

Corporate Medical Policy

Convection-Enhanced Delivery of Therapeutic Agents to the Brain

File Name: convection_enhanced_delivery_of_therapeutic_agents_to_the_brain

Origination: 2/2007

Last Review: 3/2023

Description of Procedure or Service

Despite advances in diagnostic imaging and drug discovery, primary malignant brain tumors remain fatal. Median survival for patients with the most severe forms is rarely past eight months. Malignant gliomas have a characteristic ability to infiltrate healthy brain tissue and form satellite tumors. This capacity for migration makes them exceedingly difficult to treat. Even after resection, invasive cells can give rise to tumors within centimeters of the resection site. Untreated malignant tumors can eventually spread to the contralateral hemisphere.

Many forms of systemic chemotherapy are excluded from the central nervous system by the blood-brain barrier (BBB). The blood-brain barrier is the tight lining of the cerebral vessels that protects against damaging substances such as large molecular particles from entering the brain. Most chemotherapeutic agents are large in molecular weight and are not allowed through the blood-brain barrier to treat the brain tumor when administered intravenously. The failure of conventional systemic drug delivery for glioma has motivated more direct approaches to drug delivery. Direct intracranial drug delivery would eliminate the need for chemotherapeutic agent to cross the blood-brain barrier.

Convection-enhanced delivery (CED) of therapeutic agents to the brain is an attempt to deliver an increased concentration of the agent to the brain tumor. CED is a drug delivery technique used to bypass the blood brain barrier (BBB) for the administration of therapeutic agents directly into targeted brain tissue. The brain is naturally protected from harmful agents by the BBB, which is a barrier made up of cells that selectively controls the movement of molecules between the circulating blood and the neuronal tissue. It allows the movement of substances essential to metabolic function but restricts the passage of large molecules (proteins and microorganisms). This capacity to block the entrance of large molecules has made the delivery of drugs directly to brain tissue nearly impossible. Research is being done utilizing the stereotactic method of placing catheter(s) into the brain through cranial burr holes. Therapeutic agents are delivered through the catheters using microinfusion pumps directly to the brain tumor bypassing the blood-brain barrier. This increases the drug-tumor contact time.

CED is limited by its invasiveness and by the anatomical influences on drug distribution. It requires the insertion of a catheter several centimeters deep into the brain, which can cause tissue damage and may induce air bubbles. The anatomy of the brain affects the distribution of drugs. The unpredictable flow can lead to collection of the drug either in the perivascular spaces, wound track, or under the scalp. This has caused incidences of edema and wound dehiscence.

There are ongoing clinical trials to better understand convection-enhanced delivery and its effect on health outcomes.

*****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

Convection-Enhanced Delivery of Therapeutic Agents to the Brain

Convection-enhanced delivery of therapeutic agents to the brain is considered investigational for all indications. BCBSNC does not provide coverage investigational services or procedures.

Some patients may be eligible for coverage under clinical trials. Refer to the policy on 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 Convection-Enhanced Delivery of Therapeutic Agents to the Brain is covered

Not applicable.

When Convection-Enhanced Delivery of Therapeutic Agents to the Brain is not covered

Convection-enhanced delivery of therapeutic agents to the brain is considered **investigational**.

Policy Guidelines

There continues to be a need for additional research into the use of convection-enhanced delivery of therapeutic agents to the brain to define effective agents and treatment parameters and to compare this treatment to standard medical and surgical care. There is insufficient evidence in the medical literature to demonstrate the safety and efficacy of this technique.

Some patients may be eligible for coverage under clinical trials. Refer to the Corporate Medical Policy titled Clinical Trial Services.

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 service codes: 64999

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

Medical Director review 1/2007.

