

Corporate Medical Policy

Brachytherapy, Intracavitary Balloon Catheter for Brain Cancer

File Name:	brachytherapy_intracavitary_balloon_catheter_for_brain_cancer
Origination:	01/2008
Last CAP Review:	5/2020
Next CAP Review:	5/2021
Last Review:	5/2020

Description of Procedure or Service

Intracavitary balloon catheter brain brachytherapy is an approach to localized radiation therapy delivered with an inflatable balloon catheter and being studied 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.

At present, the GliaSite® radiation therapy system (GliaSite® RTS; IsoRay Medical, Inc.) is the only device marketed in the United States for intracavitary balloon catheter brachytherapy in the brain. It includes a catheter tray with a double balloon catheter and accessories used for implantation; an aqueous saline solution of molecularly bound radioactive iodine [sodium 3-(¹²⁵I) iodo-4-hydroxybenzenesulfonate; Iotrex™] 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 Iotrex™ solution is loaded through a subcutaneous port and left in for 3 to 6 days. Prescribed radiation doses are usually 40–60 Gy measured at 0.5–1.0 cm from the balloon surface. The GliaSite® RTS received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA), as substantially equivalent to separately marketed ventricular reservoirs and catheters, manual radionuclide applicator systems, and radionuclide sources. In 2011, the modified GliaSite® RTS received 510(k) marketing clearance. 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.

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 (ODG) 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 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 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

Brachytherapy, Intracavitary Balloon Catheter for Brain Cancer

particularly poor outcome since 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), temozolamide, procarbazine, and vincristine. The most common regimen combines procarbazine, lomustine (also known as CCNU), and vincristine (PCV). 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%–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, 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 overall survival duration, it reduces local and distant recurrence of brain metastases. Thus, WBRT decreases the incidence of death from neurological causes, and may help maintain adequate quality of life, if the cumulative dose does not cause unacceptable neurotoxicity.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Brachytherapy, Intracavitary Balloon Catheter For Brain Cancer is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Some patients may be eligible for coverage under Clinical Trials. Refer to the policy titled, Clinical Trial Services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Brachytherapy, Intracavitary Balloon Catheter For Brain Cancer is covered

Not applicable

When Brachytherapy, Intracavitary Balloon Catheter For Brain Cancer is not covered

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

Brachytherapy, Intracavitary Balloon Catheter for Brain Cancer

Policy Guidelines

For individuals who have primary newly diagnosed or recurrent brain tumors who receive intracavitary balloon 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 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.

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.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 77785, 77786, 77787

CPT code 61517 is not applicable to report this procedure

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.45, 2/15/2007

Senior Medical Director review - 12/12/2007

Specialty Matched Consultant Advisory Panel - 3/2008

Specialty Matched Consultant Advisory Panel 5/2010

BCBSA-Medical Policy Reference Manual [Electronic Version] 8.01.45, 3/22/2010

Specialty Matched Consultant Advisory Panel 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 4/14/2011

Specialty Matched Consultant Advisory Panel 5/2012

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 4/12/2012

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 4/11/2013

Specialty Matched Consultant Advisory Panel 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 4/10/2014

Specialty Matched Consultant Advisory Panel 6/2014

Brachytherapy, Intracavitary Balloon Catheter for Brain Cancer

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 4/23/2015

Specialty Matched Consultant Advisory Panel 5/2015

Specialty Matched Consultant Advisory Panel 5/2016

Specialty Matched Consultant Advisory Panel 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 8/10/2017

Specialty Matched Consultant Advisory Panel 5/2018

Medical Director review 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 7/12/2018

Specialty Matched Consultant Advisory Panel 5/2019

Medical Director review 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version] 8.01.45, 8/8/2019

Specialty Matched Consultant Advisory Panel 5/2020

Medical Director review 5/2020

Policy Implementation/Update Information

- 1/28/08 New policy adopted. Reviewed with Medical Director 12/12/2007. BCBSNC will not provide coverage for Brachytherapy, Intracavitary Balloon Catheter For Brain Cancer. It is considered investigational.
- 6/2/08 Specialty Matched Consultant Advisory Panel review 3/17/08. No change to policy statement. References added.
- 1/5/09 Added new CPT codes 77785, 77786, and 77787 to the "Billing/Coding" section. Removed deleted CPT codes 77781, 77782, 77783, and 77784. (btw)
- 6/22/10 Specialty Matched Consultant Advisory Panel review 5/24/10. Description extensively revised. Added wording in the "When Not Covered" section: "Intracavitary balloon catheter brain brachytherapy is considered investigational, alone or as part of a multimodality treatment regimen, for primary or recurrent malignant gliomas and Intracavitary balloon catheter brain brachytherapy also is considered investigational, alone or as part of a multimodality treatment regimen, for metastasis to the brain from primary malignancies outside the brain." References added. (lpr)
- 6/7/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. Added statement to Description section "Intracavitary balloon catheter brain brachytherapy is an approach to localized radiation therapy delivered with an inflatable balloon catheter and being studied in the treatment of malignant brain lesions." Revised and updated Policy Guidelines section. References added. (lpr)
- 5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/2012. Reference added. No change to policy statement. Revised policy guidelines. (lpr)
- 6/11/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. Reference added. No change to policy statement. (lpr)

Brachytherapy, Intracavitary Balloon Catheter for Brain Cancer

- 7/29/14 Specialty Matched Consultant Advisory Panel review 6/24/2014. No change to policy statement. Reference added. (lpr)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. Reference added. No change to policy statement. (lpr)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. No change to policy statement. (lpr)
- 6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. No change to policy statement. (lpr)
- 9/29/17 Updated Policy Guidelines section. Reference added. No change to policy statement. (lpr)
- 6/8/18 Specialty Matched Consultant Advisory Panel review 5/2018.No changes to policy statements. Medical Director review 5/2018. (mco)
- 5/28/19 Specialty Matched Consultant Advisory Panel review 5/15/2019. No change to policy intent. Reference added. (lpr)
- 6/9/20 Specialty Matched Consultant Advisory Panel review 5/20/2020. Updated Description section. Reference added. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.