STEREOTACTIC RADIOSURGERY (SRS)

Background

This Model Policy addresses coverage for Stereotactic Radiosurgery (SRS).[1] ASTRO model policies outline correct coverage policies for radiation oncology services and do not serve as clinical guidelines. Model policies are divided on the basis of technology and the diagnosis for which that treatment approach is reasonable. A literature search was performed to determine which evidence, within set inclusion criteria, supports coverage indications involving SRS. Multiple levels within ASTRO's Health Policy Council review Model Policy content, with additional support and review provided by ASTRO's Clinical Affairs and Quality Council and related resource panels.

The SRS Model Policy was reviewed and approved by ASTRO's Board of Directors in June 2022.

Introduction

Stereotactic Radiosurgery (SRS) is a distinct discipline that utilizes externally generated ionizing radiation to ablate 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 that may consist of a radiation oncologist, medical physicist, radiation therapist and a neurosurgeon. (For a subset of tumors involving the skull base, the multidisciplinary team may include a head and neck surgeon.)

For the purpose of this document, SRS is defined as radiation therapy delivered in one fraction and stereotactic cranial radiosurgery delivered in two to five fractions, via stereotactic guidance with approximately 1 mm targeting accuracy to intracranial targets and selected tumors around the base of the skull. For coverage guidance regarding extracranial target treatments delivered with stereotactic guidance in the spine or elsewhere, refer to ASTRO's Stereotactic Body Radiation Therapy (SBRT) Model Policy.[11]

SRS couples anatomic accuracy and reproducibility with very high doses of 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 mask-based systems.

Treatment Methods and Materials

All SRS procedures include the following components:

1. Position stabilization (attachment of a frame or frameless).
2. Imaging for localization (CT, MRI, angiography, PET, etc.).
3. Computer-assisted tumor localization (i.e., "image guidance"), including stereoscopic X-ray, skull tracking, conebeam CT or fiducial-based rigid translation of a suitable tumor imaging modality.
4. Treatment planning – number of isocenters or shots; number, placement and length of arcs or angles; number of beams, beam size and weight, etc.
5. Isodose distributions, dosage prescription and calculation.
6. Setup and accuracy verification testing.
7. Simulation of prescribed arcs or fixed portals.
8. Radiation treatment delivery.

SRS Treatment Planning

SRS plans are highly customized to the target volume(s) and may be geometrically more accurate than conventionally fractionated external beam treatment plans.

a. Immobilization

The patient is immobilized via a frame affixed to the skull or a stereotactic mask fixation system ("frameless").

b. Imaging

Three-dimensional image acquisition of the target region by simulation is an essential prerequisite to SRS treatment planning. In general, a CT, MR or angiogram imaging scan of the target region is performed and serves as the baseline image set used for dose calculations and, in selected cases in which a CT was performed, for co-registration of MR and/or angiogram image sets in order to better define the target and surrounding anatomy.

c. Contouring

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

1. The radiation oncologist reviews the three-dimensional images and defines the treatment target on each slice of the image set. A neurosurgeon may be involved in the contouring process. The summation of these contours defines the Gross Tumor Volume (GTV). Some patients may not have GTVs if they have had previous treatment with surgery, in which case treatment planning will be based on Clinical Target Volumes (CTVs) as described below.
2. The radiation oncologist may draw a margin around the GTV or surgical bed to generate a CTV, which encompasses the areas at risk for microscopic disease (i.e., not visible on imaging studies).
3. To account for potential uncertainty in patient immobilization and/or imaging, a final margin may be added to create a Planning Target Volume (PTV), depending on clinical circumstances, institutional preferences and the radiosurgery system in use.
4. Nearby normal structures that could potentially be harmed by radiation (i.e., "organs at risk" or OARs) are also contoured.

d. Radiation dose prescribing

The radiation oncologist assigns specific dose requirements for the PTV or final treatment target, which typically include a prescribed dose that must be given to at least 90-95% of the PTV or target. The PTV is defined by the clinical expertise of the treating radiation oncologist and/or radiosurgery system in use. This is often accompanied by a minimum acceptable point dose within the PTV and a constraint describing an acceptable range of dose homogeneity. Additionally, PTV dose requirements routinely include 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.

