Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Monitoring of Regional Cerebral Blood Flow Using an Implanted Cerebral Thermal Perfusion Probe

Policy #: 214
Latest Review Date: September 2023
Category: Medicine
ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **monitoring of regional cerebral blood flow using an implanted cerebral thermal perfusion probe** as a **non-covered benefit** and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination

DESCRIPTION OF PROCEDURE OR SERVICE:

Cerebral blood flow (CBF) is essential for normal metabolism of the brain. Ischemic brain injury occurs when CBF is insufficient to meet metabolic demand, which can occur in acute neurological disorders (e.g. head injury, subarachnoid hemorrhage, or following neurosurgery).

Various imaging techniques have been attempted to identify individuals at risk for secondary ischemic brain injury and manage response to therapies. Some of these techniques are still evolving (e.g., stable-xenon-enhanced computed tomography (XeCT), perfusion computed tomography, perfusion magnetic resonance imaging, single photon emission computed tomography (SPECT) and positron emission tomography (PET)). While these techniques can provide regional information about CBF, the data provided is a single snap shot in time. Methods for the continuous measurement of CBF have been investigated and are now commercially available. One such method is a thermal perfusion probe, which is placed intra-cerebrally via a burr hole in the vascular area of interest in the brain. The probe is connected to a monitor that displays CBF data.

The QFlow 500 probe (Hemedex, Inc, Cambridge, MA) is an example of a commercially available thermal perfusion probe that has received 510(k) marketing clearance from the Food and Drug Administration (FDA). It is used along with the Bowman Perfusion Monitor, Model 500 (Hemedex, Inc, Cambridge, MA). According to the manufactures website, one potential application of the device is for monitoring CBF in patients with traumatic brain injury to help identify secondary ischemic injury to the brain. The manufacturer states that, by measuring continuous, real-time CBF, clinicians may identify cerebral edema and measure tissue blood flow response to therapies. Another potential neurological application is monitoring CBF following neurosurgery (e.g., aneurysm and subarachnoid hemorrhage procedures).

KEY POINTS:

The most recent literature search was performed through September 14, 2023.

Summary of Evidence
Current literature on thermal perfusion probes has focused on their feasibility and technical capabilities. Prospective clinical outcome studies are needed to determine their clinical value over other standard methods of identifying individuals at risk for secondary ischemic brain injury (e.g., head injury, subarachnoid hemorrhage, or following neurosurgery) and in monitoring response to therapies.

KEY WORDS:
Cerebral perfusion, cerebral thermal perfusion probe, Qflow 500™ Perfusion Monitoring System, subarachnoid hemorrhage, transcranial doppler (TCD)

APPROVED BY GOVERNING BODIES:
The Qflow 500™ Perfusion Monitoring System is a cerebral thermal perfusion probe that received FDA clearance through the 510(k) process in 2000. The labeled indication for the device is as follows:

"The QFlow™ is intended for extravascular monitoring of microcirculation blood flow in buried tissues. Examples of this application include (but are not limited to) 1) the monitoring of buried muscle or esophagus following free muscle transfer or esophageal free muscle transfer or esophageal reconstruction, 2) monitoring soft tissue microcirculation following reconstructive surgery, such as oral and facial reconstruction, and 3) monitoring cerebral blood flow during and following neurosurgery for head trauma."

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:
CPT Codes:
There are no specific CPT codes for cerebral thermal perfusion probes. It is likely they are reported with:

61107	Twist drill hole(s) for subdural, intracerebral, or ventricular puncture; for implanting ventricular catheter, pressure recording device, or other intracerebral monitoring device
61210	Burr hole(s); for implanting ventricular catheter, reservoir, EEG electrode(s), pressure recording device, or other cerebral monitoring device (separate procedure)

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POLICY HISTORY:

Adopted for Blue Advantage, January 2006
Available for comment January 26-March 11, 2006
Medical Policy Group, December 2006
Medical Policy Group, December 2007
Medical Policy Group, February 2009

Medical Policy Group, February 2010
Medical Policy Group, October 2019
Medical Policy Group, August 2021
Medical Policy Group, September 2022: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, September 2023: Reviewed by consensus. No new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
