

Stereotactic Radiosurgery (SRS) Including Gamma Knife and Stereotactic Body Radiotherapy (SBRT)

Policy Number: **M981201082**
Effective Date: **12/1/1998**
Sponsoring Department: **Health Care Services**
Impacted Department(s): **Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐ Confidential ☐ Restricted ☒ Public

Applies to (Line of Business):

- ☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒ MediSource; ☒ MediSource Connect; ☒ Child Health Plus; ☒ Essential Plan
☐ Medicare, if yes, which plan(s): ☒ MAPD; ☐ PDP; ☒ ISNP; ☒ CSNP
☐ Commercial, if yes, which type: ☒ Large Group; ☒ Small Group; ☒ Individual
☒ Self-Funded Services (*Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.*)

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No ☒

Purpose and Applicability:

To set forth guidelines for the appropriate use of **stereotactic radiosurgery (SRS)**, including **Gamma Knife**, a non-surgical interventional technology for selected brain lesions and other indications and for stereotactic body radiotherapy (SBRT).

Policy:

Commercial and Self-Funded:

Independent Health provides coverage for stereotactic radiosurgery for the following:

Indications:

- Arteriovenous malformation (AVM) of the brain or spine.
- Initial or recurrent primary brain tumor
 - Acoustic neuroma, also known as vestibular schwannomas
 - Meningioma
 - Hemangioma
 - Pituitary adenoma
 - Craniopharyngioma
 - Low grade glioma
 - Neoplasm of the pineal gland
 - Glomus tumors
 - Hemangioblastoma
 - Cavernous malformations
 - Reirradiation of recurrent inoperable malignant gliomas in members with good performance status (ECOG less than 3 or Karnofsky status 40 or greater with expected return to 70 or greater with treatment)
 - Low-grade astrocytoma
- Initial or recurrent brain metastases for members with:
 - Performance status (ECOG less than 3 or Karnofsky status 40 or greater with expected return to 70 or greater with treatment) and controlled systemic disease (e.g., newly diagnosed, stable systemic disease or reasonable treatment options.) and;
 - Number of lesions to be treated with no lesion greater than 5 cm and;
 - All lesions can be encompassed in a single treatment plan and;
 - no leptomeningeal disease and;
 - The primary histology is not germ cell, small cell or lymphoma and;
 - The total volume of treated lesions should be considered safe to deliver SRS.
- Previous whole brain irradiation (WBRT):
 - The patient has a Karnofsky performance status greater than or equal to 70; and
 - Systemic disease is under control; and
 - The patient's life expectancy is greater than three months.
- Previous treatment with SRS:
 - The patient has a Karnofsky performance status greater than or equal to 70; and
 - The patient's systemic disease is under control; and
 - Life expectancy is greater than six months; and
 - New lesions are present (no lesion is greater than five cm); and
 - The patient has not been treated with more than two episodes of radiosurgery in the past nine months.
- No previous WBRT:
 - Recurrence involves one to five lesions; and
 - More than six months have elapsed since RT; and
 - The patient has a Karnofsky performance status greater than or equal to 70; and
 - Systemic disease is under control.

- Post-operative SRS:
 - The patient has a combination of up to four resected and unresected lesions, each of which, individually, is less than four cm. in size.
- Non-operable spinal tumor (primary, recurrent or metastatic) that is causing compression or intractable pain.
- Trigeminal neuralgia that has not responded to other, more conservative, treatments.
- Uveal tract melanoma (melanoma of the iris, ciliary body and choroid).
- Mesial temporal epilepsy refractory to medical management when standard alternative surgery is not an option.
- Stereotactic cingulotomy is considered medically necessary when it is used as a last resort to provide pain relief for members with terminal cancer pain.
 - All other indications for stereotactic cingulotomy including but not limited to chronic intractable non-malignant pain, are considered experimental.

Independent Health provides coverage for stereotactic body radiation for the following:

- Non-Small Cell Lung Cancer and all of the following:
 - Stage I disease; and
 - The lesion cannot be removed surgically either because the tumor location makes removal difficult or,
 - The member is not a surgical candidate or if the patient refuses surgery.
- Recurrent or residual nasopharyngeal carcinoma at primary site when radiation therapy treatments such as three-dimensional conformal or Intensity-modulated radiation therapy (IMRT) cannot be utilized;
- Spinal or vertebral body tumors (metastatic or primary) in patients who have received prior radiation therapy;
- Pancreatic cancer:
 - Preoperative (neoadjuvant resectable or borderline resectable), following a minimum of two cycles of chemotherapy, and restaging in which there is no evidence of tumor progression; or
 - As definitive treatment for medically or surgically inoperable or locally advanced, following a minimum of two cycles of chemotherapy and restaging when there is no evidence of tumor progression, and the disease volume can be entirely encompassed in the radiation treatment volume.

