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Medicare Advantage Medical Coverage Policy

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Disclaimer

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Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to <u>CMS website</u> for the most current applicable National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/CMS Online Manual System/Transmittals.

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Туре	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
LCD	Stereotactic Radiation Therapy: Stereotactic Radiosurgery (SRS)	<u>L35076</u>	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
LCA	and Stereotactic Body Radiation Therapy (SBRT)	<u>A56874</u>	JK - National Government Services, Inc. (Part A/B MAC	CT, NY, ME, MA, NH, RI, VT
LCD		L37485	J6 - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI
LCA	Prostate Rectal Spacers	<u>A56539</u>	JK - National Government Services, Inc. (Part A/B MAC	CT, NY, ME, MA, NH, RI, VT

Description

Stereotactic radiosurgery (SRS) is a form of radiation therapy in which three-dimensional (3D) images are utilized to specifically direct focused radiation to obliterate abnormal tissues in the head and neck (facilitated by a rigid head frame), while sparing surrounding healthy tissue. This technique differs from conventional radiation therapy, which involves exposing large areas of tissue to relatively broad fields of radiation. SRS can be utilized for, but may not be limited to, the treatment of arteriovenous malformations (AVMs), aneurysms, benign or malignant brain tumors and acoustic neuromas (vestibular schwannoma).

Stereotactic body radiation therapy (SBRT) is similar in technique to intracranial SRS except the target areas are in the body (utilizing a body frame) and do not include the head or neck (extracranial). SBRT involves a single high-dose radiation delivery, or a series of fractionated radiation deliveries given over several days, with the intention of decreasing the short and long-term side effects of radiation therapy, while permitting a higher total radiation dosage in some situations.

Delivery systems for SRS and SBRT include, but may not be limited to:

• **CyberKnife** is a radiation delivery system that consists of a lightweight linear accelerator device (LINAC) that is mounted to a multijointed robotic arm. This device utilizes a proprietary real-time image-guidance system to deliver SRS or radiotherapy. It was designed to access hard to reach or complex shaped tumors that may not be accessible by surgery and other radiosurgical technologies.

- Gamma Knife (eg, Akesis Galaxy and Akesis Galaxy RTi, Elekta Esprit, Gamma Knife Icon Leksell, Perfexion SRS system,) is a radiosurgery technology, which is designed to treat brain tumors. The device utilizes ionizing radiation (gamma rays) produced by 201 radioactive colbalt-60 sources to ablate intracranial targets via a fixed stereotactic frame.
- **GammaPod** is a stereotactic radiotherapy system that is designed to deliver SBRT by purportedly using thousands of individual focused beams from 36 rotating radioactive Cobalt-60 sources. It is intended for use in the noninvasive stereotactic delivery of radiation to a portion of the breast in conjunction with breast conserving treatment. The individual lies prone on a table with the breast immobilized in a vacuum-assisted cup, which reportedly provides increased accuracy in the delivery of the radiation.¹⁶³

The placement of a **transperineal biodegradable spacer** also known as **prostate rectal spacers (eg, Barrigel**, **SpaceOAR, SpaceOAR Vue)** positions the anterior (frontal) section of the rectal wall away from the prostate during external beam radiotherapy treatments for prostate cancer with the goal of limiting the radiation exposure to the anterior rectum. Because this material is biodegradable, it is absorbed over time by the individual's body. SpaceOAR is comprised of a synthetic, absorbable polyethylene glycol-based hydrogel. SpaceOAR Vue contains PEGylated iodine, which is designed to enhance visibility via CT scan. Barrigel injectable gel is similar to the SpaceOAR product; however, it is made of stabilized hyaluronic acid.

Coverage Determination Criteria

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

SRS will be considered medically reasonable and necessary when the following requirements are met:

- Arteriovenous malformations (AVMs)^{53,49,56,97}
 - Individual is a poor surgical risk; OR
 - Surgically inaccessible AVM; OR
- Brain malignancies (primary or metastatic)^{29,33}
 - Lesions less than 5cm; AND
 - \circ No active systemic disease (defined as extracranial disease that is stable or in remission); OR
- Intracranial tumors which includes, but may not be limited to, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastoma:^{9,33}

- Not amenable to surgical interventions; OR
- Not completely resectable or unresectable; OR
- Ocular melanomas
- Pituitary adenomas
- Severe essential tremor^{9,36}
 - o Not amenable for alternative procedures (eg, deep brain stimulation); AND
 - Symptoms refractory to medical therapy; OR
- Spinal cord metastases^{52,77}
 - No clinically significant spinal instability; AND
 - $\circ~$ No evidence of spinal cord compression; AND
 - Not amenable for additional conventional irradiation or surgery; AND
 - Well-circumscribed lesion (easily outline for treatment planning); OR
- Trigeminal neuralgia⁴⁰
 - Not amenable to surgical excision; OR
 - Symptoms refractory to medical therapy

