

Protocol

Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas

(80145)

Medical Benefit		Effective Date: 06/01/20	Next Review Date: 03/21
Preauthorization	No	Review Dates: 05/09, 05/10, 05/11, 05/12, 05/13, 03/14, 03/15, 03/16, 03/17, 03/18, 03/19, 03/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none">• With primary newly diagnosed or recurrent brain tumors	Interventions of interest are: <ul style="list-style-type: none">• Intracavitary balloon catheter brain brachytherapy as an adjunct to resection	Comparators of interest are: <ul style="list-style-type: none">• Other forms of radiotherapy	Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Symptoms• Treatment-related morbidity
Individuals: <ul style="list-style-type: none">• With metastases to the brain from other tumors	Interventions of interest are: <ul style="list-style-type: none">• Intracavitary balloon catheter brain brachytherapy as an adjunct to resection	Comparators of interest are: <ul style="list-style-type: none">• Other forms of radiotherapy	Relevant outcomes include: <ul style="list-style-type: none">• Overall survival• Symptoms• Treatment-related morbidity

DESCRIPTION

Intracavitary balloon catheter brain brachytherapy is an approach to localized radiotherapy using liquid I-125 delivered with an inflatable balloon catheter to treat malignant brain lesions.

SUMMARY OF EVIDENCE

For individuals who have primary newly diagnosed or recurrent brain tumors who receive intracavitary balloon catheter brain brachytherapy as an adjunct to resection, the evidence includes early-phase feasibility and dose-ranging studies, case series, and a retrospective review. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The evidence is limited by the lack of randomized controlled trials and comparators in nonrandomized studies. The heterogeneity of tumor metastatic tumor types limits the interpretation of reported short-term survival outcomes. Long-term outcome studies have not been reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have metastases to the brain from other tumors who receive intracavitary balloon catheter brain brachytherapy as an adjunct to resection, the evidence includes a multicenter, nonrandomized, single-arm study. Relevant outcomes are overall survival, symptoms, and treatment-related morbidity. The evidence is limited by the lack of randomized controlled trials or comparators in nonrandomized studies. The only outcomes

data reported have been the local control rates at one year. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Intracavitary balloon catheter brain brachytherapy is considered **investigational**, alone or as part of a multimodality treatment regimen, for primary or recurrent malignant brain tumors.

Intracavitary balloon catheter brain brachytherapy is considered **investigational**, alone or as part of a multimodality treatment regimen, for metastasis to the brain from primary solid tumors outside the brain.

BACKGROUND

BRAIN TUMORS

Malignant Gliomas

Diffuse fibrillary astrocytoma is the most common glial brain tumor in adults. It is classified histologically into three grades: grade II astrocytoma, grade III anaplastic astrocytoma, and grade IV glioblastoma multiforme. Oligodendrogliomas are diffuse neoplasms closely related to diffuse fibrillary astrocytomas clinically and biologically. However, these tumors generally have better prognoses than diffuse astrocytomas, with mean survival times of 10 years vs. two to three years. Also, oligodendrogliomas apparently are more chemosensitive than astrocytomas. The most aggressive and chemoresistant astrocytoma, glioblastoma multiforme has survival times of less than two years for most patients.

Treatment

Treatment of primary brain tumors begins with surgery with curative intent or optimal tumor debulking, usually followed by radiotherapy and/or chemotherapy. Survival after chemoradiotherapy largely depends on the extent of residual tumor after surgery. Therefore, tumors arising in the midline, basal ganglia, or corpus callosum or those arising in the eloquent speech or motor areas of the cortex have a particularly poor outcome, because they typically cannot be extensively resected. Recurrence is common after surgery for malignant gliomas, even if followed by chemoradiotherapy because the tumors are usually diffusely infiltrating and develop resistance to chemotherapy; also, neurotoxicity limits cumulative doses of whole-brain radiation. Chemotherapy regimens for gliomas usually rely on nitrosourea alkylating agents (carmustine or lomustine), temozolomide, procarbazine, vincristine, and platinum-based agents. The most common regimen combines procarbazine, lomustine, vincristine, and single or multiagent therapy with temozolomide. A biodegradable polymer wafer impregnated with carmustine (Gliadel® Wafer; Guilford Pharmaceuticals) also can be implanted into the surgical cavity as an adjunct to surgery and radiation. It is indicated for newly diagnosed high-grade malignant glioma and for recurrent glioblastoma multiforme.

