

**Policy: MP101**

**Section: Medical Benefit Policy**

**Subject: Intracavitary Balloon Catheter Brain Brachytherapy**

**Applicable line of business:**

|                   |          |                 |          |
|-------------------|----------|-----------------|----------|
| <b>Commercial</b> | <b>x</b> | <b>Medicaid</b> | <b>x</b> |
| <b>Medicare</b>   | <b>x</b> | <b>ACA</b>      | <b>x</b> |
| <b>CHIP</b>       | <b>x</b> |                 |          |

**I. Policy:** Intracavitary Balloon Catheter Brain Brachytherapy

**II. Purpose/Objective:**

To provide a policy of coverage regarding Intracavitary Balloon Catheter Brain Brachytherapy

**III. Responsibility:**

- A. Medical Directors
- B. Medical Management

**IV. Required Definitions**

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

**Commercial**

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicare**

Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

**CHIP**

Geisinger Health Plan Kids (GHP Kids) is a Children’s Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

**Medicaid**

Geisinger Health Plan Family (GHP Family) is a Medical Assistance (Medicaid) insurance program offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization

**V. Additional Definitions**

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

### **Medicaid Business Segment**

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age

### **DESCRIPTION:**

GliaSite® is a balloon catheter device used to deliver liquid brachytherapy to the brain. It is intended for the treatment of surrounding tissue after a malignant brain tumor is surgically removed. The system delivers site-specific, internal radiation, treating the target area while minimizing exposure to healthy tissue. The device is a balloon catheter that is inserted into the cavity created by surgical removal of the malignant brain tumor and filled with **lotrex™**, a proprietary liquid radiation source. Over a course of three to seven days, GliaSite® delivers radiation directly to the tissue surrounding the cavity, where the tumors are most likely to recur.

IsoRay Medical has terminated the supply, manufacture, and distribution of the GliaSite RTS due to poor sales.

### **EXCLUSIONS:**

Intracavitary balloon catheter brain brachytherapy for malignant gliomas or metastasis to the brain is considered **Unproven** and therefore **NOT COVERED**. Though no longer in use due to a high rate of radionecrosis, GliaSite was an FDA-approved balloon catheter device that was placed in the resection cavity immediately after tumor removal.

### **Medicaid Business Segment:**

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

**CODING ASSOCIATED WITH:** GliaSite® Radiation Therapy

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at [www.cms.gov](http://www.cms.gov) or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.*

**no specific coding**

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

### **LINE OF BUSINESS:**

**Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.**

### **REFERENCES:**

Geisinger Clinic Technology Assesment Committee Triage Group, GliaSite® Radiation Therapy, Feb 12, 2003.

Canadian Coordinating Office for Health Technology Assessment, GliSite® Radiation Therapy, No. 9, August 2001.

ECRI, HTAIS Hotline Response, GliSite® Radiation Therapy for Brain Cancer, Dec. 17, 2002.

ECRI, HTAIS Target database. Intracavitary liquid brachytherapy for brain cancer. Feb. 2004.

ECRI, Health Technology Forecast. Brachytherapy for brain tumors. Mar. 2004.

GliSite® Radiation Therapy System, Proxima Therapeutics, Inc. Product Information.

<http://www.proximatherapeutics.com>

Stubbs JB, Frankel RH, Schultz K, Crocker I, Dillehay D, Olson JJ, “ Pre-clinical Evaluation of a Novel Device for Delivering Brachytherapy to the Margins of Resected Brain Tumor Cavities”, *Journal of Neurosurgery*, 96:335-343, Feb. 2002.

Van den Berge JH, Blaauw G, Breeman WAP, Rahmy A, Wijngaarde R.,” Intracavitary Brachytherapy of Cystic Craniopharyngiomas”, *Journal of Neurosurgery*. 77:545-550, Oct. 1992.

Chan TA, Weingart JD, Parisi RN, Hughes MA, Olivi A, Borzillary S, Alahakone D, Detorie NA, Wharam MD, Kleinberg L. Treatment of recurrent glioblastoma multiforme with gliasite brachytherapy. *Int. J Radiation Oncology Biol Phys*. 2005;62(4):1133-1139.

Tatter SB, Shaw EG, Rosenblum ML, Karvelis KC, Kleinsburg L, Weingart J, Olson JJ, Crocker IR, Brem S, Pearlman JL, Fisher JD, Carson KA, Grossman SA et al. An inflatable balloon catheter and liquid <sup>125</sup>I radiation source (GliSite Radiation Therapy System) for treatment of recurrent malignant glioma: multicenter safety and feasibility trial. *J Neurosurg* 2003;99:297-303.

Welsh J, Sanan A, Gabayan AJ, Green SB, Lustig R, Burri S, Kwong E, Stea B. Gliasite Brachytherapy boost as part of initial treatment of glioblastoma multiforme: A retrospective multi-institutional pilot study. *Int J Radiation Oncology Biol Phys*. 2007:

Rogers LR, Rock JP, Sills AK, Vogelbaum MA et al. Results of a phase II trial of the Gliasite radiation therapy system for the treatment of newly diagnosed, resected single brain metastases. *J Neurosurg* 2006;105:375-384.

Gabayan Aj, Green SB, Sanan A, Jenrette J, Schultz C et al. Gliasite Brachytherapy for treatment of recurrent malignant gliomas: a retrospective multi-institutional analysis. *Neurosurgery* 2006;58:701-709.

Nicholas S, Mathios D, et al. Current trends in glioblastoma multiforme treatment: radiation therapy and immune checkpoint inhibitors. *Brain Tumor Research and Treatment* 2013;1(1):2-8

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology - Central Nervous System Cancers v5.2024

Leskinen S, Ben-Shalom N, et al. Brachytherapy in Brain Metastasis Treatment: A Scoping Review of Advances in Techniques and Clinical Outcomes. *Cancers (Basel)*. 2024 Jul 31;16(15):2723.

This policy will be revised as necessary and reviewed no less than annually.

**Devised:** 4/03

**Revised:** 4/04, 4/06(added Ref.); 4/07; 4/08 (coding); 4/25 (Title Change; Revise coverage position)

**Reviewed:** 4/05, 4/09, 5/10, 5/11, 5/12, 5/13, 4/15, 4/16, 4/17, 4/18, 4/19, 4/20, 4/21, 4/22, 4/23, 4/24

**CMS UM Oversight Committee Approval:** 12/23, 7/24, 6/25

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Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at <https://www.geisinger.org/health-plan/providers/ghp-clinical-policies>

Please be advised that the use of the logos, service marks or names of Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company on a marketing, press releases or any communication piece regarding the contents of this medical policy is strictly prohibited without the prior written consent of Geisinger Health Plan. Additionally, the above medical policy does not confer any endorsement by Geisinger Health Plan, Geisinger Quality Options, Inc. and Geisinger Indemnity Insurance Company regarding the medical service, medical device or medical lab test described under this medical policy.