This Model Policy addresses coverage for Stereotactic Body Radiation Therapy (SBRT).

Description

SBRT is a treatment that couples a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation, thereby maximizing the cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues. SBRT is used to treat extra-cranial sites as opposed to stereotactic radiosurgery (SRS) which is used to treat intra-cranial and spinal targets. However, some of the CPT® codes discussed here are also utilized in the billing process for SRS and are discussed accordingly in the SRS model policy.

The adjective “stereotactic” describes a procedure during which a target lesion is localized relative to a known three-dimensional reference system that allows for a high degree of anatomic accuracy and precision. Examples of devices used in SBRT for stereotactic guidance may include a body frame with external reference markers in which a patient is positioned securely, a system of implanted fiducial markers that can be visualized with low-energy (kV)X-rays and CT-imaging-based systems used to confirm the location of a tumor immediately prior to treatment.

Treatment of extra-cranial sites requires accounting for internal organ motion as well as for patient motion. Thus, reliable immobilization or repositioning systems must often be combined with devices capable of decreasing organ motion or accounting for organ motion e.g. respiratory gating. Additionally, all SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization prior to delivery of each fraction. The ASTRO/ACR Practice Guidelines for SBRT outline the responsibilities and training requirements for personnel involved in the administration of SBRT.

SBRT may be delivered in one to five sessions (fractions). Each fraction requires an identical degree of precision, localization and image guidance. Since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT and is not to be billed using these codes. SBRT is meant to represent a complete course of treatment and not be used as a boost following a conventionally fractionated course of treatment.

1 ASTRO model policies were developed as a means to efficiently communicate what ASTRO believes to be correct coverage policies for radiation oncology services. The ASTRO model policies do not serve as clinical guidelines and they are subject to periodic review and revision without notice. The ASTRO Model Policies may be reproduced and distributed, without modification, for noncommercial purposes.

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Indications and Limitations of Coverage and/or Medical Necessity

This Model Policy addresses only the CPT® codes for SBRT treatment management - 77435, and SBRT treatment delivery -77373, G0251, G0339 and G0340.

When billing for SBRT delivery, it is not appropriate to bill more than one treatment delivery code on the same day of service, even though some types of delivery may have elements of several modalities (for example, a stereotactic approach with intensity-modulated static beams or arcs). Also, only one delivery code is to be billed even if multiple lesions are treated on the same day.

Indications for SBRT:

SBRT is indicated for primary tumors of and tumors metastatic to the lung, liver, kidney, adrenal gland or pancreas as well as for pelvic and head and neck tumors that have recurred after primary irradiation when and only when each of the following criteria are met, and each specifically documented in the medical record. Multiple ICD diagnosis codes (ICD-9 or ICD-10) fit this description and are listed in this coverage policy.

1. The patient’s general medical condition (notably, the performance status) justifies aggressive treatment to a primary cancer or, for the case of metastatic disease, justifies aggressive local therapy to one or more discrete deposits of cancer within the context of efforts to achieve total clearance or clinically beneficial reduction in the patient’s overall burden of systemic disease.
2. The tumor burden can be completely targeted with acceptable risk to critical normal structures.

Other Neoplasms

Prostate Cancer:

Many clinical studies supporting the efficacy and safety of SBRT in the treatment of prostate cancer have been published. At least one study has shown excellent five year biochemical control rates with very low rates of serious toxicity. Additionally, numerous studies have demonstrated the safety of SBRT for prostate cancer after a follow-up interval long enough (two to three years) to provide an opportunity to observe the incidence of late GU or GI toxicity. While it is necessary to observe patients treated for prostate cancer for extended intervals to gauge the rate of long term (beyond 10 years) biochemical control and overall survival, the interim results reported appear at least as good as other forms of radiotherapy administered to patients with equivalent risk levels followed for the same duration post-treatment.

It is ASTRO’s opinion that data supporting the use of SBRT for prostate cancer have matured to a point where SBRT could be considered an appropriate alternative for select patients with low to intermediate risk disease.

