

## STEREOTACTIC BODY RADIATION THERAPY (SBRT)

This Model Policy<sup>1</sup> addresses coverage for *stereotactic body radiation therapy* (SBRT).

### DESCRIPTION

SBRT is a radiation treatment modality that couples a high degree of anatomic targeting accuracy and reproducibility with very high doses of extremely precise, externally generated, ionizing radiation. The therapeutic intent of SBRT is to maximize cell-killing effect on the target(s) while minimizing radiation-related injury in adjacent normal tissues. Stereotactic Radiosurgery (SRS) is similar in concept to SBRT; however, SRS generally refers to stereotactically guided radiation therapy delivered to intracranial targets and selected tumors near the base of the skull, whereas SBRT generally describes stereotactic therapy to extracranial sites. For further discussion of SRS, refer to [ASTRO's SRS Model Policy](#)<sup>11</sup>.

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. 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

#### SBRT Treatment Planning

Treatment planning for SBRT generally follows the same process and procedures as IMRT and three-dimensional conformal therapy plans. As with other treatment planning methods, SBRT planning determines the field size(s), gantry angles and other beam characteristics to achieve the desired radiation dose distribution. SBRT plans are highly customized to the target volume(s) and may be geometrically more accurate than conventionally fractionated external beam treatment plans.

#### Imaging

Three-dimensional image acquisition of the target region by simulation is an essential prerequisite to SBRT treatment planning. In general, a CT scan of the target region is performed and serves as the baseline image set used for dose calculations and, for selected cases, for co-registration of MR or PET images sets in order to better define the target and surrounding anatomy. If respiratory or other normal organ motion is expected to produce significant movement of the target region during radiation therapy delivery, the radiation oncologist may additionally elect to order multiphasic treatment planning image sets to account for motion when rendering target volumes. Some SBRT treatment systems such as automated robotic delivery may not require multiphasic imaging but is still able to deliver motion corrected treatment.

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<sup>1</sup> 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.

### a. Contouring

Defining the target and avoidance structures is a multi-step process:

- i. The radiation oncologist reviews the three-dimensional images and outlines the treatment target on each slice of the image set. The summation of these contours defines the Gross Tumor Volume (GTV). For multiple image sets, the physician may outline separate GTVs on each image set to account for the effect of normal organ motion upon target location and shape. Some patients may not have GTVs if they have had previous treatment with surgery or chemotherapy, in which case treatment planning will be based on CTVs as described below.
- ii. The radiation oncologist draws a margin around the GTV to generate a Clinical Target Volume (CTV), which encompasses the areas at risk for microscopic disease (i.e., not visible on imaging studies). Other CTVs may be created based on the estimated volume of residual disease. For multiple image sets, the physician may draw this margin around an aggregate volume containing all image set GTVs to generate an organ-motion CTV, or Internal Target Volume (ITV).
- iii. To account for potential daily patient setup variation and/or organ and patient motion, a final margin is then added to create a Planning Target Volume (PTV).
- iv. Nearby normal structures that could potentially be harmed by radiation (i.e., “organs at risk” or OARs) are also contoured.

### b. Radiation dose prescribing

The radiation oncologist assigns specific dose requirements for the PTV, which typically includes a prescribed dose that is given to approximately 90 to 95 percent of the PTV. Additionally, treatment prescription usually includes dose constraints for the OARs (e.g., upper limit of mean dose, maximum allowable point dose and/or a critical volume of the OAR that must not receive a dose above a specified limit). A treatment plan that satisfies these requirements and constraints should maximize the potential for disease control and minimize the risk of radiation injury to normal tissue.

### c. Dosimetric planning, calculations and dose verification

The medical physicist or a supervised dosimetrist calculates a multiple static beam and/or modulated arc treatment plan to deliver the prescribed radiation dose to the PTV and simultaneously satisfy the normal tissue dose constraints by delivering significantly lower doses to nearby organs. Dose-volume histograms are prepared for the PTV and OARs. In this example, an arc is defined as a discrete complete or partial rotation of the linear accelerator gantry during which there is continuous motion of the multileaf collimator (MLC) to deliver an optimized radiation dose distribution within the patient. The calculated beams or arcs are then delivered either to a phantom or a dosimetry measuring device to confirm that the calculated dose distribution for the patient is accurate and that the beams or arcs are technically feasible.