e. 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. Here, 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 current guidance for performing treatment/patient specific QA for SRS recommends verification of dose using independent dose calculations or dosimetric measurements. It is recommended that the level of QA for SRS be significantly more stringent than other radiation therapy techniques to ensure dose delivery is within 1 mm accuracy. Patient specific QA includes verification of patient setup/immobilization, independent check of approved treatment plan and associated treatment delivery parameters, dose delivery measurements when appropriate, chart round and/or peer review and a dry run of the approved treatment plan to check for potential collision. If fixed conical collimators are used, dose delivery measurements are prudent to verify the integrity of treatment but are not essential as the measured dosimetric characteristics (profile, output, Tissue Phantom Ratio, etc.) are directly applied to the dose calculation. When the MLC is applied to modulate dose, dose delivery measurements should be performed prior to treatment to verify the absolute dose to the reference point. For gamma ray-based SRS system, a single shot or combination of shots are used to create a highly conformal isodose distribution around the target.

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

SRS Treatment Delivery

SRS can be delivered using a variety of stereotactic and convergent-beam technologies, including but not limited to: multiple convergent cobalt sources; protons; multiple, coplanar or non-coplanar photon arcs or angles; fixed photon arcs; or image-directed robotic devices that meet the criteria. Despite the variety of stereotactic radiosurgical techniques, many commonalities exist. The shape of the beam aperture used with linear accelerator-based systems is usually defined by secondary collimation positioned near the patient or multi-leaf collimators. A large number of such beams sequentially irradiate the target, typically using a dynamic delivery. Gamma ray treatment devices also position the collimation near the patient's skin surface to control the penumbra. In this case, numerous gamma ray beams, depending on the model, simultaneously irradiate a single point (called the isocenter) within the patient. Robotic, non-isocentric, frameless SRS is a type of SRS treatment consisting of dozens of non-isocentric and non-coplanar beams with distinctive quality assurance procedures and continuous target tracking that result in comparable dose conformality and reduction in intrafraction systematic error. IMRT is also used for SRS. In this case, a single isocenter can be used with off-axis beams created by an MLC so that the equivalent effect obtained with multiple isocenters is achieved.

While being irradiated, the patient is immobilized, and patient and target positioning are verified to ensure accurate treatment delivery. The target is defined by high-resolution stereotactic imaging. Stereotactic localization of the lesion uses an appropriate imaging modality to identify a reference point for positioning the individual treatment beams. This type of localization procedure allows physicians to perform image-guided procedures with a high degree of anatomic accuracy and precision. Traditionally, a rigid frame that included a fiducial system for precisely locating coordinate positions within the frame was attached to the patient's head. Alternatively, "frameless" approaches can be used. SRS typically is performed in a single session; however, it can be performed in a limited number of sessions, up to a maximum of five.

Imaging, planning and treatment typically are performed in close temporal proximity. The delivery of a high dose of ionizing radiation that conforms to the shape of the lesion mandates an overall accuracy of approximately 1 mm. This leaves little room for error in the overall process. Strict protocols for quality assurance (QA) must be followed and multiple checking, preferably repeated by different individuals, is required at critical junctures. Additional information can be found in the ASTRO QA White Paper, which critically evaluates guidance and literature on the safe delivery of stereotactic radiotherapy and provides recommendations on how to reduce or eliminate errors.[10]

Documentation Requirements

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 Status and Eastern Cooperative Oncology Group (ECOG) Performance Status listed under "Indications and Limitation of Coverage."

Documentation should include the date and the current treatment dose. The radiosurgery physician(s) must evaluate the clinical aspects of the treatment and document and sign this evaluation as well as the resulting management decisions. A radiation oncologist and medical physicist must evaluate the technical aspects of the treatment and document and sign this evaluation as well as the resulting treatment management decisions.

Indications and Limitations of Coverage and/or Medical Necessity

Stereotactic radiosurgery is considered proven and medically necessary for the following indications. A list of clinical references consulted begins on page 10 of the Model Policy.

Indications for Coverage:

1. Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions.
2. Primary and secondary tumors involving the brain parenchyma, meninges/dura or any immediately adjacent bony structures such as the cranial vault or skull base.
3. Benign brain tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors or hemangioblastomas.
4. Arteriovenous malformations and cavernous malformations.
5. 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.
6. 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).
7. Metastatic brain lesions , independent of the number of lesions, if other positive clinical indications exist, e.g., 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 (and expected to return to 2 or less with treatment).
8. Relapse in a previously irradiated cranial field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
9. Uveal or ocular melanoma.
10. 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. At this time, no indications are deemed inappropriate for CED.

