



Louisiana

Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain

Policy # 00434

Original Effective Date: 10/15/2014

Current Effective Date: 12/20/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers intracavitary balloon catheter brain brachytherapy, alone or as part of a multimodality treatment regimen, for primary or recurrent malignant brain tumors to be **investigational**.*

Based on review of available data, the Company considers intracavitary balloon catheter brain brachytherapy, alone or as part of a multimodality treatment regimen, for metastasis to the brain from primary solid tumors outside the brain to be **investigational**.*

Background/Overview

Intracavitary balloon catheter brain brachytherapy is an approach to localized radiation therapy delivered with an inflatable balloon catheter in the treatment of malignant brain lesions.

Intracavitary Balloon Catheter Brain Brachytherapy

Intracavitary balloon catheter brain brachytherapy is localized radiation therapy 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 3 grades: grade II astrocytoma, grade III anaplastic astrocytoma, and grade IV glioblastoma multiforme (GBM). Oligodendrogliomas (ODGs) 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 versus 2 to 3 years. Also, ODGs apparently are more chemosensitive than astrocytomas. GBM, the most aggressive and chemoresistant astrocytoma, has survival times of less than 2 years for most patients.

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Treatment of primary brain tumors begins with surgery with curative intent or optimal tumor debulking, usually followed by radiation therapy 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 (also known as CCNU), vincristine (PCV) and single or multiagent therapy with temozolomide. A biodegradable polymer wafer impregnated with carmustine (Gliadel[®]; Guilford Pharmaceuticals Inc.) 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 GBM.

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 goals in these patients include local control of existing metastases, regional control to prevent growth of undetected metastases, extending the duration of overall survival (OS), and maintaining quality of life. Surgical resection followed by whole brain radiation therapy (WBRT) is the mainstay of treatment for patients with 1 to 3 operable brain metastases and with adequate performance status and control of extracranial disease. Resection plus WBRT extends the duration of survival, when compared with biopsy plus WBRT. Although adding WBRT to resection does not increase OS duration, it reduces local and distant recurrence of brain metastases. Thus, WBRT decreases the incidence of death from neurologic causes and may help maintain adequate quality of life, if the cumulative dose does not cause unacceptable neurotoxicity.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2001, the Gliasite[®] Radiation Therapy System (Gliasite RTS; IsoRay Medical) was cleared for marketing by the U.S. 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

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afterloading and retrieving the radioactive material. One to 3 weeks after resection and balloon implantation, the Iotrex solution is loaded through a subcutaneous port and left in for 3 to 6 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 FDA through the 510(k) process (K132996).

FDA product code: KXK.

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"). 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.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

Assessment of efficacy for intracavitary balloon brain brachytherapy involves a determination of whether the intervention improves health outcomes. Evidence from randomized controlled trials (RCTs) that includes clinically relevant measures of health outcomes would be optimal. Because primary brain tumors and brain metastases from other tumors have a poor prognosis and are treatment resistant, nonrandomized comparative studies and uncontrolled studies may provide useful information on health outcomes.

PRIMARY BRAIN TUMORS

Malignant Gliomas and Astrocytoma

No RCTs or other controlled studies were identified. All published studies were uncontrolled case series.

In 2003, Tatter et al reported on a multicenter safety and feasibility study of the GliaSite RTS device for recurrent high-grade gliomas (n=21; 15 with GBM), 5 with anaplastic astrocytoma, 1 with anaplastic ODG). All patients (n=11) received first-line therapy with resection and radiation, with or without systemic chemotherapy. Time from end of first-line therapy to repeated resection for recurrent disease was not reported. Although not a primary end point, median OS was 12.7 months (95% confidence interval [CI], 6.9 to 15.3), and a Kaplan-Meier curve showed estimated OS at 1 year as just over 50%. Investigators reported no serious device-related adverse events during brachytherapy and no symptomatic radiation necrosis during follow-up.