❖ Note: for palliative situations, SBRT is considered not medically necessary.

- Primary liver cancer (Hepatocellular Carcinoma [HCC]) in the definitive setting to concurrently treat one or more tumors, when there is evidence of the ability to protect an adequate volume of uninvolved liver.
- Intrahepatic bile duct cancer (cholangiocarcinoma) when unresectable and localized in the definitive treatment setting.
- Any of the following neoplasms presenting with one to three metastases in the synchronous setting when local control is expected, and treatment of the metastases may result in an increased disease-free interval and possible survival:
 - For an individual with colorectal cancer who:
 - has had or will undergo curative treatment of the primary tumor; and

- whose metastases are in the lung or liver; and
- for whom surgical resection is not possible.
- Any of the following neoplasms where the primary tumor was previously controlled and metachronous metastases have presented, under the following circumstances:
 - Clinical presentation of one to three metastases of to the adrenal gland, lung, liver, or bone when the following criteria are met:
 - the histology is non-small cell lung, colon, breast, sarcoma, renal cell or melanoma; and
 - disease free interval of one year or greater from the initial diagnosis; and
 - the primary tumor received curative therapy and is controlled; and there is no prior evidence of metastatic disease (cranial or extracranial)
- ❖ Note, all metastatic lesions present on imaging will be treated concurrently in a single episode.
- SBRT to three or more sites other than those indications listed above is considered experimental/investigational.
- Based upon our criteria and assessment of the peer-reviewed literature, SBRT has not been medically proven to be effective and, therefore, is considered investigational to induce the abscopal effect.
- Based upon our criteria and assessment of the peer-reviewed literature, SBRT does not improve patient outcomes for individuals with oligoprogression (progression of a limited number of metastatic sites while other metastatic disease sites remain controlled), and, therefore, is considered not medically necessary.
- Prostate cancer when the disease is clinically localized and when used as definitive treatment when not treating pelvic lymph nodes.
- Pulmonary metastasis from soft tissue sarcoma that is within, or immediately adjacent to an area that has received radiation treatments as part of the primary management.
- Head and neck cancer, as retreatment of patients who have no evidence of metastatic disease.
- Reirradiation of recurrent, inoperable malignant gliomas in individuals who maintain a good performance status.
- Stage I or node-negative stage IIA limited small cell lung cancer.

Stereotactic Radiation Therapy (SRS/SBRT) has not been proven to be superior to conventional therapy and is not a standard treatment option for the treatment of the following conditions:

- Other non-central nervous system cancers unless noted above
- Lung (unless above criteria is met)
- Other cancers including but not limited to, breast, colon, liver and pancreas, bile duct
- Parkinson's disease and other movement disorders (e.g., essential tremors)
- Chronic pain syndromes
- Treatment of functional disorders other than trigeminal neuralgia
- ❖ **Note:** Gamma Knife used for Obsessive-Compulsive Disorder (OCD) is considered experimental.

Medicare Advantage:

There is currently a Local Coverage Determination (LCD) and a Local Coverage Article (LCA) for stereotactic radiosurgery. Please refer to the links listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:

MediSource, MediSource Connect, Child Health Plus and Essential Plan cover SRS/SBRT utilizing the Commercial criteria above.

MediSource does not cover Gamma Knife for OCD or depression.

Pre-Authorization Required? Yes ☐ No ☐ Other ☒

Preauthorization is required for cingulotomy codes 61720, 61735, 88381, and 63052

Pre-authorization is not required for all other services not noted above at the present time. Criteria above will be utilized upon retro-review.

Definitions

ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.).

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 housework, office work.

Grade 2: Ambulatory and capable of all self-care but unable to carry out 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

Gamma knife surgery, also known as stereotactic radiosurgery (SRS), is a procedure that involves the precise 3-dimensional targeting of ionic radiation to obliterate abnormal tissues such as vascular malformation and malignant or benign tumors. The objective of stereotactic radiosurgery is to cause destruction of the target tissue while minimizing the amount of radiation delivered to surrounding normal tissue.

Karnofsky Performance Status Scale is an assessment tool for functional impairment, comparing effectiveness of different therapies and to assess the prognosis in individual patients. The lower the Karnofsky score, the worse the likelihood of survival.

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

Stereotactic radiosurgery (SRS) refers to a single-fraction treatment of intracranial and spinal targets, whereas stereotactic body radiation therapy (SBRT) refers to multifractional (typically two to five fractions) treatment of intracranial, spinal, or extracranial sites, such as the lung, head and neck, liver, pancreas, and prostate.

References

Related Policies, Processes and Other Documents

N/A

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This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No ☐

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