

Policy: MP196

Section: Medical Benefit Policy

Subject: Convection-Enhanced Drug Delivery

I. Policy: Convection-Enhanced Drug Delivery

II. Purpose/Objective:

To provide a policy of coverage regarding Convection-Enhanced Drug Delivery

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:

Convection-enhanced drug delivery (CED) is an innovative drug delivery technique used to circumvent the blood-brain barrier and deliver therapeutic agents directly into the parenchyma. CED uses a pressure gradient established at the tip of an infusion catheter that creates a bulk flow, which “pushes” the drug in the extracellular space. As a result, the drug is thought to be distributed more evenly, at higher concentrations, and over a large area.

EXCLUSIONS:

The Plan does **NOT** provide coverage for the use of Convection-Enhanced Drug Delivery into the parenchyma of the brain for any indication because it is considered **experimental, investigational or unproven**. There is insufficient evidence in the peer-reviewed published medical literature to establish the safety and effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Convection-Enhanced Drug Delivery

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.

41019 Placement of needles, catheters, or other device(s) into the head and/or neck region (percutaneous, transoral, or transnasal) for subsequent interstitial radioelement application)

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:

Smith JH, Humphrey JA. Interstitial transport and transvascular fluid exchange during infusion into brain and tumor tissue. *Microvasc Res.* 2006 Oct 24; [Epub ahead of print]

Raghavan R, Brady ML, Rodriguez-Ponce MI, Hartlep A, Pedain C, Sampson JH. Convection-enhanced delivery of therapeutics for brain disease and its optimization. *Neurosurg Focus* 2006; 20(3):E12.

Institute for Clinical Systems Improvement (ICSI). Blood brain barrier disruption chemotherapy. Technical Assessment Report: 59. Bloomington, MN: ICSI; November 2001. Available at: <http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=268>.

Vandergrift WA, Patel SJ, Nicholas JS, Varma AK. Convection-enhanced delivery of immunotoxins and radioisotopes for treatment of malignant gliomas. *Neurosurg Focus* 2006;20(4):E13.

Hall WA, Sherr GT. Convection-enhanced delivery: targeted toxin treatment of malignant glioma. *Neurosurg Focus* 2006; 20(4):E10.

Kunwar S, Chang SM, Prados MD, Berger MS, Sampson JH, Croteau D, Sherman JW, Grahn AY, Shu VS, Dul JL, Husain SR, joshi BH, Pedain C, Puri RK. *Neurosurg Focus* 2006;20(3):E15.

Hall WA, Rustamzadeh E, Asher AL. Convection-enhanced delivery in clinical trials. *Neurosurg Focus* 2003; 14(2):Article 2.

Sampson JH, Akabani G, Friedman AH, Bigner D, Kunwar S, Berger MS, Bankiewicz KS. Comparison of intratumoral bolus injection and convection-enhanced delivery of radiolabeled antitenascin monoclonal antibodies. *Neurosurg Focus* 2006;20(4):E14

Sampson JH, Brady ML, Petry NA, Croteau D, Friedman AH, Friedman HS, Wong T, Bigner DD, Pastan I, Puri RK, Pedain C. Intracerebral infusate distribution by convection-enhanced delivery in Humans with malignant gliomas: descriptive effects of target anatomy and catheter positioning. *Neurosurgery* 2007; 60(ONS Suppl1): 89-99.

Sampson JH, Akabani G, Archer GE, et al. Intracerebral infusion of an EGFR-targeted toxin in recurrent malignant brain tumors. *Neuro Oncol.* 2008;10(3):320-329.

Fiandaca MS, Forsayeth JR, Dickinson PJ, Bankiewicz KS. Image-guided convection-enhanced delivery platform in the treatment of neurological diseases. *Neurotherapeutics.* 2008;5(1):123-127.

ECRI Institute Health Technology Forecast (online). Anti-tenascin radiolabeled antibody for glioblastoma multiforme. Lansdale: ECRI Institute Current as of August 14, 2009.

Sampson JH, Archer G, Pedain C, et al; PRECISE Trial Investigators. Poor drug distribution as a possible explanation for the results of the PRECISE trial. *J Neurosurg.* 2010;113(2):301-309.

Bidros DS, Liu JK, Vogelbaum MA. Future of convection-enhanced delivery in the treatment of brain tumors. *Future Oncol.* 2010;6(1):117-125

Barua NU, Gill SS, Love S. Convection-enhanced drug delivery to the brain: therapeutic potential and neuropathological considerations. *Brain Pathol.* 2014; 24(2):117-127.

Barua NU, Hopkins K, Woolley M, et al. A novel implantable catheter system with transcutaneous port for intermittent convection-enhanced delivery of carboplatin for recurrent glioblastoma. *Drug Deliv.* 2014 May 2.

Lonser RR, Oldfield EH. Beyond the blood-nervous system barrier: Convection-enhanced delivery targets CNS disorders. *American Association of Neurological Surgeons (AANS) Bulletin.* 2004; 13(4).

Zhou Z, Singh R, Souweidane MM, et al. Convection-enhanced delivery for diffuse intrinsic pontine glioma treatment. *Curr Neuropharmacol.* 2016 Jun 13

Garg T, Bhandari S, Rath G, Goyal AK. Current strategies for targeted delivery of bio-active drug molecules in the treatment of brain tumor. *J Drug Target.* 2015;23(10):865-887.

Stockwell J, Abdi N, Lu X, et al. Novel central nervous system drug delivery systems. *Chem Biol Drug Des.* 2014;83(5):507-520.

Lewis O, Woolley M, Johnson D, et al. Chronic, intermittent convection-enhanced delivery devices. *J Neurosci Methods.* 2016; 259:47-56.

Patel MM, Patel BM. Crossing the blood-brain barrier: Recent advances in drug delivery to the brain. *CNS Drugs.* 2017;31(2):109-133.

Jahangiri A, Chin AT, Flanigan PM, et al. Convection-enhanced delivery in glioblastoma: A review of preclinical and clinical studies. *J Neurosurg.* 2017;126(1):191-200.

NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers v2.2021

Bander ED, Ramos AD, Wembacher-Schroeder E, et al. Repeat convection-enhanced delivery for diffuse intrinsic pontine glioma. *J Neurosurg Pediatr.* 2020 Sep 25

Szychot E, Walker D, Collins P, et al. Clinical experience of convection-enhanced delivery (CED) of carboplatin and sodium valproate into the pons for the treatment of diffuse intrinsic pontine glioma (DIPG) in children and young adults after radiotherapy. *Int J Clin Oncol.* 2021;26(4):647-658.

Wang Y, Jiang Y, Wei D, et al. Nanoparticle-mediated convection-enhanced delivery of a DNA intercalator to gliomas circumvents temozolomide resistance. Nat Biomed Eng. 2021 May 27

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

Devised: 12/2006

Revised: 3/08 (coding); 3/09

Reviewed: 3/10, 3/11 (refs), 3/12, 3/13, 3/14, 3/15, 3/16, 2/17, 2/18, 2/19, 2/20, 2/21, 2/22

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.

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.