Stereotactic body radiation therapy (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.

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.

All SBRT is performed with at least one form of image guidance to confirm proper patient positioning and tumor localization. To minimize intra-treatment tumor motion associated with respiration or other motion, some form of motion control or "gating" should be used.

SBRT may be fractionated (up to 5 fractions). Each fraction requires an identical degree of precision, localization and image guidance. Since the goal of SBRT is to intensify 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.

This LCD addresses only CPT codes 77373 and 77435. Other radiation oncology services (professional and technical) are coded separately and are addressed in the separate LCDs: Radiation Oncology: External Beam/Teletherapy and Intensity Modulated Radiation Therapy. All other acceptable uses of CPT codes 77373 and 77435 are described in the companion LCD, Stereotactic Radiosurgery.
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 IMRT). Only one delivery code is to be billed.

**Indications**

A. **SBRT for lung, liver, kidney, and, or pancreas neoplasms:**

SBRT is covered for primary and metastatic tumors of the **lung, liver, kidney, or pancreas** when and only when each of the following criteria is met, and each specifically documented in the medical record:

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 discreet 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. Typically, such a patient would have also been a potential candidate for alternate forms of intense local therapy applied for the same purpose (e.g. surgical resection, radiofrequency ablation, cryotherapy, etc).

2. Other forms of radiotherapy, including but not limited to external beam and IMRT, cannot be as safely or effectively utilized.

3. The tumor burden can be completely targeted with acceptable risk to critical normal structures.

4. If the tumor histology is germ cell or lymphoma, effective chemotherapy regimens have been exhausted or are otherwise not feasible.

5. Other forms of focal therapy, including but not limited to radiofrequency ablation and cryotherapy, cannot be as safely or effectively utilized.

B. **SBRT for Prostate Neoplasms:**

SBRT of the prostate is covered as monotherapy for patients with low risk and low/intermediate risk prostate cancer when and only when each of the following criteria is met, and each specifically documented in the medical record:

1. The patient’s general medical condition (notably, the performance status) justifies aggressive treatment to a primary cancer. Typically, such a patient would have also been a potential candidate for alternate forms of intense local therapy applied for the same purpose.

2. Other forms of radiotherapy, including but not limited to external beam and IMRT or seed implantation, cannot be as safely or effectively utilized.
3. The tumor burden can be completely targeted with acceptable risk to critical normal structures.

C. **Other Neoplasms:**
Lesions of bone, breast, uterus, ovary and other internal organs not listed above are not covered for primary definitive SBRT as literature does not support an outcome advantage over other conventional radiation modalities, but may be appropriate for SBRT in the setting of recurrence after conventional radiation modalities.

D. **Other Indications for SBRT:**
Except as above, any lesion with a documented necessity to treat using a high dose per fraction of radiation. When using high radiation doses per fraction, high precision is required to avoid surrounding normal tissue exposure.

Lesions which have received previous radiotherapy or are immediately adjacent to previously irradiated fields, where the additional precision of stereotactic radiotherapy is required to avoid unacceptable tissue radiation will be covered when other conditions of coverage are met (see Limitations below) and this necessity is documented in the medical record.

**Limitations:**
Coverage will be denied for each of the following:
1. Treatment unlikely to result in clinical cancer control and/or functional improvement,
2. Patients with wide-spread cerebral or extra-cranial metastases,
3. Patients with poor performance status (Karnofsky Performance Status less than 40 or ECOG Performance Status greater than 3) - See Performance Status scales below.

