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Subject: Stereotactic Body Radiotherapy

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DESCRIPTION:

Stereotactic body radiation therapy (SBRT) (also known as stereotactic body radiotherapy) is an external beam radiation therapy used to deliver a high dose of radiation to extracranial target(s) within the body. Small fields and rigid fixation based on frame or imaging based stereotaxy are used to minimize exposure of the delivered radiation to the healthy tissue around the target. SBRT delivers highly focused convergent beams sparing adjacent structures. It may offer a non-invasive alternative to invasive surgery, particularly for patients unable undergo surgery or for lesions that are difficult to access surgically or are adjacent to vital organs.

The emerging trend in recent years has been toward shorter, more “hypofractionated” courses (radiation treatment that delivers more than one treatment session per day), such as with SBRT. SBRT may be given with a single session (fraction) or up to five fractions, referred to as fractionated stereotactic radiotherapy. Fractionation has been made possible by the ability to duplicate the treatment plan from one session to the next. Fractionation of stereotactic radiotherapy aims to optimize the therapeutic ratio; that is the ratio between tumor control and late effects on normal tissues. The main advantage of fractionation is that it allows higher total doses to be delivered to the tumor because of increased tolerance of the surrounding healthy tissues to each individual, fractionated dose.

SBRT can be applied using noninvasive or minimally invasive stereotactic localization and radiation delivery techniques. SBRT may be delivered by a number of commercially available devices (e.g., Accuray’s, Cyberknife®, Brain Lab’s Novallis®, Varian’s Trilogy®, Electra’s Synergy®). These devices may incorporate robotics and real-time imaging. SBRT devices (e.g., Accuray’s, Cyberknife®, Brain Lab’s Novallis®, Varian’s Trilogy®, Electra’s Synergy®) have received clearance for marketing by the U.S. Food and Drug Administration (FDA).

Summary and Analysis of Evidence: Stereotactic body radiotherapy (SBRT) for liver tumors, non-small cell lung cancer, oligometastases, pancreatic cancer, renal cell carcinoma, prostate cancer and spinal or vertebral (tumors, metastases), the evidence includes nonrandomized and prospective studies (Jeppesen 2013; Shah 2013; Shioyama 2005; Colosimo 2022; Falcinelli 2022; Borghesi 2022; Ghaly 2021;

Rühle 2019; Chen 2013; Freeman 2011; Jabbari 2012; Katz 2013; Oermann 2011; Pasqualetti 2022; Yang 2023; Zhuang 2020; Wowra 2008).

POSITION STATEMENT:

Note: For stereotactic radiosurgery, refer to Stereotactic Radiosurgery (Intracranial), 02-77371-01.

Stereotactic body radiotherapy **meets the definition of medical necessity** for the following indications:

- Liver tumors (primary or metastatic), as an alternative locoregional treatment for members with inoperable primary or metastatic lesions
- Members with stage T1 or T2a non-small cell lung cancer (not >5 cm) showing no nodal or distant disease and who are not candidates for surgical resection
- Oligometastases involving the lung, adrenal glands, and bone (other than spine or vertebral body)
- Pancreatic cancer (locally advanced or recurrent disease without distant metastasis)
- Primary renal cell carcinoma in members who are not good surgical candidates or who have metastatic renal cell carcinoma
- Prostate cancer
- Spinal or vertebral body tumors (primary or metastatic) in members who have received prior spinal radiotherapy
- Spinal or vertebral metastases that are radioresistant (e.g., renal cell carcinoma, melanoma, sarcoma).

Stereotactic body radiotherapy to treat a previously irradiated field **meets the definition of medical necessity** for the following indications:

- Bone metastases
- Colorectal cancer and anal cancer
- Gastrointestinal cancers (cholangiocarcioma, esophageal, gastric)
- Genitourinary cancers (bladder, penile, testicular)
- Gynecologic cancers (cervical, fallopian tube, ovarian, uterine, vulvar, vaginal)
- Head and neck cancers (including thyroid)
- Hepatocellular carcinoma
- Liver metastases
- Lymphoma (Hodgkin and Non-Hodgkin)
- Pancreatic cancer
- Primary lung cancers (non-small cell, small cell, mestatic lung lesions)
- Prostate cancer (low, intermediate and high risk of recurrence, post-prostatectomy)
- Spine lesions (primary or metastatic).

BILLING/CODING INFORMATION:

Codes may not be all inclusive.