Bone Metastases:

SBRT has been demonstrated to achieve durable tumor control when treating lesions in vertebral bodies or the paraspinous region, where extra care must be taken to avoid excess irradiation of the spinal cord when tumor- ablative doses are administered. There is an important clinical distinction between the status of patients described above and a patient with widely metastatic disease for whom palliation is the major objective. In one setting, a patient with limited metastatic disease and good performance status is treated with the intention of eradicating all known active disease or greatly reducing the total disease burden in a manner that can extend progression-free survival. For such a patient, SBRT can be a reasonable therapeutic intervention. However, for uncomplicated, previously untreated bone metastases in a patient with widespread progressive disease in the spine or elsewhere, where the prognosis is unfavorable, it is generally appropriate to use a less technically complex form of palliative radiotherapy rather than SBRT.
Other Indications for SBRT:

For patients with tumors of any type arising in or near previously irradiated regions, SBRT may be appropriate when a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues. Also, in other cases where a high dose per fraction treatment is indicated SBRT may be appropriate. The necessity should be documented in the medical record.

Limitations:

SBRT is not considered medically necessary under the following circumstances:

1. Treatment unlikely to result in clinical cancer control and/or functional improvement.
2. The tumor burden cannot be completely targeted with acceptable risk to critical normal structures.
3. Patients with poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of 3 or worse) - see Karnofsky Performance Status and ECOG Status below.

Karnofsky Performance Status Scale

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Normal; no complaints, no evidence of disease</td>
</tr>
<tr>
<td>90</td>
<td>Able to carry on normal activity; minor signs or symptoms of disease</td>
</tr>
<tr>
<td>80</td>
<td>Normal activity with effort; some signs or symptoms of disease</td>
</tr>
<tr>
<td>70</td>
<td>Cares for self; unable to carry on normal activity or to do active work</td>
</tr>
<tr>
<td>60</td>
<td>Requires occasional assistance but is able to care for most needs</td>
</tr>
<tr>
<td>50</td>
<td>Requires considerable assistance and frequent medical care</td>
</tr>
<tr>
<td>40</td>
<td>Disabled; requires special care and assistance</td>
</tr>
<tr>
<td>30</td>
<td>Severely disabled; hospitalization is indicated although death not imminent</td>
</tr>
<tr>
<td>20</td>
<td>Very sick; hospitalization necessary; active supportive treatment is necessary</td>
</tr>
<tr>
<td>10</td>
<td>Moribund, fatal processes progressing rapidly</td>
</tr>
<tr>
<td>0</td>
<td>Dead</td>
</tr>
</tbody>
</table>

ECOG Performance Status Scale

Grade 0: Fully active, able to carry on all pre-disease performance without restriction.

Grade 1: Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, office work.

Grade 2: Ambulatory and capable of all self-care but unable to carry out and work activities. Up and about more than 50% of waking hours.

Grade 3: Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.

Grade 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.

Grade 5: Dead

Eastern Cooperative Oncology Group, Robert Comis MD, Group Chair.


PHYSICIANS’ CURRENT PROCEDURAL TERMINOLOGY (CPT®)/HCPCS SECTION
[[Note – CPT is a trademark of the American Medical Association (AMA)]]

CPT/HCPCS Codes:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>77435</td>
<td>Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions (The same physician should not report both the stereotactic radiosurgery services [32701, 63620, 63621] and radiation treatment management [77435])&lt;br&gt;This code will be paid only once per course of treatment and should not be reported in conjunction with any other treatment management codes (77427-77432).</td>
</tr>
<tr>
<td>77373</td>
<td>Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions (For single fraction cranial lesions, see 77371, 77372)&lt;br&gt;This code should not be reported in conjunction with any other treatment delivery codes e.g. 77401-77416, 77418. This code will be paid only once per day of treatment regardless of the number of sessions or lesions.</td>
</tr>
<tr>
<td>G0339</td>
<td>Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment&lt;br&gt;This code includes all image guidance on the days of treatment delivery, so do not report G0339 in conjunction with 77421 or 77014 on the days of treatment delivery. This code will be paid only once per day of treatment regardless of the number of sessions or lesions.</td>
</tr>
</tbody>
</table>
G0340  Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment

For reporting fractions 2 through 5 after reporting G0339 for the first fraction. This code includes all image guidance on the days of treatment delivery, so do not report G0340 in conjunction with 77421 or 77014 on the days of treatment delivery. This code will be paid only once per day of treatment regardless of the number of sessions or lesions.

G0251  Linear accelerator based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, maximum five sessions per course of treatment

This code should be utilized only by hospital outpatient departments to report non-robotic Linac based treatments for fractions two through five. This code is excluded from MPFS by regulation.

The CPT® codes discussed in this Model Policy are applicable to all diagnoses listed in the ASTRO SRS Model Policy, a companion document to the SBRT model policy.

