

Policy: MP101

Section: Medical Benefit Policy

Subject: GliSite® Radiation Therapy

I. Policy: GliSite® Radiation Therapy

II. Purpose/Objective:

To provide a policy of coverage regarding GliSite® Radiation Therapy

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.

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

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit 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.

INDICATIONS:

GliaSite is a covered service when used to deliver intracavitary radiation therapy (brachytherapy) to patients with malignant brain tumors such as, but not limited to malignant gliomas, following tumor resection surgery.

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, will 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 or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

- 61770 Stereotactic localization, including burr hole(s), with insertion of catheter(s) or probe(s) for placement of radiation source
- 77263 Therapeutic radiology treatment planning; complex
- 77290 Therapeutic radiology simulation-aided setting; complex
- 77300 Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician.
- 77370 Special medical radiation physics consultation
- 77470 Special treatment procedure (eg, total body irradiation, hemibody radiation, per oral, endocavitary or intraoperative cone irradiation)
- 77761 Intracavitary radiation source application
- 77762 Intracavitary radiation source application
- 77763 Intracavitary radiation source application
- 77770 remote afterloading high dose rate radionuclide brachytherapy; 1 channel
- 77771 remote afterloading high dose rate radionuclide brachytherapy; 2-12 channels
- 77772 remote afterloading high dose rate radionuclide brachytherapy; over 12 channels
- 64999 Unlisted neurosurgical code: removal of catheter
- 0735T Preparation of tumor cavity, with placement of a radiation therapy applicator for intraoperative radiation therapy (IORT) concurrent with primary craniotomy (List separately in addition to code for primary procedure)
- A9527 Iodine I-125, sodium iodide solution, therapeutic, per millicurie
- C2634 Brachytherapy source, non-stranded, High Activity, iodine-125, greater than 1.01 MCI (NIST), per source
- C2639 Brachytherapy source, non-stranded, iodine-125, per source

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.

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

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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.

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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.

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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.

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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. v2.2021

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)

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

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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.