Documentation of all aspects of the treatment planning process is essential.

### SBRT Treatment Delivery

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., use of respiratory gating or robotic target tracking for target sites in the chest or upper abdomen. 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<sup>9</sup>.

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 radiation therapy 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 as such. SBRT is meant to represent a complete course of treatment and not be used as a boost following a conventionally fractionated course of treatment.

SBRT may be used as an alternative to surgery for treating various lesions and may be a more effective and safer alternative than conventional radiation therapy for certain presentations of cancers and other non-cancer targets. Direct physician involvement, image guidance and immobilization are integral to stereotactic treatment for these diverse body sites. The medical physicist should perform a second check calculation before initiating the first treatment to ensure the monitor units used to deliver the planned treatment are correct. With a radiation oncologist, the medical physicist should ensure all of the treatment parameters are correct, including image guidance, respiratory motion compensation or any other complex positioning aids that may be employed to accurately treat the patient.

## DOCUMENTATION REQUIREMENTS

The patient's record must support the medical necessity of treatment. Supporting clinical records should include not only the patient's medical history and physical examination findings but also the patient's current functional status, commonly described by an overall performance status score (e.g., Karnofsky Performance Status or Eastern Cooperative Oncology Group (ECOG) Performance Status score). A radiation oncologist must evaluate the clinical and technical aspects of the treatment and document this evaluation as well as the resulting management decision. Clinical record documentation of the technical aspects of treatment planning and delivery should include details of the prescribed dose to the target and relevant dose-limiting normal structures and the actual dose delivered and dates of treatment delivery.

## INDICATIONS AND LIMITATIONS OF COVERAGE AND/OR MEDICAL NECESSITY

### Indications for Coverage

SBRT is indicated for primary malignant tumors of the lung, liver, kidney, adrenal gland, pancreas, bone, and prostate, and primary malignant and benign tumors of the spine and spinal cord. The patient's general medical condition (namely, the performance status) must justify aggressive, curative treatment to a primary, non-metastatic tumor and be specifically documented in the medical record.

SBRT is indicated for treatment of (1) secondary, or metastatic, tumors and (2) recurrent tumors or (3) any tumor arising within or near previously irradiated volumes when at least one of the following criteria is met and specifically documented in the medical record:

1. The patient's general medical condition (namely, the performance status) justifies aggressive local therapy to one or more deposits of metastatic cancer in an effort either to achieve total disease clearance in the setting of oligometastatic disease or to reduce the patient's overall burden of systemic disease for a specifically defined clinical benefit.
2. Recurrent disease requiring palliation or any tumor cannot be treated as effectively or safely by other radiotherapy methods due to proximity of previously irradiated volumes and a high level of precision and accuracy is needed to minimize the risk of injury to surrounding normal tissues.

Multiple ICD diagnosis codes fit this description of covered indications and are listed below under ICD-10-CM Codes That May be Associated with Medical Necessity.

### Additional Coverage Considerations

#### a. Spinal Metastases

SBRT has been demonstrated to achieve durable tumor control when treating lesions in vertebral bodies or the paraspinal 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 and where the prognosis is unfavorable, it is generally appropriate to use a less technically complex form of palliative radiation therapy rather than SBRT.

#### b. Other Indications for SBRT

While SBRT is not a new technology, there is a need for continued clinical evidence development and comparative effectiveness analyses for the appropriate use of SBRT for various disease sites. Indications not listed above are suitable for Coverage with Evidence Development (CED). For example, SBRT as adjuvant therapy for localized breast cancer might be suitable for CED. Radiation therapy for patients treated under the CED paradigm should be covered by the insurance carrier so 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. At this time, no indications are deemed inappropriate for CED.