**Karnofsky Performance Scale** (Perez and Brady, p 225)

<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>---------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>0 Fully active, able to carry on all pre-disease performances without restriction</td>
<td></td>
</tr>
<tr>
<td>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</td>
<td></td>
</tr>
<tr>
<td>2 Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours</td>
<td></td>
</tr>
<tr>
<td>3 Capable of only limited self-care, confined to bed or chair more than 50% of waking hours</td>
<td></td>
</tr>
<tr>
<td>4 Completely disabled. Cannot carry on any self care. Totally confined to bed or chair</td>
<td></td>
</tr>
<tr>
<td>5 Dead</td>
<td></td>
</tr>
</tbody>
</table>

**Bill Type Codes:**
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims. N/A

**Revenue Codes:**
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes. N/A

**CPT/HCPCS Codes**

**Group 1 Paragraph:** (Use of 77373 and 77435 are addressed in both this LCD and in the Stereotactic Radiosurgery LCD.) 77373 and 77435 are used in free standing facilities and as of January 1, 2014, Outpatient Prospective Payment System (OPPS) and Ambulatory Service Center (ASC).
Group 1 Codes:

STEREOTACTIC BODY RADIATION THERAPY, TREATMENT DELIVERY, PER FRACTION TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS
77373

STEREOTACTIC BODY RADIATION THERAPY, TREATMENT MANAGEMENT, PER TREATMENT COURSE, TO 1 OR MORE LESIONS, INCLUDING IMAGE GUIDANCE, ENTIRE COURSE NOT TO EXCEED 5 FRACTIONS
77435

Group 2 Paragraph: Effective for services furnished on or after January 1, 2014, hospitals must report SRS planning and delivery services using only the CPT codes that accurately describe the service furnished. (Use code 77373 in place of the “G” codes listed below. The “C” code is for use in OPPS.)

Group 2 Codes:

PLACEMENT OF INTERSTITIAL DEVICE(S) FOR RADIATION THERAPY/SURGERY GUIDANCE (EG, FIDUCIAL MARKERS, DOSIMETER), FOR OTHER THAN THE FOLLOWING SITES (ANY APPROACH): ABDOMEN, PELVIS, PROSTATE, RETROPERITONEUM, THORAX, SINGLE OR MULTIPLE IMAGE-GUIDED ROBOTIC LINEAR ACCELERATOR-BASED STEREOTACTIC RADIOSURGERY, COMPLETE COURSE OF THERAPY IN ONE SESSION OR FIRST SESSION OF FRACTIONATED TREATMENT
C9728

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
G0339

G0340

Group 3 Paragraph: Codes for the surgeons' work

Group 3 Codes:
BRONCHOSCOPY, RIGID OR FLEXIBLE, INCLUDING FLUOROSCOPIC GUIDANCE, WHEN PERFORMED: WITH
PLACEMENT OF FIDUCIAL MARKERS, SINGLE OR MULTIPLE
PLACEMENT OF INTERSTITIAL DEVICE(S) FOR RADIATION THERAPY GUIDANCE (EG, FIDUCIAL MARKERS, DOSIMETER), PERCUTANEOUS, INTRA-THORACIC, SINGLE OR MULTIPLE
PLACEMENT OF INTERSTITIAL DEVICE(S) FOR RADIATION THERAPY GUIDANCE (EG, FIDUCIAL MARKERS, DOSIMETER), PERCUTANEOUS, INTRA-ABDOMINAL, INTRA-PELVIC (EXCEPT PROSTATE), AND/OR RETROPERITONEUM, SINGLE OR MULTIPLE
PLACEMENT OF INTERSTITIAL DEVICE(S) FOR RADIATION THERAPY GUIDANCE (EG, FIDUCIAL MARKERS, DOSIMETER), PROSTATE (VIA NEEDLE, ANY APPROACH), SINGLE OR MULTIPLE

Please refer to the CMS website for the ICD-10 Codes that Support Medical Necessity.

Associated Information
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. See Karnofsky Performance Scale or ECOG Performance Status listed under Coverage Indication, Limitation, and/or Medical Necessity above.

Documentation should include the date and the current treatment dose. A radiation oncologist must evaluate the clinical and technical aspects of the treatment, and document this evaluation as well as the resulting management decisions.

All documentation must be available upon request of the Medicare contractor.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

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 redetermination (formerly appeal), providers must include all relevant documentation with the request.

Utilization Guidelines
1. Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

2. CPT 77435 will be paid only once per course of treatment of SBRT.

3. CPT 77373 will be paid only once per day of treatment regardless of the number of sessions or lesions.

Reviewed/Approved by Michael Pentecost, MD, Chief Medical Officer