ICD-10-CM Codes 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 ICD-10-CM codes will be reviewed by ASTRO, and coverage should not be presumed until the results of such review have been published/posted.

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.

SYSTEM	SITE	ICD-10 CODES
Neoplasm of Optic Tract	Uvea, Iris, Ciliary Body, Choroid; Malignant	C69.31, C69.32, C69.41, C69.42, C69.91, C69.92
Neoplasms of the Central Nervous System	Brain/Spinal Cord: –Malignant –Secondary –Benign –Uncertain Behavior –Unspecified Nature	C71.0 – C71.9 C79.31 D33.0 – D33.2 D43.0 –43.4* D43.8-43.9* D43.4* D49.6*
	Other Nervous System; Secondary	C79.40 – C79.49* C79.89 – C79.9*
	Spine	C79.51 – C79.52*
	Cerebral Meninges: –Malignant –Secondary –Benign –Uncertain Behavior	C70.0 – C70.9 C79.32 D32.0 – D32.9 D42.0 - D 42.9
	Cranial Nerves: –Malignant –Benign	C72.20 – C72.59 D33.3
Neoplasms of the Endocrine Gland	Pituitary, Pineal, Aortic Body and Other Paraganglia: –Malignant –Benign –Uncertain Behavior –Unspecified Nature	C75.1 – C75.5 D35.2 – D35.5 D35.6*; D44.3 – D44.5 D44.6 – D44.7* D49.7*
Diseases of the Nervous System	Parkinson's Disease Tremor	G20; G21.4** G25.0 – G25.2**
	Epilepsy	G40.411 – G40.419 G40.301– G40.319 G40.911 – G40.919
	Trigeminal Nerve Disorders	G50.0 G50.8 G50.9##
	Facial Nerve Disorders	G51.0 – G51.9
	Disorders of Other Cranial Nerves	G52.0 – G53*
Other	Congenital Abnormalities of Cerebrovascular System	Q28.2 – Q28.3*
Reirradiation	Various Regions	T66.XXXA#

* ICD-10-CM codes are all limited to use for lesions occurring either above the neck or in the spine.
**ICD-10-CM codes G20, G21.4, G25.0 – G25.2 are limited to the patient who cannot be controlled with medication, has major systemic disease or coagulopathy, and who is unwilling or unsuited for open surgery.
ICD-10-CM codes G50.0, G50.8 and G50.9 are limited to the patient who cannot be controlled with medication.
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 SRS in lieu of other radiation therapy. An ICD diagnosis code for the anatomic diagnosis must also be used.

Limitations of Coverage

SRS is not considered medically necessary under the following circumstances:

1. Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
2. Patients with widespread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
3. 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.
4. For ICD-10-CM code 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.

Karnofsky Performance Status Scale[6]

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% of waking hours.
Grade 3:	Capable of only limited self-care, confined to bed or chair more than 50% of waking hours.
Grade 4:	Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair.
Grade 5:	Dead.

Eastern Cooperative Oncology Group, Robert Comis, MD, Group Chair.

Physicians' Current Procedural Terminology (CPT®)/HCPCS Section

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

SRS Treatment Planning

There are no specific codes for clinical treatment planning and simulation for SRS. However, because of the complexity of SRS and the need for three-dimensional conformal or IMRT dosimetric treatment planning, the following codes are usually appropriate for SRS cases. Use of IMRT planning is based on the delivery system and medical necessity. Whether a physician treats one or more lesions, treatment planning CPT code 77295 or CPT code 77301 should only be used once for the entire episode.

CPT® CODE	DESCRIPTION	SRS-SPECIFIC GUIDELINES
77263	Therapeutic radiology treatment planning; complex	Given the complexity of SRS, a complex treatment planning code is justified.
77295 OR 77301	Three-dimensional radiotherapy plan, including dose-volume histogram 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 [e.g., 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)	At a minimum, three-dimensional simulation is essential to provide accurate stereotactic treatment delivery. Report once per course of therapy.

Medical Radiation Physics, Dosimetry and Treatment Devices

There are no SRS 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	SRS-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 static beam in a linear accelerator system maximum of 10 units. 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)	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 unique cone size for 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, then typically one CPT 77338 would be used to code for the MLC devices.

Treatment devices are billed separately from the planning and delivery codes if appropriate.

SRS Treatment 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 (e.g., a stereotactic approach with IMRT). Only one delivery code is to be billed.