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Gabayan et al (2006) reported on a retrospective multi-institutional analysis of the GliSite RTS device for recurrent high grade gliomas (n=95; 80 with GBM, 9 with anaplastic astrocytoma, 4 with anaplastic ODG, 1 each with a mixed anaplastic tumor or gliosarcoma). All patients received external beam radiotherapy (EBRT) after initial resection, and 55 (58%) also received systemic chemotherapy. Time from end of front-line therapy to repeated resection for recurrent disease was not reported. Fifteen patients (16%) who had previously been treated with EBRT following maximal debulking surgery were treated with GliSite (average dose, 60 Gy) on tumor recurrence. Median OS from the time of GliSite placement was 9.1 months (95% CI, 7.8 to 10.4), and OS at 1 year was 31.1% (95% CI, 21.2% to 41.0%). Only 2 patients experienced Radiation Therapy Oncology Group (RTOG) grade 3 toxicity attributable to radiation, and none experienced grades 4 or 5. However, 10 adverse events were attributed to surgery. The authors concluded that survival benefit was modest and that these data were similarly inconclusive to previous feasibility studies. The retrospective analysis on GliSite did not report important prognostic factors available from the Gliadel randomized trial (eg, median interval from first operation; cumulative radiation dose and proportion given whole brain radiotherapy [WBRT] vs local radiation vs both in first-line therapy and completeness of the second resections). The authors concluded that it is a challenge to assess survival value from these studies without better comparative evidence on demonstrably similar patient groups, preferably from a randomized comparative trial.

In 2010, Wernicke et al published a single institution, dose escalation study to investigate the safety and feasibility of GliSite following surgical resection of localized newly diagnosed and recurrent brain tumors. The balloon was implanted during surgery in 10 consecutive patients; then 2 to 3 weeks later, aqueous solution of 125-I was introduced for times ranging from 68 to 120 hours. Median total dose was 52 Gy. Median survival for this cohort was 14 months. There were no reports of RTOG grade 3 or 4 toxicities. Similarly to the other studies cited, results from this trial suggest that the GliSite RTS is relatively safe and well-tolerated in patients with localized brain tumors. However, further studies would be required to assess efficacy.

In 2011, Gobitti et al reported on 15 patients treated with GliSite brachytherapy after surgical resection of recurrent grade 3 or 4 gliomas (10 with GBM, 4 anaplastic astrocytoma, 1 anaplastic xanthoastrocytoma). Patients were followed from 1 to 30 months. Only 2 patients survived to 30 month follow-up. Eleven patients experienced local tumor recurrence. After GliSite brachytherapy, median OS was 13 months, and median disease-free survival was 7 months. Late radiation necrosis was experienced by 3 patients; 2 subsequently died of further complications. One patient had hemiparesis and dysphagia, which resolved over 6 months. The authors concluded that reintervention followed by GliSite brachytherapy should not be offered as a standard treatment for recurrent high-grade glioma, because of the high rate of late complications, treatment-related deaths, and high treatment costs.

There are no published studies using liquid cesium 131 for this indication.

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Section Summary: Malignant Gliomas and Astrocytoma

The evidence for the use of intracavitary balloon brain brachytherapy for malignant gliomas and astrocytomas consists of early phase feasibility and dose ranging studies, a small case series, and a retrospective review. There are no published RCTs. The evidence does not support conclusions on the effects of the technology on health outcomes.

Glioblastoma Multiforme

No RCTs or other controlled studies were identified. All published studies were uncontrolled case series.

Johannesen et al (1999) reported on 44 newly diagnosed GBM patients implanted with intracavitary balloon catheters at resection. Two to 3 days after surgery, high dose-rate 192-Ir sources were inserted twice daily for 15 minutes over 5 to 6 days, using remote afterloading devices designed and fabricated by the investigators. Cumulative radiation doses were 60 (n=33) or 72 Gy (n=11). Median survival was 11.7 months (range, 2.7-50.9) for all patients, 12.8 months for those treated with 60 Gy, and 9.9 months for those treated with 72 Gy. OS at 1 year was 46%. Relapses occurred in 89% of patients at a median follow-up time of 8.3 months after treatment (range, 1.2-34.7). These outcomes are similar to those of conventional WBRT after resection, although investigators emphasized the shorter treatment time (1 vs 5-6 weeks) with balloon catheter brachytherapy. While the authors asserted that hospital stays were shorter (median, 21 days) and quality of life over the first 6 months was better than after conventional WBRT, they did not report data to support these claims.

