

# Protocol

## Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas

(80145)

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

***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"><li>• With primary brain tumors</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>• Intracavitary balloon catheter brain brachytherapy</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>• Other forms of radiotherapy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>• Overall survival</li><li>• Symptoms</li><li>• Treatment-related morbidity</li></ul>

### 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 brain tumors who receive intracavitary balloon brain brachytherapy, 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 or comparators in nonrandomized studies. The heterogeneity of tumor metastatic tumor types limits the interpretation of reported short-term survival outcomes. The technical feasibility of the balloon catheter implantation has been demonstrated without significant short-term complications. Long-term outcome studies have not been reported. 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.

**Note:** This protocol policy statement does not address metastasis to the brain.

## Background

### *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.

### *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 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.

## Regulatory Status

In 2001, the GliSite® Radiation Therapy System (GliSite® RTS; IsoRay Medical) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (K003206). The 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 GliSite® RTS was cleared for marketing by the FDA through the 510(k) process (K111931). GliSite® 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) for use with GliaSite RTS was cleared for marketing by the FDA through the 510(k) process (K132996).

FDA product code: KXX.

In April 2016, IsoRay Medical filed a notice with the U.S. Securities and Exchange Commission indicating that it decided to terminate all agreements related to the patent license, supply, manufacture, and distribution of its GliaSite® Radiation Therapy System and certain ancillary products (“GliaSite® Product”).<sup>1</sup> The reason cited was marginal sales. This decision affected licensing agreements with Dr. Reddy’s Laboratories and Hologic for U.S. operations and Karlheinz Goehl-Medizintechnik for international agreements.

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