# **Stereotactic Body Radiation Therapy and Stereotactic Radiosurgery**

**MEDICAL POLICY NUMBER: 229** 

Effective Date: 1/1/2024	COVERAGE CRITERIA	. 2
Last Review Date: 11/2023	POLICY CROSS REFERENCES	. 4
Next Annual Review: 10/2024	POLICY GUIDELINES	. 4
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**INSTRUCTIONS FOR USE:** Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

# PLAN PRODUCT AND BENEFIT APPLICATION

<b>⊠</b> Commercial	☐ Medicaid/OHP*	☐ Medicare**

#### \*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Notice to Medicaid Policy Readers: For comprehensive rules and guidelines pertaining to this policy, readers are advised to consult the Oregon Health Authority. It is essential to ensure full understanding and compliance with the state's regulations and directives. Please refer to OHA's prioritized list for the following coverage guidelines:

Stereotactic Body Radiation: Guideline Note 142, Line 262

#### \*\*Medicare Members

This <u>Company</u> policy may be applied to Medicare Plan members only when directed by a separate <u>Medicare</u> policy. Note that investigational services are considered "not medically necessary" for Medicare members.

### **COVERAGE CRITERIA**

#### Stereotactic Body Radiation Therapy (SBRT)

- I. SBRT may be considered **medically necessary** 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 when the patient's general medical condition (namely, the performance status) must justify aggressive, curative treatment to a primary, non-metastatic tumor and is specifically documented in the medical record.
- II. SBRT may be considered **medically necessary** for the treatment of secondary, or metastatic, tumors and recurrent tumors or any tumor arising within or near previously irradiated volumes when at least one of the following criteria (A.- B.) is met and specifically documented in the medical record:
  - a. 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 (1.-2.):

- i. Achieve total disease clearance in the setting of oligometastatic disease or
- ii. To reduce the patient's overall burden of systemic disease for a specifically defined clinical benefit, **or**
- b. 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.
- III. SBRT is considered **not medically necessary** when either criteria I. or II. above is not met, including but not limited to the following circumstances (A.-C.):
  - A. Treatment is unlikely to result in clinical cancer control and/or functional improvement.
  - B. The tumor burden cannot be completely targeted with acceptable risk to nearby critical normal structures.
  - C. 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).

#### **Stereotactic Radiosurgery (SRS)**

- IV. SRS may be considered **medically necessary** when at least one of the following indications are met (A.-I):
  - A. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions <5 cm.
  - B. Primary and secondary tumors involving the brain parenchyma, meninges/dura or immediately adjacent bony structures.
  - C. Benign brain tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors or hemangioblastomas.
  - D. Arteriovenous malformations and cavernous malformations.
  - E. Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy, movement disorders such as Parkinson's disease and essential tremor, and hypothalamic hamartomas.
  - F. As a boost treatment for larger cranial or spinal lesions that have been treated initially with external beam radiation therapy or surgery (e.g., sarcomas, chondrosarcomas, chordomas, and nasopharyngeal or paranasal sinus malignancies).
  - G. Metastatic brain, independent of the number of lesions if other positive clinical indications exist, with stable systemic disease, Karnofsky Performance Status 40 or greater (and expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations, OR ECOG Performance Status of 3 or less (or expected to return to 2 or less with treatment).
  - H. Relapse in a previously irradiated cranial where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.

- I. Uveal or ocular melanoma.
- J. Patients treated under the paradigm of Coverage with Evidence Development (CED) provided the patient is enrolled in either an IRB-approved clinical trial or in a multi-institutional patient registry adhering to Medicare requirements for CED.
- V. SRS is considered **not medically necessary** when criterion VII. above is not met, including but not limited to the following circumstances (A.-D.):
  - A. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
  - B. Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
  - C. Patients with poor performance status (Karnofsky Performance Status less than 40 or ECOG Performance greater than 3); see below for further scoring information regarding Karnofsky and ECOG Performance Status scales.
  - D. For ICD-10 codes G25.0-G25.2, essential tremor, coverage should be limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for invasive surgical procedure. Coverage should further be limited to unilateral thalamotomy.

Link to Evidence Summary

## **POLICY CROSS REFERENCES**

• Proton Beam Radiation Therapy

The full Company portfolio of current Medical Policies is available online and can be accessed here.

## **POLICY GUIDELINES**

#### **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.

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#### **DEFINITIONS**

This policy is based primarily on the American Society for Radiation Oncology (ASTRO) policies on stereotactic body radiation therapy (SBRT) and stereotactic radiosurgery (SRS).<sup>1,2</sup>

#### **Karnofsky Performance Status Scale**

- **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**

- 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 house work, office work.
- **Grade 2:** Ambulatory and capable of all self-care but unable to carry out and 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.

#### **BACKGROUND**

#### Stereotactic Body Radiation Therapy (SBRT)

The American Society for Radiation Oncology (ASTRO) describes SBRT as the following:

"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. SBRT is used to

treat extra-cranial sites as opposed to stereotactic radiosurgery (SRS), which is used to treat intra-cranial.