In a 2007, multicenter, retrospective study, Welsh et al compiled data from 20 patients with GBM at 8 centers (median age and Karnofsky Performance Status: 59 and 89, respectively). Following maximal tumor debulking, patients were treated with GliaSite (median dose, 60 Gy) before EBRT (median dose, 110 Gy). In this cohort, average survival was 11.4 months (range, 4-29), 4 months longer than historical controls (95% CI, 0.23 to 4.9). RTOG grade 3 central nervous system toxicity was observed in 3 patients (14%). It is noteworthy that 50% of treatment failures had balloons placed 2 cm or more from the margin of the tumor. While this study may suggest that administration of increased doses (up to 100 Gy) using GliaSite is feasible and relatively well-tolerated, the authors acknowledged that putative survival advantage must be interpreted with caution. Additional studies using GliaSite in conjunction with EBRT following surgery for newly diagnosed GBM would be required to adequately assess safety and efficacy.

In a 2005 study (n=24) on recurrent GBM performed at Johns Hopkins Medical Center, investigators reported results to be inconclusive. Front-line therapy included surgery followed by EBRT. Time from primary resection (or from end of primary treatment) to recurrence was not reported. Median OS was 23.3 months (range, 9.3–64.1 months) from diagnosis of the primary tumor, and 9.1 months (range, 1.3-23.6 months) from GliaSite RTS treatment. Kaplan-Meier analyses showed OS at 1 year to be approximately 33%. GliaSite was relatively well-tolerated in this cohort with few serious adverse events. Acute adverse effects were reportedly mild; 1 patient experienced mild nausea and vomiting, and 10 experienced mild to moderate headaches. Late complications included 1 case of global aphasia and 2 incidents of symptomatic necrosis.

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In 2013, Waters et al reported on a retrospective review of 11 patients with newly diagnosed glioblastoma who received brain brachytherapy 2 to 3 days postsurgical resection before EBRT and temozolomide.10 Brachytherapy was delivered at 45 to 60 Gy with GliaSite in 9 patients and with MammoSite in 2 patients. While progression-free survival trended toward improvement at 6 months, OS did not differ from historical controls.

There are no published studies using liquid cesium 131 for this indication.

Section Summary: Glioblastoma Multiforme

The evidence for the use of intracavitary balloon brain brachytherapy to treat GBM is limited to case series. The evidence is insufficient to determine the effects of the technology on health outcomes.

Brain Metastasis From Other Primary Solid Malignancies

No RCTs were identified. However, in 2006, Rogers et al published a multicenter, nonrandomized comparative study including 71 patients with 1 to 3 brain metastases from a solid tumor of distant origin. Enrolled patients received either GliaSite (n=62) or standard brachytherapy with Iotrex solution (n=54). Outcomes were analyzed without an intention-to-treat model. Primary malignancies included non-small-cell lung (54%) and gastrointestinal tract (13%) cancers, melanoma (13%), renal carcinoma (6%), and others (15%). While most patients (57%) had only brain metastases, many (43%) also had extracranial metastases. Prior therapies varied widely and included no treatment (22%), surgery (31%), surgery and radiation (33%), or surgery in addition to chemotherapy followed by radiation (24%). Estimated local control at 1 year was 79%, and median duration of local control exceeded 16.5 months. Median OS was 10 months (95% CI, 7.8 to 15), OS at 1 year was 40%, and median duration of functional independence was 10 months (95% CI, 7.3 to 20.8). Symptomatic imaging changes led to repeated operation in 13 patients, 9 of whom had radiation necrosis, 2 had mixed tumor and necrosis, and 2 had tumor recurrence only. A total of 9 grade 3 and 1 grade 4 toxicities were reported in the treated population.

Investigators indirectly compared the rate of local control in the GliaSite-treated population: 79% with historical data showing 80% to 90% local control after resection plus WBRT and only 40% after resection only. However, an accompanying editorial cautions that the rate of new metastases elsewhere in the brain was 50% by 1 year after treatment and attributes this to omission of WBRT. The editorial also stressed the need for direct comparative evidence to determine whether neurocognitive function and quality of life are adequately maintained for longer durations with initially focal treatment and WBRT at recurrence or with focal treatment immediately combined with WBRT.

There are no published studies using liquid cesium 131 for this indication.

Section Summary: Brain Metastasis From Other Primary Solid Tumors

The evidence for the use of intracavitary balloon brain brachytherapy to treat brain metastases from other tumors is limited to a nonrandomized, single-arm study. The relevance of outcomes indirectly demonstrating local control of 79% at 1 year is confounded by the varying radiosensitivity of the tumors, and the OS was

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impacted by the rate of extracranial metastatic disease. The evidence does not support conclusions on the effects of the technology on health outcomes.