CPT Coding:

32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment
63620	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 spinal lesion
63621	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional spinal lesion (List separately in addition to code for primary procedure)
77301	Intensity modulated radiotherapy plan, including dose-volume histograms for target and critical structure partial tolerance specifications (Note: when specified as treatment planning for SBRT.)
77338	Multi-leaf collimator (MLC) device(s) for intensity modulated radiation therapy (IMRT), design and construction per IMRT plan (Note: when specified as devices for SBRT.)
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions
77435	Stereotactic body radiation therapy, treatment management, per treatment course, to one or more lesions, including image guidance, entire course not to exceed 5 fractions

HCPCS Coding:

G0339	Image guided robotic linear accelerator base 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 session per course of treatment

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, plan of treatment and reason for stereotactic body radiotherapy.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

Plan of treatment	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Benign: not cancerous. Benign tumors may grow larger but do not spread to other parts of the body. Also called nonmalignant.

Metastatic: having to do with metastasis, which is the spread of cancer from the primary site (place where it started) to other places in the body.

Oligometastasis: a type of metastasis in which cancer cells from the original (primary) tumor travel through the body and form a small number of new tumors (metastatic tumors (oligometastatic)) in one or two other parts of the body.

Tumor: a new growth of tissue in which the multiplication of cells is uncontrolled and progressive; also called neoplasm (benign or malignant).

RELATED GUIDELINES:

Stereotactic Radiosurgery (Intracranial), 02-77371-01

OTHER:

Other names used to report stereotactic body radiotherapy:

Stereotactic Ablative Radiotherapy (SABR)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 07/25/24.

GUIDELINE UPDATE INFORMATION:

09/15/08	New Medical Coverage Guideline.
01/01/09	Annual HCPCS coding update: added codes 63620 and 63621.
11/15/09	Annual review. Maintain position statements. Add program exception for Medicare. Updated references.
06/15/10	Annual review. Updated description. Added G0251. Updated Medicare Advantage program exception; added indications for cranial lesions and ICD-9 codes that support medical necessity. Deleted related Internet link. Updated references.
05/15/11	Updated Medicare program exception.
01/01/13	Annual HCPCS coding update; added 32701.
07/15/14	Annual review; updated description, added spinal or vertebral body tumors (metastatic or primary) in members who have received prior radiation therapy, added spinal or vertebral metastases that are radioresistant (e.g., renal cell carcinoma, melanoma, sarcoma), added stereotactic body radiation therapy performed using fractionation for the above indications meets the definition of medical necessity, updated Medicare Advantage products program exceptions, and updated references.
07/15/15	Annual review. Added position statement for clinically localized prostate cancer. Updated reference.
05/01/16	Revision; added/revised indications: bone metastases, breast cancer, CNS cancers, intracranial lesions, medulloblastoma, supratentorial, PNET, ependymoma, CNS lymphoma, metastatic brain lesions, benign brain lesions, pituitary adenomas, meningioma, other benign brain tumors (acoustic neuromas, carniopharyngiomas, pineal gland tumors, schwannomas), ocular lesions, retinoblastoma, spine lesions (primary or metastatic), other neurologic indication (trigeminal neuralgia), colorectal and anal cancers, gastrointestinal cancers, non-colorectal (cholangiocarcinoma, esophageal, gastric, liver and pancreatic), genitourinary cancers (bladder, penile and testicular), gynecologic cancers (cervical, fallopian tube, ovarian, uterine, and

	vulvar/vaginal), head and neck cancers (including thyroid cancer), lung cancer (small cell and non-small cell), other tumor types (including other malignancies), and prostate cancer; added code 77280, 72285, 77290, 77295, 77338, 77402, 77407 and 77412; added ICD-10 codes; added LOINC codes; updated program exception; updated references.
08/15/16	Updated program exceptions.
11/15/16	Revision; revised position statement. Updated references.
01/01/17	Annual HCPCS code update. Revised 77402, 77407 and 77412 code descriptor.
10/15/17	Revision; revised position statement. Added Hodgkin and Non-Hodgkin lymphoma. Updated references.
02/15/18	Revision; updated position statement, ICD-10 diagnoses codes and definitions. Added position statement for pediatric.
03/15/21	Review/revision. Updated description. Bone metastases: Revised re-treatment with EBRT, deleted spinal cord and added adjacent cord. Added CNS indications and criteria. Hepatocellular carcinoma: Deleted Karnofsky Performance Scale. Liver metastases: Deleted other therapy options. Pancreatic cancer: Revised criteria. Added locally advanced or recurrent disease without evidence of distant metastasis. Non-small cell lung cancer: Revised criteria. Small cell lung cancer: Revised criteria. Added alternatives to surgical resection and criteria. Metastatic lesions in the lung: Deleted Karnofsky Performance Scale. Added fractionation and criteria for non-small cell lung cancer. Prostate cancer: Revised criteria for risk of recurrence (high and local). Localized prostate cancer: Deleted negative bone scan. Added oligometastatic extracranial disease and criteria. Updated CPT and ICD-10 codes. Updated references.
02/15/22	Updated program exceptions.
05/15/23	Review: revised position statement. Updated coding and references.
08/21/23	Update to Program Exceptions section.
08/15/24	Review; no change to position statement. Updated references.