inconsistent with the medical evidence, and we seek a revision that would consider SBRT as a covered indication for pancreatic cancers. 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 SBRT Model Policy was most recently revised in 2015 and is enclosed for your review.

Anthem provides the following rationale for not covering SBRT for pancreatic cancer patients, “The existing literature consists of uncontrolled trials of small numbers of participants. These studies cannot confirm that SBRT, either alone or in combination with chemotherapy, results in an improvement in the relevant outcome of progression-free survival (Hoyer, 2005; Koong, 2005; Mahadevan, 2011)” (page 3). ASTRO disagrees with this statement, as these citations are largely outdated. Numerous more recent publications have demonstrated convincingly the efficacy and safety of SBRT for pancreas cancer. The enclosed ASTRO SBRT Model Policy cites more recent data, and we also offer the following added comments and selected citations here:

The paper by Hoyer et al from 2005 upon which the Anthem policy is partly based is particularly problematic from a technical standpoint, though important lessons were learned from it. The treatment in that early study was given without image guidance, and the target volumes were extremely large, in retrospect, inappropriately large. Specifically, in this study, a median volume of 136 mL received a dose greater than 10 Gy in each of the 3 fractions; a large portion of this 10-Gy volume encompassed the adjacent duodenum. In the Stanford quantitative analysis of intestinal toxicity after SBRT, when the duodenal volume receiving 10 Gy in a single fraction exceeded 16 mL, the risk of grade 2 to 4 toxicity escalated from 15% to 46%, and it would be expected to be even higher after an additional 2

\(^1\) 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.
treatments. Contempory techniques incorporate high-quality diagnostic and near-real-time imaging studies for accurate treatment delivery and precise assessment of physiologic tumor motion, along with stringent normal tissue dose limits.

A 2012 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 (2). Thus, SBRT should also be considered as a palliative option for unresectable pancreatic adenocarcinoma.”

Additionally, a 2010 study of 85 consecutive patients with locally advanced and recurrent, unresectable pancreatic adenocarcinoma concluded that SBRT for unresectable pancreatic carcinoma, “Can be delivered in three fractions with minimal morbidity and a local tumor control rate of 91.7%. The survival is comparable or better than the reported results for advanced pancreatic cancer, specifically for the group of previously untreated patients.”

A phase II multi-institutional trial published by Herman and colleagues in 2015 studied the use of gemcitabine and SBRT. Forty-nine patients with LAPC were treated with up to 3 doses of gemcitabine chemotherapy then had a 1-week break and SBRT to a dose of 33 Gy delivered in 5 fractions. Median overall survival was 13.9 months, and freedom from local progression at 1 year was 78%. These results compare favorably with those achievable with conventionally fractionated radiotherapy, and the substantial convenience to patients adds value to the SBRT regimens.

As a result of these and many other published studies, the American Society of Clinical Oncology clinical practice guideline for locally advanced pancreatic carcinoma includes among others the following recommendations:

- “If there is local disease progression after induction chemotherapy, but without evidence of systemic spread, then SBRT may be offered to patients who meet the following criteria: First-line chemotherapy treatment is completed or terminated because of progression or toxicity; ECOG PS ≤ 2; a comorbidly profile that is adequate, including adequate hepatic and renal function and hematologic status; and patient preference (Type: evidence based, benefits outweigh harms; Evidence quality: intermediate; Strength of recommendation: strong).

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- SBRT may be offered to patients who have responded to an initial 6 months of chemotherapy or have stable disease but have developed unacceptable chemotherapy-related toxicities or show a decline in performance status, as a consequence of chemotherapy toxicity (Type: evidence-based, benefits outweigh harms; Evidence quality: intermediate; Strength of recommendation: strong).
- If there is response or stable disease after 6 months of induction chemotherapy, SBRT may be offered as an alternative to continuing chemotherapy alone for any patient with LAPC (Type: evidence based, benefits outweigh harms; Evidence quality: intermediate; Strength of recommendation: strong)."

This evidence has also elevated the role of SBRT to “First-line therapy” for locally advanced unresectable patients with “good performance status” according to the 2017 NCCN Clinical Practice Guidelines for Pancreas.7

Finally, a 2011 study by the American Cancer Society emphasized that SBRT is not only an effective pancreatic cancer treatment, but cost effective. The study states,

“The primary cost-effectiveness analysis, including all 4 treatment options, demonstrated that SBRT had an ICER of $69,500 per quality-adjusted life-year (QALY) compared with alone (Table 2). SBRT dominated the more costly and less effective options of RT and IMRT.”8

This issue is best summarized by another 2015 study: “Although the majority of treating physicians prefer SBRT to standard radiation, pancreas SBRT may be underutilized due to difficulty obtaining insurance approval or protocol.”9 Therefore, ASTRO urges Anthem to edit its Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT) policy to include pancreatic cancer among the covered indications. As it is written, the current policy limits providers and disrupts the process of care for patients receiving SBRT.

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

Sincerely,

Laura Thevenot
Chief Executive Officer

Enclosed: ASTRO SBRT Model Policy

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