ICD Diagnosis Codes that Support Medical Necessity

Note: Diagnosis codes are based on the current ICD-9-CM codes that are effective at the time of Model Policy publication. Any updates to ICD-9-CM or ICD-10-CM codes will be reviewed by ASTRO, and coverage should not be presumed until the results of such review have been published/posted. These ICD diagnosis codes support medical necessity under this Model Policy:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>ICD-9 Code(s)</th>
<th>ICD-10 Code(s)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary lung cancer</td>
<td>162.2 – 162.9</td>
<td>C34.00 – C34.92</td>
<td></td>
</tr>
<tr>
<td>Thoracic lymph nodes</td>
<td>196.1</td>
<td>C77.1</td>
<td></td>
</tr>
<tr>
<td>Lung metastasis</td>
<td>197.0</td>
<td>C78.00 – C78.02</td>
<td></td>
</tr>
<tr>
<td>Primary liver or bile duct cancer</td>
<td>155.0, 155.1, 155.2</td>
<td>C22.0 – C22.9</td>
<td></td>
</tr>
<tr>
<td>Liver metastasis</td>
<td>197.7</td>
<td>C78.7</td>
<td></td>
</tr>
<tr>
<td>Primary Pancreas cancer</td>
<td>157.0 – 157.9</td>
<td>C25.0 – C25.9</td>
<td></td>
</tr>
<tr>
<td>Kidney cancer or metastasis</td>
<td>189.0, 189.1, 198.0</td>
<td>C64.1 – C65.9, C79.00 – C79.02</td>
<td></td>
</tr>
<tr>
<td>Adrenal Gland primary or metastasis</td>
<td>194.0, 194.6, 198.7</td>
<td>C74.00 – C74.92, C75.5, C79.70 – C79.72</td>
<td></td>
</tr>
<tr>
<td>Prostate cancer</td>
<td>185</td>
<td>C61</td>
<td></td>
</tr>
<tr>
<td>Pelvic cancer</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Abdomen and Pelvis</td>
<td>195.2, 195.3</td>
<td>C76.2, C76.3</td>
<td>recurrent after prior conventionally fractionated RT</td>
</tr>
<tr>
<td>▪ Gynecological</td>
<td>179 – 184.9</td>
<td>C51.0 – C58</td>
<td></td>
</tr>
<tr>
<td>▪ Rectum and Anus</td>
<td>154.0 – 154.8</td>
<td>C19 – C21.8</td>
<td></td>
</tr>
<tr>
<td>▪ Effects of Radiation</td>
<td>990*</td>
<td>T66.XXXA*</td>
<td></td>
</tr>
<tr>
<td>Head &amp; Neck cancer, multiple primary sites</td>
<td>140.0 – 146.8, 990*</td>
<td>C00.0 – C10.8, T66.XXXA*</td>
<td>recurrent after prior conventionally fractionated RT</td>
</tr>
<tr>
<td>Nodal metastasis</td>
<td>196.0 – 196.9</td>
<td>C77.0 – C77.9</td>
<td>recurrent after prior conventionally fractionated RT</td>
</tr>
</tbody>
</table>

*ICD-9-CM 990 or ICD-10-CM T66.XXXA (Effects of Radiation, Unspecified) may only be used where prior radiation therapy to the site is the governing factor necessitating SBRT in lieu of other radiotherapy. An ICD diagnosis code for the anatomic diagnosis must also be used.

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General Information

Documentation Requirements
The patient’s record must support the necessity and frequency of treatment. Medical records should include not only the standard history and physical but also the patient’s functional status and a description of current performance status (Karnofsky Performance Status or ECOG Performance Status). See Karnofsky Performance Status or ECOG Performance Status listed under Limitations above. A radiation oncologist must evaluate the clinical and technical aspects of the treatment, and document this evaluation as well as the resulting management decisions. Documentation of the technical aspects of treatment planning and delivery should include details of target dose and relevant dose-limiting normal structures. Documentation should include the date and the current treatment dose. All documentation must be available upon request of the insurer. For Medicare claims, the HCPCS/CPT® code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.
References

**Bone Metastasis**


**Head and Neck**


**Kidney**


**Liver**


Lung


**Pancreas**


73. Schellenberg D, Quon A, Yuriko Minn A et al. 18 Fluorodeoxyglucose PET is prognostic of progression-free and overall survival in locally advanced pancreas cancer treated with stereotactic radiotherapy. *Int J Radiat Oncol Biol Phys.* 2010; 77(5): 1420-1425.

**Pelvic**


**Prostate**