Specialty Matched Consultant Advisory Panel - 4/2007

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Centers for Medicare and Medicaid Services (CMS). Medicare Coverage Database. NCD for Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors. 2007 Mar 20. Retrieved 1/15/09 from http://www.cms.hhs.gov/MCD/viewncd.asp?ncd_id=110.20&ncd_version=1&basket=ncd%3A110%2E20%3A1%3ABlood+Brain+Barrier+Osmotic+Disruption+for+Treatment+of+Brain+Tumors+%28Effective+March+20%7C%7C+2007%29

Specialty Matched Consultant Advisory Panel - 4/2009

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Retrieved 1/25/11 from http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel – 3/2011

Specialty Matched Consultant Advisory Panel – 3/2012

Barua NU, Bienemann AS, Hesketh S, et al. Intrastriatal convection-enhanced delivery results in widespread perivascular distribution in a pre-clinical model. *Fluids Barriers CNS.* 2012;9(1):2

Fiandaca MS, Forsayeth JR, Dickinson PJ, Bankiewicz KS. Image-guided convection-enhanced delivery platform in the treatment of neurological diseases. *Neurotherapeutics.* 2008 Jan;5(1):123-7.

Specialty Matched Consultant Advisory Panel – 3/2013

Specialty Matched Consultant Advisory Panel – 3/2014

Specialty Matched Consultant Advisory Panel - 3/2015

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Retrieved 3/4/2016 from: http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel - 3/2016

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Retrieved 3/8/2017 from: http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel - 3/2017

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Retrieved 2/28/2018 from: http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel - 3/2018

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National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Retrieved 3/18/2019 from:
http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel - 3/2019

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Retrieved 2/20/2020 from:
http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel 3/2020

Medical Director review 3/2020

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 3.2020-September 11, 2020. Retrieved 3/1/2021 from:
https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel 3/2021

Medical Director review 3/2021

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 2.2021-September 8, 2021. Retrieved 2/9/2022 from:
https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel 3/2022

Medical Director review 3/2022

National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 2.2022-September 29, 2022. Retrieved 2/17/2022 from:
https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

Specialty Matched Consultant Advisory Panel 3/2023

Medical Director review 3/2023

Policy Implementation/Update Information

2/26/07 New policy issued.

5/21/07 Specialty Matched Consultant Advisory Panel review 4/25/2007. No changes to policy statement. References added.

5/18/09 Description section expanded for clarity. Updated rationale for policy in Policy Guidelines section. References updated. Specialty Matched Consultant Advisory Panel review 4/21/09. No changes to policy statement. (btw)

6/22/10 Policy Number(s) removed (amw)

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- 4/26/11 Specialty Matched Consultant Advisory Panel review March 30, 2011. No changes to policy. References added. (btw)
- 4/17/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. No change to policy. (btw)
- 4/16/13 Specialty Matched Consultant Advisory Panel review 3/20/2013. No change to policy. References added. (btw)
- 4/15/14 Specialty Matched Consultant Advisory Panel review 3/25/2014. No change to policy. (btw)
- 4/28/15 Specialty Matched Consultant Advisory Panel review 3/25/2015. No change to policy intent. (lpr)
- 4/29/16 Specialty Matched Consultant Advisory Panel review 3/30/2016. Reference added. No change to policy statement. (lpr)
- 12/30/16 Deleted CPT code 0169T and added unlisted CPT code 64999 to Billing/Coding section for effective date 1/1/2017. (lpr)
- 4/28/17 Specialty Matched Consultant Advisory Panel review 3/29/2017. Reference added. No change to policy statement. (lpr)
- 4/13/18 Specialty Matched Consultant Advisory Panel review 3/28/2018. No change to policy statement. (lpr)
- 4/16/19 Specialty Matched Consultant Advisory Panel review 3/20/2019. Reference added. No change to policy statement. (lpr)
- 3/31/20 Specialty Matched Consultant Advisory Panel review 3/18/2020. Reference added. No change to policy statement. (lpr)
- 4/6/21 Specialty Matched Consultant Advisory Panel review 3/17/2021. Reference added. No change to policy statement. (lpr)
- 4/19/22 Specialty Matched Consultant Advisory Panel review 3/16/2022. Reference added. No change to policy statement. (lpr)
- 3/31/23 Specialty Matched Consultant Advisory Panel review 3/15/2023. Updated description section and references. 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.