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."

### **Stereotactic Radiosurgery**

The American Society for Radiation Oncology (ASTRO) describes SRS as the following:

"Stereotactic radiosurgery (SRS) is a distinct discipline that utilizes externally generated ionizing radiation to inactivate or eradicate definite target(s) in the head without the need to make an incision. To assure quality of patient care, the procedure involves a multidisciplinary team consisting of a neurosurgeon, radiation oncologist and medical physicist. (For a subset of tumors involving the skull base, the multidisciplinary team may include a head and neck surgeon with training in SRS).

For the purpose of this document, SRS is strictly defined as radiation therapy delivered in one to five fractions via stereotactic guidance, with approximately 1 mm targeting accuracy to intracranial targets and selected tumors around the base of the skull.

SRS couples anatomic accuracy and reproducibility with very high doses of highly precise, externally generated, ionizing radiation, thereby maximizing the ablative effect on the target(s) while minimizing collateral damage to adjacent 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. Examples of devices used in SRS for stereotactic guidance may include a rigid head frame affixed to a patient, fixed bony landmarks, a system of implanted fiducial markers or other similar systems."<sup>2</sup>

# **REGULATORY STATUS**

#### U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

## **BILLING GUIDELINES AND CODING**

CPT codes 77373, 77435, G0339, and G0340 will only be considered medically necessary and covered when billed with one of the following ICD-10 diagnosis codes:

- C00.0-C10.8
- C11.0-C14.8
- C19-C21.8
- C22.0-C22.9
- C25.0-C25.9
- C30.0-C32.9
- C34.00-C34.92
- C40.00-C41.9
- C51.0-C58
- C61
- C64.1-C65.9
- C70.0-C70.9
- C71.0-C71.9
- C72.0-C72.1
- C72.20-C72.59
- C74.00-C74.92
- C75.1-C75.5

- C76.2-C76.3
- C77.0-C77.9
- C78.00-C78.02
- C78.7
- C79.00-C79.02
- C79.31-C79.32
- C79.40-C79.49
- C79.51-C79.52
- C79.70-C79.72
- C79.89-C79.9
- D16.6
- D32.0-D32.9
- D33.0-D33.4
- D35.2-D35.6
- D42.0-D42.9
- D43.0-D43.4
- D43.8-D43.9

- D44.3-D44.7
- D49.6-D49.7
- G20-G21.4
- G25.0-G25.2
- G40.411-G40.419
- G40.301-G40.319
- G40.911-G40.919
- G50.0
- G50.8
- G50.9
- G51.0-G51.9
- G52.0-G53
- Q28.2-Q28.3
- T66.XXXA
- Z92.3

All other diagnosis codes billed with 77373, 77435, G0339, and G0340 will deny as not medically necessary and not covered.

CPT codes 77371, 77372, and 77432 will only be considered medically necessary and covered when billed with one of the following ICD-10 diagnosis codes:

- C11.0-C11.9
- C30.0-C31.9
- C69.31
- C69.32
- C69.41
- C69.42
- C69.91
- C69.92
- C70.0-C70.9
- C71.0-C71.9
- C72.20-C72.59 • C75.1-C75.5
- C79.31-C79.32

- C79.40-C79.49
- C79.51-C79.52
- C79.89-C79.9
- D32.0-D32.9
- D33.0-D33.2
- D33.3
- D35.2-D35.5
- D35.6
- D42.0-D42.9
- D43.0-D43.4
- D43.8-D43.9
- D44.3-D44.7
- D49.6-D49.7

- G20-G21.4
- G25.0-G25.2
- G40.301-G40.319
- G40.411-G40.419
- G40.911-G40.919
- G50.0
- G50.8
- G50.9
- G51.0-G51.9
- G52.0-G53
- Q28.2-Q28.3
- T66.XXXA

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All other diagnosis codes billed with 77371, 77372, and 77432 will deny as not medically necessary and not covered.

CODES	S*	
СРТ	77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt 60 based
	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
HCPCS	C9795	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions
	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

#### \*Coding Notes:

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code
  is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted
  code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior
  authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP)
   bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for

Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

# **REFERENCES**

- 1. American Society for Radiation Oncology (ASTRO) Model Policy: Stereotactic Body Radiation Therapy (SBRT).
  - https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTROSBRTModelPolicy.pdf. Published 2020. Accessed 8/29/2023.
- American Society for Radiation Oncology (ASTRO) Model Policy: Stereotactic Radiosurgery (SRS). <a href="https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTRO-SRS\_ModelPolicy.pdf">https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTRO-SRS\_ModelPolicy.pdf</a>. Published 2021. Accessed 8/29/2023.

# **POLICY REVISION HISTORY**

DATE	REVISION SUMMARY	
2/2023	Converted to new policy template.	
11/2023	Annual review. No changes.	
1/2024	Q1 2024 code set update	