SBRT will be considered medically reasonable and necessary for the treatment of recurrence in or near previously irradiated regions when a high level of precision and accuracy or a high dose per fraction is indicated to minimize the risk of injury to surrounding normal tissues and treatment with conventional methods is not appropriate or safe for the particular individual.³⁰

SBRT will be considered medically reasonable and necessary when the following requirements are met:

- Adrenal metastases^{52,82}; **OR**
- Cholangiocarcinoma, unresectable;^{52,75} OR
- Hepatocellular carcinoma/liver metastases^{52,91}
 - o Additional treatment needed (eg, limited disease, symptom palliation); AND
 - Not amenable to surgical excision; AND
 - $\circ~$ Sufficient amount of uninvolved liver to tolerate treatment course; OR
- Lung metastases^{20,30,52,86}

- 1-3 metastases present; AND
- o Additional treatment needed (eg, curative intent, palliation of symptoms); AND
- Medically inoperable or refuses surgery; AND
- Stable extrathoracic disease as evidenced by imaging studies (eg, CT scan, PET-CT) prior to beginning treatment; OR
- Non-small cell lung cancer (NSCLC)^{3,20,86}
 - Inoperable stage 1 or 2 node negative peripheral lesions that are less than 5 cm in maximal dimension; AND
 - Need for additional treatment (curative intent); AND
 - Medically inoperable or refuses surgery; AND
 - No lymph node metastases; OR
- Pancreatic cancer, locally advanced for the following indications:^{52,88}
 - $\circ~$ First-line therapy, either alone or combined with chemotherapy; OR
 - Use as palliative therapy; OR
- Prostate cancer^{26,52,89}
 - Low-risk disease
 - <u>Gleason grade</u> less than or equal to 6; AND
 - Life expectancy of 10 years or greater; AND
 - Prostate-specific antigen (PSA) less than 10; AND
 - <u>Stage T1-T2</u> (organ-confined) prostate cancer; OR
 - Intermediate-risk disease or high-risk
 - <u>Gleason grade</u> 7 10; AND
 - Prostate-specific antigen (PSA) 10 or greater; AND
 - <u>Stage T2b/T2c</u> or <u>T3a</u> prostate cancer; OR
- Spinal Metastases^{52,77}
 - In tumors that are considered resistant to conventional external beam radiation therapy (EBRT) (eg, sarcoma, melanoma, renal cell carcinoma, NSCLC, colon carcinoma); AND
 - Need for additional treatment (eg, symptom palliation); AND
 - No cord compression; AND

- No spinal fracture or instability; OR
- Spinal Tumors⁷⁷
 - $\circ~$ Not amenable to surgical excision

Transperineal biodegradable spacer also known as **prostate rectal spacers** (eg, Barrigel, SpaceOar, SpaceOAR Vue) will be considered medically reasonable and necessary for use during prostate cancer radiation therapy.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 -</u> <u>Particular services excluded from coverage</u>

SRS/SBRT will not be considered medically reasonable and necessary when the following requirements are met:

- Treatment is unlikely to result in clinical cancer control and/or functional impairment;³⁰ AND
- Tumor burden cannot be completely targeted with acceptable risk to critical normal structures;³⁰ AND
- Poor performance status (<u>Karnofsky Performance Status less than 40</u> or <u>Eastern Oncology Group (ECOG)</u> <u>status of 3 or worse</u>);³⁰ AND
- Recurrent (other than pelvis and head and neck tumors) or metastatic disease could be treated by conventional methods (record must describe why other radiation therapy measures are not appropriate or safe for the individual);³⁰ AND
- Course of radiation treatment extending beyond 5 fractions as the goal of SBRT is to maximize the
 potency of radiotherapy by completing an entire course of treatment within an extremely accelerated
 time frame. Extending beyond 5 fractions is not considered SBRT and not to be used as a boost following
 a conventionally fractionated course of treatment;³⁰ AND

SRS/SBRT will not be considered medically reasonable and necessary for the following diagnoses:

• Breast cancer; **OR**

- Thyroid cancer; **OR**
- GammaPod

A review of the current medical literature shows that there is <u>no evidence</u> to determine that this service is standard medical treatment. There is an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