Safety Considerations

Overall, adverse events with GliSite do not differ greatly from those observed with other brain brachytherapy techniques; however, in 2008, Adkison et al reported a case in which linens of a patient with the GliSite implant were contaminated with radiation. 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. Some cases of brain hemorrhage have been reported, so careful coagulation control is critical.

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.

For individuals who have metastases to the brain from other tumors who receive intracavitary balloon brain brachytherapy, 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 1 year. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

1. Blue Cross and Blue Shield Association, [Medical Policy Reference Manual](#), "Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas or Metastasis to the Brain", 8.01.45, 8:2017.
2. Chino K, Silvain D, Grace A et al. Feasibility and safety of outpatient brachytherapy in 37 patients with brain tumors using the GliSite Radiation Therapy System. *Med Phys* 2008; 35(7):3383-8. PMID 18697562
3. Tatter SB, Shaw EG, Rosenblum ML et al. An inflatable balloon catheter and liquid 125I radiation source (GliSite Radiation Therapy System) for treatment of recurrent malignant glioma: multicenter safety and feasibility trial. *J Neurosurg* 2003; 99(2):297-303. PMID 12924704
4. Gabayan AJ, Green SB, Sanan A et al. GliSite brachytherapy for treatment of recurrent malignant gliomas: a retrospective multi-institutional analysis. *Neurosurgery* 2006; 58(4):701-9; discussion 01-9.
5. Wernicke AG, Sherr DL, Schwartz TH, et al. The role of dose escalation with intracavitary brachytherapy in the treatment of localized CNS malignancies: outcomes and toxicities of a prospective study. *Brachytherapy*. Jan-Mar 2010;9(1):91-99. PMID 19850535
6. Wernicke AG, Sherr DL, Schwartz TH, et al. Feasibility and safety of GliSite brachytherapy in treatment of CNS tumors following neurosurgical resection. *J Cancer Res Ther*. Jan-Mar 2010;6(1):65-74. PMID 20479550

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7. Gobitti C, Borsatti E, Arcicasa M, et al. Treatment of recurrent high-grade gliomas with GliSite brachytherapy: a prospective mono-institutional Italian experience. *Tumori*. Sep-Oct 2011;97(5):614-619. PMID 22158493
8. Johannesen TB, Watne K, Lote K, et al. Intracavity fractionated balloon brachytherapy in glioblastoma. *Acta Neurochir (Wien)*. 1999;141(2):127-133. PMID 10189493
9. Welsh J, Sanan A, Gabayan AJ, et al. GliSite brachytherapy boost as part of initial treatment of glioblastoma multiforme: a retrospective multi-institutional pilot study. *Int J Radiat Oncol Biol Phys*. May 1 2007;68(1):159-165. PMID 17331666
10. Chan TA, Weingart JD, Parisi M, et al. Treatment of recurrent glioblastoma multiforme with GliSite brachytherapy. *Int J Radiat Oncol Biol Phys*. Jul 15 2005;62(4):1133-1139. PMID 15990019
11. Waters JD, Rose B, Gonda DD, et al. Immediate post-operative brachytherapy prior to irradiation and temozolomide for newly diagnosed glioblastoma. *J Neurooncol*. Jul 2013;113(3):467-477. PMID 23673513
12. Rogers LR, Rock JP, Sills AK, et al. Results of a phase II trial of the GliSite radiation therapy system for the treatment of newly diagnosed, resected single brain metastases. *J Neurosurg*. Sep 2006;105(3):375-384. PMID 16961129
13. Barker FG, 2nd. Brain metastasis. *J Neurosurg*. Sep 2006;105(3):371-372; discussion 372-374. PMID 16961128
14. Adkison JB, Thomadsen B, Howard SP. Systemic iodine 125 activity after GliSite brachytherapy: safety considerations. *Brachytherapy*. Jan-Mar 2008;7(1):43-46. PMID 18201938
15. Gerber DE, Grossman SA, Chan TA, et al. Intracranial hemorrhage during GliSite RTS manipulation in an anticoagulated patient. *J Radiother Pract*. 2007;6:53-57. PMID 19173012
16. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. V.2.2014. http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed February 27, 2015.

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10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. New policy.
01/01/2015	Coding Update
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date:	12/2018

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HCPCS	A9527, C2644
ICD-10 Diagnosis	All related diagnoses

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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