**DIAGNOSIS THAT MAY BE ASSOCIATED WITH MEDICAL NECESSITY**

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

The following ICD diagnosis codes support the clinical indications listed in the prior section. However, other ICD-10 diagnosis codes may be appropriately covered under CED:

DIAGNOSIS	ICD-10 CODE(S)
<b>PRIMARY TUMORS</b>	
Lung cancer	C34.00 – C34.92
Prostate cancer	C61
Pancreatic cancer	C25.0 – C25.9
Renal cancer	C64.1 – C65.9
Liver or bile duct cancer	C22.0 – C22.9
Adrenal gland cancer	C74.00 – C74.92
Benign spinal cord tumor	D33.4
Primary spinal cancer	C41.2
Benign spinal tumor	D16.6
Bone tumors	C40.00 – C41.9
<b>METASTATIC TUMORS</b>	
Lung metastasis	C78.00 – C78.02
Liver metastasis	C78.7
Renal metastasis	C79.00 – C79.02
Adrenal gland metastasis	C79.70 – C79.72
Bone metastasis	C79.51, C79.52
Abdominal lymph nodes metastasis	C77.2
Pelvic lymph node metastasis	C77.5
Spine Cord metastasis	C72.0, C72.1
Spinal Meninges metastasis	C70.1
<b>RECURRENT TUMORS AFTER PRIOR RT</b>	
Thoracic lymph nodes metastasis	C77.1
Abdominal and pelvic cancer	C76.2, C76.3
Gynecologic cancer	C51.0-C57.9
Rectal and anal cancer	C19-C21.8
Head and neck cancer	C00.0-C10.8 C11.0- C14.8 C30.0-C32.9, C76.0
Lymph node metastasis	C77.0-C77.9
Prior radiotherapy, any site	Z92.3, T66.XXXA*

\* 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 radiation therapy. An ICD diagnosis code for the anatomic diagnosis must also be used.



## LIMITATIONS OF COVERAGE

SBRT is not considered medically necessary under any of the following circumstances:

1. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
2. The tumor burden cannot be completely targeted with acceptable risk to nearby critical normal structures.
3. Patients with poor performance status (Karnofsky Performance Status less than 40 or ECOG Status of 3 or worse; see below for further scoring information regarding Karnofsky Performance Status and ECOG Status).

### Karnofsky Performance Status Scale<sup>4</sup>

- 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.

### ECOG Performance Status Scale<sup>8</sup>

- 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 housework, office work.
- Grade 2: Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50 percent of waking hours.
- Grade 3: Capable of only limited self-care, confined to bed or chair more than 50 percent of waking hours.
- Grade 4: Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
- Grade 5: Dead.

**PHYSICIANS’ CURRENT PROCEDURAL TERMINOLOGY (CPT®)/HCPCS SECTION**

*Note: CPT is a trademark of the American Medical Association (AMA).*

**SBRT Treatment Planning**

There are no specific codes for clinical treatment planning and simulation for SBRT. However, because of the complexity of SBRT and the need for three-dimensional conformal or IMRT dosimetric treatment planning, the following codes are usually appropriate for SBRT cases. Use of IMRT planning is based on the delivery system and medical necessity.

CPT® CODE	DESCRIPTION	SBRT-SPECIFIC GUIDELINES
77263	Therapeutic radiology treatment planning; complex	Given the complexity of clinical decision-making for SBRT, a complex clinical treatment planning code is justified.
+77293	Respiratory motion management simulation (List separately in addition to code for primary procedure).	May be reasonable to perform and report once per course of SBRT for cases in which target movement during respiration must be accounted for during treatment planning (e.g., tumors of the thorax and upper abdomen).
77295 OR 77301	3-dimensional radiotherapy plan, including dose-volume histograms  Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications  (Dose plan is optimized using inverse planning technique for modulated beam delivery [eg, binary, dynamic MLC] to create highly conformal dose distribution. Computer plan distribution must be verified for positional accuracy based on dosimetric verification of the intensity map with verification of treatment set-up and interpretation of verification methodology)	
77470	Special treatment procedure (eg, total body irradiation, hemibody radiation, per oral or endocavitary irradiation)  (77470 assumes that the procedure is performed 1 or more times during the course of therapy, in addition to daily or weekly patient management)  For intraoperative radiation treatment delivery and management, see 77424, 77425, 77469)	Given additional time and effort required of SBRT, a special treatment procedure code may be justified with appropriate specific documentation.

