Indications and Limitations of Coverage and/or Medical Necessity

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

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.
American Society for Radiation Oncology (ASTRO)
Stereotactic Body Radiation Therapy (SBRT) Model Coverage Policy

This Model Policy addresses only the CPT codes for SBRT treatment management - 77435, and SBRT treatment delivery - 77373, 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 & 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-9 codes fit this description and they are not listed in detail here.

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:

SBRT is currently under investigation for other indications, including the primary treatment of prostate cancer (ICD-9 code 185). An insurer should cover treatment of these patients entered on IRB approved clinical trials.

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 Scale** (Perez and Brady, p 225)
100 Normal; no complaints, no evidence of disease
90 Able to carry on normal activity; minor signs or symptoms of disease
80 Normal activity with effort; some signs or symptoms of disease
70 Cares for self; unable to carry on normal activity or to do active work
60 Requires occasional assistance but is able to care for most needs
50 Requires considerable assistance and frequent medical care
40 Disabled; requires special care and assistance
30 Severely disabled; hospitalization is indicated although death not imminent
20 Very sick; hospitalization necessary; active supportive treatment is necessary
10 Moribund, fatal processes progressing rapidly
0 Dead

<table>
<thead>
<tr>
<th>ECOG PERFORMANCE STATUS*</th>
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<tbody>
<tr>
<td>Grade</td>
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<td>0</td>
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<tr>
<td>1</td>
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<td>2</td>
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<td>4</td>
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<td>5</td>
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</tbody>
</table>

Eastern Cooperative Oncology Group, Robert Comis M.D., Group Chair.

* As published in Am. J. Clin. Oncol.:

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.
CPT/HCPCS Codes

77435 Stereotactic body radiation therapy, treatment management, per treatment course, to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

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).

The same physician should not report both the stereotactic radiosurgery services (63620, 63621) and radiation treatment management (77435).

77373 Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions

This code should not be reported in conjunction with any other treatment delivery codes e.g. 77401-77416, 77418.

G0339 Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session, or first session of fractionated treatment

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

CPT 77373, G0339 and G0340 will be paid only once per day of treatment regardless of the number of sessions or lesions.

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-9 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 codes will be reviewed by ASTRO, and coverage should not be presumed until the results of such review have been published/posted. These ICD-9-CM codes support medical necessity under this Model Policy:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>ICD-9 Code(s)</th>
<th>comment</th>
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<tbody>
<tr>
<td>Primary lung cancer</td>
<td>162.2, 162.3, 162.4, 162.5, 162.8, 162.9</td>
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</tr>
<tr>
<td>Thoracic lymph nodes</td>
<td>196.1</td>
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<tr>
<td>Lung metastasis</td>
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<tr>
<td>Primary liver or bile duct cancer</td>
<td>155.0, 155.1, 155.2</td>
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<tr>
<td>Liver metastasis</td>
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<tr>
<td>Kidney cancer or metastasis</td>
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<tr>
<td>Adrenal Gland primary or metastasis</td>
<td>194.0, 194.6, 198.7</td>
<td></td>
</tr>
</tbody>
</table>
Diagnosis | ICD-9 Code(s) | comment
--- | --- | ---
Pelvic cancer (rectal, gynecologic) | multiple ICD-9 codes, 990* | recurrent after prior conventionally fractionated RT
Head & Neck cancer, multiple primary sites | 140.0 through 146.8, inclusive of numbers between, 990* | recurrent after prior conventionally fractionated RT

*990 EFFECTS OF RADIATION UNSPECIFIED

ICD-9-CM 990 may only be used where prior radiation therapy to the site is the governing factor necessitating SBRT in lieu of other radiotherapy. An ICD-9-CM code for the anatomic diagnosis must also be used.

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 Indications and Limitation of Coverage and/or Medical Necessity 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. When requesting a written re-determination (formerly appeal), providers must include all relevant documentation with the request.
SBRT References

General


Liver

American Society for Radiation Oncology (ASTRO)  
Stereotactic Body Radiation Therapy (SBRT) Model Coverage Policy


Lung


Pancreas


Prostate


Spine


**Head and Neck**


2. Kawaguchi K, Sato K, et al. Stereotactic radiosurgery may contribute to overall survival for patients with recurrent head and neck carcinoma. Radiation Oncology 2010; 5(51)


**Kidney**

American Society for Radiation Oncology (ASTRO)  
Stereotactic Body Radiation Therapy (SBRT) Model Coverage Policy  

Breast


Pelvic
