Policy Statement

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

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

Policy Guidelines

There are no CPT codes specific to implantation of this type of balloon catheter. It is possible that the provider may use the following CPT code:

- **64999**: Unlisted procedure, nervous system

The administration of the radiation source would likely be coded using one of the CPT codes for radiation source application or remote afterloading of high dose brachytherapy:

- **77761**: Intracavitary radiation source application; simple
- **77762**: Intracavitary radiation source application; intermediate
- **77763**: Intracavitary radiation source application; complex
- **77770**: Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel
- **77771**: Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2-12 channels
- **77772**: Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels

There is a HCPCS code specific to the radiation solution used in this procedure:

- **A9527**: Iodine I-125, sodium iodide solution, therapeutic, per millicurie

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these
instances, plans may have to consider the coverage eligibility of the FDA-approved technologies on the basis of medical necessity alone.

**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). 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 GliaSite® RTS was cleared for marketing by the 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; lotrex™) as the radiation source; and an access tray with items used for afterloading and retrieving the radioactive material. One to 3 weeks after resection and balloon implantation, the lotrex™ 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, CESTRX (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”). 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.

**Rationale**

**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 3 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 2 to 3 years. Also, oligodendrogliomas apparently are more chemosensitive than astrocytomas. The most aggressive and chemoresistant astrocytoma, glioblastoma multiforme has survival times of less than 2 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.

**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 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 1 to 3 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 overall survival 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.

**Literature Review**

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 GlaSite Radiation Therapy System (RTS) device for recurrent high-grade gliomas (n=21; 15 with glioblastoma multiforme [GBM], 5 with anaplastic astrocytoma, 1 with anaplastic oligodendrogliomas). All patients 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 overall survival (OS) was 12.7 months (95% confidence interval [CI], 6.9 to 15.3 months), and a Kaplan-Meier curve showed the estimated OS rate 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.
Gabayan et al (2006) reported on a retrospective multi-institutional analysis of the GliaSite RTS device for recurrent high-grade gliomas (n=95; 80 with GBM, 9 with anaplastic astrocytoma, 4 with anaplastic oligodendrogliomas, one each with a mixed anaplastic tumor or gliosarcoma).3 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 (16%) patients who had previously been treated with EBRT following maximal debulking surgery were treated with GliaSite RTS (average dose, 60 gray [Gy]) on tumor recurrence. Median OS from the time of GliaSite placement was 9.1 months (95% CI, 7.8 to 10.4 months), and the OS rate at 1 year was 31.1% (95% CI, 21.2% to 41.0%). Only 2 patients experienced Radiation Therapy Oncology Group grade 3 toxicity attributable to radiation, and none experienced grade 4 or 5 toxicity. However, 10 adverse events were attributed to surgery. The authors concluded that survival benefit was modest and that, similar to previous feasibility studies, these data were inconclusive. The retrospective analysis on GliaSite3 did not report important prognostic factors available from the Gliadel randomized trial (e.g., 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). 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 report on a single-institution, dose-escalation study investigating the safety and feasibility of GliaSite after surgical resection of localized newly diagnosed and recurrent brain tumors.4,5 The balloon was implanted during surgery in 10 consecutive patients; then 2 to 3 weeks later, aqueous solution of iodine 125 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 Radiation Therapy Oncology Group grade 3 or 4 toxicities. Similarly to the other studies cited, results from this trial suggested that the GliaSite 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 GliaSite brachytherapy after surgical resection of recurrent grade 3 or 4 gliomas (10 with GBM, 4 anaplastic astrocytoma, 1 anaplastic xanthoastrocytoma).6 Patients were followed for 1 to 30 months. Only 2 patients survived to 30-month follow-up. Eleven patients experienced local tumor recurrence. After GliaSite brachytherapy, median OS was 13 months, and median disease-free survival was 7 months. Late radiation necrosis was experienced by 3 patients; two subsequently died of further complications. One patient had hemiparesis and dysphagia, which resolved over 6 months. The authors concluded that reintervention followed by GliaSite 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.

**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.

Johannessen et al (1999) reported on 44 newly diagnosed GBM patients implanted with intracavitary balloon catheters at resection.7 Two to 3 days after surgery, high dose-rate iridium 192 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 months) for all patients, 12.8 months for those treated with 60 Gy and 9.9 months for those treated with 72 Gy. The OS rate at 1 year was 46% Relapses occurred in 89% of patients at a median follow-up of 8.3 months after treatment (range, 1.2-34.7 months). These outcomes are similar to those of conventional WBRT after resection, although investigators emphasized the shorter treatment time (1 weeks 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, 59 years; median Karnofsky Performance Status score, 89). 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 months), 4 months longer than historical controls (95% CI, 0.23 to 4.9). Radiation Therapy Oncology Group grade 3 central nervous system toxicity was observed in 3 (14%) patients. It is noteworthy that 50% of treatment failures had balloons placed 2 cm or more from the margin of the tumor. While this study might 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 cautiously. Additional studies using GliaSite with EBRT following surgery for newly diagnosed GBM would be required to assess safety and efficacy adequately.

In a 2005 study (N=24) on recurrent GBM performed at university medical center, Chan et al 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 an OS rate 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 a case of global aphasia and 2 incidents of symptomatic necrosis. In 2013, Waters et al retrospectively reviewed 11 patients with newly diagnosed GBM who received brain brachytherapy 2 to 3 days after surgical resection before EBRT and temozolomide. 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 noncomparative study including 71 patients with 1 to 3 brain metastases from a solid tumor of distant origin. Enrolled patients received placement of the GliaSite balloon followed by installation of aqueous iodine-125 radiotherapy solution with the prescribed total dose for each patient of 60 Gy at a 1-cm depth to be delivered at a rate of 40 to 60 centigray per hour. The primary study end point was the 1-year local control rate. 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 plus radiotherapy (33%), or surgery plus chemotherapy followed by radiotherapy (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 months), OS rate at 1 year was 40% and
median duration of functional independence was 10 months (95% CI, 7.3 to 20.8 months).
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. Nine
grade 3 and 1 grade 4 toxicities were reported in the treated population.

Investigators indirectly compared the local control rate 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 cautioned that the rate of new
metastases elsewhere in the brain was 50% by 1 year after treatment and attributed this to the
omission of WBRT.12 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 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 GliaSite 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 GliaSite implant were contaminated with radiation.13 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.14

**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.
Supplemental Information
Practice Guidelines and Position Statements
National Comprehensive Cancer Network guidelines (v.1.2016) for central nervous system cancers mention brachytherapy as one of several treatment options used by radiation oncologists. However, the terms GliaSite, intracavitary, or balloon (related to central nervous system cancers) are not mentioned in these guidelines.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
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.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in July 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

References


**Documentation for Clinical Review**

Please provide the following documentation (if/when requested):
- History and physical and/or consultation notes including:
  - Tumor classification and past medical and/or surgical treatment and response
- Operative report(s) or procedure report(s)
- Pathology report(s)
- Radiation treatment plan including: type of brachytherapy, therapy schedule and number of treatments

**Post Service**
- Daily radiation treatment records

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

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

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ICD-10 Diagnosis: All Diagnoses

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.
Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.