**Medical Radiation Physics, Dosimetry and Treatment Devices**

There are no SBRT specific codes for medical radiation physics, dosimetry, treatment devices and special services. However, the following codes can be used as described below.

CPT® CODE	DESCRIPTION	SBRT-SPECIFIC GUIDELINES
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician	One unit for each arc in linear accelerator system.  One unit for each shot in Cobalt-60. Maximum limit of 10 units.
77370	Special medical radiation physics consultation	May be reasonable and necessary if ordered by the radiation oncologist.
77334	Treatment devices, design and construction; complex (irregular blocks, special shields, compensators, wedges, molds or casts), custom immobilization devices	One unit for each unique combination of beam angle and collimator pattern or each unique arc; certain carrier limitations may apply. One unit for each helmet in Cobalt-60.
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction, per IMRT plan	If IMRT planning code 77301 is used for coding treatment planning then one CPT 77338 should be used to code for the MLC pattern. One would still use 77334 to code for the immobilization device.

**SBRT Treatment Delivery**

Historically, in the hospital outpatient environment, CMS has utilized G-codes to distinguish between robotic and non-robotic SBRT and SRS. The agency recently reviewed current radiation therapy equipment technology and found that most linac-based treatment platforms incorporate some type of robotic capability. CMS therefore concluded that it is no longer necessary to continue distinguishing robotic and non-robotic linear accelerators.

CPT® CODE	DESCRIPTION	SBRT-SPECIFIC GUIDELINES
77373	<i>Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions</i>  (Do not report 77373 in conjunction with 77385, 77386, 77401, 77402, 77407, 77412, G6003-G6016)  (For single fraction cranial lesion[s], see 77371, 77372)	This code includes all image guidance on the days of treatment delivery; therefore, do not report 77373 in conjunction with 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.

When reporting SBRT delivery, it is not appropriate to bill more than one treatment delivery code on the same date of service, even though stereotactic therapy may be delivered using either conformal or intensity modulated techniques (e.g., SBRT delivered using MLC-modulated beams should be reported using CPT code 77373 only and not using 77373 with 77385, 77386, G6015, or G6016). Likewise, only one SBRT delivery unit is to be reported even if multiple targets are treated using different setup and field arrangement parameters on the same day.



**Radiation Treatment Management**

CPT® Category I code 77435 (SBRT treatment management) should be used by the radiation oncologist to report treatment management during SBRT. This code may be reported once per SBRT course.

The physician work for 77435 can be summarized as follows: The radiation oncologist evaluates the patient prior to the procedure. Under the direct supervision of the radiation oncologist, the patient is set up on the treatment table and all the treatment parameters are verified. Image guidance and respiratory correlation, if required, may be achieved through a variety of methods, all of which are supervised, corrected and approved in real-time by the physician. The physician assesses and approves all of the ongoing images used for localization, tumor tracking and any gating application, as well as any complementary single (beam’s eye) view localization images for any of the fields or arcs used to deliver a dose. The radiation oncologist remains available throughout SBRT treatment to manage the execution of the treatment and make real-time adjustments in response to patient motion, target movement or equipment issues to ensure accuracy and safety. The physician also evaluates the patient post-procedure. All other work generally associated with CPT code 77427 (Radiation treatment management, five treatments) is included and should not be separately coded.

Much of the radiation oncologist’s work in establishing the above treatment parameters is performed in conjunction with the qualified medical physicist, who should be present and participate in delivering SBRT.

CPT® CODE	DESCRIPTION	SBRT-SPECIFIC GUIDELINES
77435	<p><i>Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions (Do not report 77435 in conjunction with other treatment management codes 77427- 77432, 77469)</i></p> <p>(The same physician should not report both stereotactic radiosurgery services (32701, 63620, 63621) and radiation treatment management (77435)</p>	<p>Professional charge for treatment management performed by the radiation oncologist.</p> <p>This code can be reported only once for the entire course of treatment and not per fraction. It will apply to all lesions treated during that entire course of treatment. It should not be reported in conjunction with any other treatment management codes (77427-77432, 77469).</p>


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