BRAIN METASTASIS FROM OTHER PRIMARY MALIGNANCIES

Intracranial metastases are a frequent occurrence seen at autopsy in 10% to 30% of deaths from cancer. Lung cancer is the most common source of brain metastasis (relative prevalence, 48%), followed by breast cancer (15%), unknown primary (12%), melanoma (9%), and colon cancer (5%).

Treatment

Treatment goals in these patients include local control of existing metastases, regional control to prevent the growth of undetected metastases, extending the duration of overall survival, and maintaining quality of life. Surgical resection followed by whole-brain radiotherapy (WBRT) is the mainstay of treatment for patients with one

to three operable brain metastases and with adequate performance status and control of extracranial disease. Resection plus WBRT extends the duration of survival compared with biopsy plus WBRT. Although adding WBRT to resection does not increase the duration of overall survival, it reduces local and distant recurrence of brain metastases. Thus, WBRT decreases the incidence of death from neurologic causes and may help maintain an adequate quality of life, if the cumulative dose does not cause unacceptable neurotoxicity.

INTRACAVITARY BALLOON CATHETER BRAIN BRACHYTHERAPY

Intracavitary balloon catheter brain brachytherapy is localized temporary high-dose radiotherapy in the brain that requires placement of an inflatable balloon catheter in the surgical cavity, before closing the craniotomy of a resection to remove or debulk a malignant brain mass. A radiation source is then placed in the balloon to expose surrounding brain tissue to radiation, either continuously or in a series of brief treatments. After the patient completes therapy, the radiation source is permanently removed, and the balloon catheter is surgically explanted.

Safety Considerations

Overall, adverse events with GliaSite do not differ greatly from those observed with other brain brachytherapy techniques; however, Adkison et al (2008) reported a case in which linens of a patient with the GliaSite implant were contaminated with radiation.¹ Recovery studies confirmed that systemic absorption is greater than anticipated. Adkison et al concluded that precaution with a Foley catheter should be taken in patients with urinary incontinence. Gerber et al (2007) reported cases of brain hemorrhage have, suggesting the need for careful coagulation control.²

REGULATORY STATUS

In 2001, the GliaSite® Radiation Therapy System (GliaSite® RTS; IsoRay Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K003206). FDA determined that this device was substantially equivalent to separately marketed ventricular reservoirs and catheters, manual radionuclide applicator systems, and radionuclide sources.

In 2011, a modified GliaSite® RTS was cleared for marketing by FDA through the 510(k) process (K111931). GliaSite® RTS includes a catheter tray with a double balloon catheter and accessories used for implantation of an aqueous saline solution of molecularly bound radioactive iodine (sodium 3 [I-125] iodo-4-hydroxybenzenesulfonate; Iotrex™) as the radiation source; and an access tray with items used for afterloading and retrieving the radioactive material. One to three weeks after resection and balloon implantation, the Iotrex™ solution is loaded through a subcutaneous port and left in for three to six days. Prescribed radiation doses are usually 40 to 60 gray measured at 0.5 to 1.0 cm from the balloon surface. This procedure has been performed on an inpatient basis.

In December 2013, CESITRX (Liquid Cesium131 solution) was cleared for marketing by FDA through the 510(k) process (K132996) for use with GliaSite RTS.

In April 2016, IsoRay Medical terminated the supply, manufacture, and distribution of the GliaSite® RTS due to poor sales. Other intracavitary balloon brachytherapy systems have also been cleared for marketing by the FDA through the 510(k) process, such as the MammoSite (2004) and Contura (2008) Systems manufactured by Hologic for the treatment of breast cancer.³

FDA product code: KXX.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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