- Bone metastasis excluding spine; OR
- Colon/rectal cancer; OR
- Epilepsy; OR
- Gynecologic cancer (eg, cervical, endometrial, ovarian, uterine, vulvar) OR;
- Kidney/renal cancer; OR
- Pancreatic cancer; OR

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

Bone metastases

Advanced radiation techniques (eg, SBRT) as primary treatment for painful bone metastases should be considered in the setting of a clinical trial since there is currently insufficient data to routinely support this treatment.¹⁰

Colon/rectal cancer

SBRT for the treatment of extrahepatic disease can be considered in select cases, or as part of a clinical trial. Ablative SBRT should only be used in the setting of a clinical trial or in the setting of oligometastases (eg, lung, liver).^{90.}

Epilepsy

Due to the lack of data, it is not possible to compare efficacy and safety profiles of different radiosurgery methods for the treatment of epilepsy.⁴²

Gynecological cancers

SBRT is not considered an appropriate alternative to brachytherapy.⁷⁸

Kidney/renal cancer

SBRT in the management of localized renal masses at present remains investigational.²⁸ Further randomized trials comparing SBRT to standard treatment approaches, such as surgical resection and other ablative techniques, are necessary prior to integrating this technique into clinical practice.¹²³

Pancreatic cancer

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There are limited data to support specific radiation therapy dosing for SBRT; therefore, it should preferably be utilized as part of a clinical trial or at an experienced, high-volume center.⁸⁸ Until randomized trials comparing this approach with conventional systemic and other radiation therapies the place of SBRT as a treatment option for locally advanced pancreatic cancer will remain uncertain and cannot be recommended as a standard approach.¹⁰⁴

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
32701	Thoracic target(s) delineation for stereotactic body radiation therapy (SRS/SBRT), (photon or particle beam), entire course of treatment	
55874	Transperineal placement of biodegradable material, peri- prostatic, single or multiple injection(s), including image guidance, when performed	
61796	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 simple cranial lesion	
61797	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, simple (List separately in addition to code for primary procedure)	
61798	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion	
61799	Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); each additional cranial lesion, complex (List separately in addition to code for primary procedure)	
61800	Application of stereotactic headframe for stereotactic radiosurgery (List separately in addition to code for primary procedure)	
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)	
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based	

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77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based	
77373	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions	
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)	
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	
CPT®		
Catagory	Description	Comments
Code(s)	Description	comments
Code(s) No code(s) ic	lentified	comments
Code(s) No code(s) ic HCPCS Code(s)	lentified Description	Comments
Code(s) No code(s) ic HCPCS Code(s) C1889	Implantable/insertable device, not otherwise classified	Comments
Code(s) No code(s) id HCPCS Code(s) C1889 G0339	Implantable/insertable device, not otherwise classified Image guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment	Comments

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Appendix

Appendix A

Karnofsky Performance Status Criteria

Able to carry on normal	100	Normal, no complaints; no evidence of disease
care needed.	90	Able to carry on normal activity; minor signs or symptoms of disease
	80	Normal activity with effort; some signs or symptoms of disease
Unable to work; able to live at home and care for most	70	Cares for self; unable to carry on normal activity or to do active work
personal needs; varying amount of assistance needed.	60	Requires occasional assistance but is able to care for most of personal needs
	50	Requires considerable assistance and frequent medical care
Unable to care for self;	40	Disabled; requires special care and assistance
requires equivalent of institutional or hospital care;	30	Severely disabled; hospital admission is indicated although death not imminent
aisease may be progressing	20	Moribund; fatal processes progressing rapidly
	0	Dead

Appendix B ECOG Performance Status

Grade	ECOG
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, eg, light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours

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Grade	ECOG
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Dead

Appendix C TNM Staging System⁸⁵

The T category describes the original (primary) tumor.

ТХ	Primary tumor cannot be evaluated
Т0	No evidence of primary tumor
Tis	Carcinoma in situ (early cancer that has not spread to neighboring tissue)
T1-T4	Size and/or extent of the primary tumor -

The N category describes whether the cancer has reached nearby lymph nodes

NX	Regional lymph nodes cannot be evaluated
NO	No regional lymph node involvement (no cancer found in the lymph nodes)
N1-N3	Involvement of regional lymph nodes (number and/or extent of spread)

The M category tells whether there are distant metastases

M0	No distant metastasis
M1	Distant metastasis

Appendix C

Gleason Grading System

Grade Group	Gleason Score	Gleason Pattern
1	Less than or equal to 6	Less than or equal to 3+3
2	7	3+4
3	7	4+3
4	8	4+4, 3+5, 5+3
5	9 or 10	4+5, 5+4, 5+5

Change Summary

- Click or tap to enter a date. New Policy.

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