Protocol

Intracavitary Balloon Catheter Brain Brachytherapy for Malignant Gliomas of the Brain

(80145)

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

Medical Benefit		**Effective Date**: 03/01/14	**Next Review Date**: 03/15
Preauthorization	No	**Review Dates**: 05/09, 05/10, 05/11, 05/12, 05/13, 03/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; documentation must be submitted to Utilization Management.*** *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.*

Description

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.

Background

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 U.S. for intracavitary balloon catheter brachytherapy in the brain. It 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 40–60 Gy measured at 0.5–1.0 cm from the balloon surface. This procedure has been performed on an inpatient basis; however, feasibility of outpatient GliaSite® RTS implantation has been explored. (1) The GliaSite® RTS received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) in 2001, 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.

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 (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 two to three years. Also, ODGs apparently are more chemosensitive than astrocytomas. GBM, the most aggressive and chemoresistant astrocytoma, 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 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, 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), temozolomide, procarbazine, vincristine, and platinum-based agents. The most common regimen combines procarbazine, lomustine (also known as CCNU), vincristine (PCV) and single or multi-agent 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 10–30% 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 one to three 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 neurological causes and may help maintain adequate quality of life, if the cumulative dose does not cause unacceptable neurotoxicity.

Policy (Formerly Corporate Medical Guideline)

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.

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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