CPT® CODE	DESCRIPTION	SRS-SPECIFIC GUIDELINES
77371	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; multi-source Cobalt-60 based. (For radiation treatment management, use 77432)	Technical charge for single fraction treatment delivery using cobalt-60.
77372	Radiation treatment delivery, stereotactic radiosurgery (SRS), complete course of treatment of cranial lesion(s) consisting of 1 session; linear accelerator based. (For radiation treatment management, use 77432)	Technical charge for single fraction treatment delivery using a Linac (linear accelerator).
77373	Stereotactic body radiation therapy, or stereotactic cranial radiosurgery 2-5 fractions-treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions (Do not report 77373 in conjunction with 77385, 77386, 77401, 77402, 77407, 77412) (For single fraction cranial lesion[s], see 77371, 77372)	Technical charge for multi fraction (2-5) treatment delivery for cranial lesions.

Radiation Treatment Management

There is one radiation treatment management code specific to SRS, CPT® code 77432, and this code can only be used for single fraction cranial SRS. If cranial SRS is delivered in two to five fractions, use the SBRT management CPT code 77435 for the entire course of treatment. One can no longer bill CPT 77432 for the first fraction and CPT code 77427 (Radiation treatment management, 5 treatments) or 77431 (Radiation therapy management with complete course therapy consisting of 1 or 2 fractions only) for the remaining fractions, for the same treatment volume. For all spinal radiosurgery (one to five fractions) use the SBRT management CPT code 77435 once for the entire course of treatment. CPT code 77432 and CPT code 77435 cannot be billed for the same patient for the same episode of care, and Medicare does not reimburse CPT code 77432 and CPT code 77470 (Special treatment procedure) on the same day of service. A prolonged (four- to six-week) course of cranial radiation therapy should be billed using appropriate codes for conventionally fractionated radiation therapy. Fractionated stereotactic cranial and body radiation therapy codes apply only to hypofractionated (one to five fractions) radiosurgery using large doses per fraction. SRS treatments are to be performed under the direct supervision of a qualified medical physicist and a radiation oncologist.

CPT® CODE	DESCRIPTION	SRS-SPECIFIC GUIDELINES
77432	Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session) (The same physician should not report both stereotactic radiosurgery services [61796-61800] and radiation treatment management [77432 or 77435] for cranial lesions). (For stereotactic body radiation therapy treatment, use 77435)	For use of single fraction, complete course of therapy.
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 (Do not report 77435 in conjunction with other treatment management codes 77427- 77432) (The same physician should not report both stereotactic radiosurgery services [32701, 63620, 63621] and radiation treatment management [77435])	Professional charge for treatment management performed by the radiation oncologist. It includes the work of image guidance during treatment. This code can be reported only once for the entire course of treatment and not per fraction. This will apply to all SBRT up to a maximum of 5 fractions and all fractionated cranial SRS up to a maximum of 5 fractions. It will apply to all lesions treated during that entire course of treatment.

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 that are arranged to deliver a dose. The radiation oncologist remains available throughout SRS 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 SRS treatment.

Other Specialist Coding

Usually, a radiation oncologist will work with a neurosurgeon to perform SRS. Radiation oncologists and neurosurgeons have separate CPT® billing codes for SRS. CPT codes 61781–61783 or 61796–61800 are reported for the work attributed to the neurosurgeon. These codes are mutually exclusive with the radiation oncology CPT codes 77432 and 77435; therefore, the same physician should not bill for both of these codes.

No one physician may bill both the neurosurgical codes 61781–83 or 61796–61800 and the radiation oncology 77XXX codes. If either the radiation oncologist, neurosurgeon or head and neck surgeon does not fully participate in the patient's care, that physician must take care to indicate this change by use of the appropriate -54 modifier (followed by any appropriate -55 modifier) on the global procedure(s) submitted. As the services are collegial in nature with different specialties providing individual components of the treatment, surgical assistants will not be reimbursed.

The following codes may be used by the neurosurgeon to code for involvement in the procedure.

CPT® CODE	DESCRIPTION
61796	Stereotactic radiosurgery (particle beam, gamma ray or linear accelerator); 1 simple cranial lesion
+61797	Each additional cranial lesion, simple (List separately in addition to code for primary procedure)
61798	1 complex cranial lesion
+61799	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)

Additional Information

Coding Guidelines

For Medicare claims, 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.

CLINICAL EVIDENCE

General

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Brain Metastases

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