BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 214
Category: Medicine

Latest Review Date: October 2019
Policy Grade: **Effective June 29, 2011: Active Policy but no longer scheduled for regular literature reviews and updates.**

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:

Effective for dates of service on or after March 12, 2006:

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:

Assessment of cerebral perfusion is considered an important component of the management of patients with head trauma, post neurological surgery or strokes of a variety of etiologies, including subarachnoid hemorrhage. For example, cerebrovasospasm leading to decreased cerebral blood flow and ischemia and delayed neurological deterioration is one of the major causes of morbidity and mortality after subarachnoid hemorrhage (SAH). All patients with SAH are initially treated with the calcium channel blocker nifedipine to prevent vasospasm, which typically occurs between Day 5 and Day 14 after the initial bleed. Ongoing assessment of vasospasm is performed during this period to determine the need for additional treatment. If vasospasm is detected, patients may be treated with "Triple H" therapy, consisting of induced hypertension, hypervolemia with colloids and hemodilution. If the vasospasm is marked, persistent, focal, or associated with neurological defects, then the patient may undergo angiogram and angioplasty. Neurological deterioration is an important clinical sign of vasospasm, but neurologic assessment is obviously difficult in sedated or comatose patients.

Bedside transcranial doppler (TCD) is the technique most commonly used to assess cerebral perfusion, but this technique is technically difficult, can take over an hour, visualizes a small proportion of vessels, and not infrequently, cannot be done at all if temporal bone windows are dense. A variety of other techniques have been investigated to measure cerebral perfusion, including numerous protocols for CT scans, PET scans or other radionuclide studies. A major limitation of these techniques is the fact that they cannot be performed at the bedside.

Recently, a cerebral thermal perfusion probe has been investigated, which has the additional advantage of being able to provide continuous bedside monitoring. In contrast to other techniques like TCD, which can assess the entire brain, the thermal perfusion probe will assess regional cerebral blood flow. 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."

The device consists of two thermistors embedded at the distal tip of the probe, which is placed intracerebrally via a burr hole in the vascular area of interest in the brain. The probe is connected to a probe monitor that continuously displays the perfusion data. The power dissipated in the thermistor provides a measure of the ability of the tissue to carry heat by both thermal conduction within the tissue and by thermal convection due to tissue blood flow.

As noted above, the labeled indication for the device is not limited to its intracerebral use. However, this policy is only focused on the intracerebral use of the device to assess cerebral perfusion.

KEY POINTS:

The most recent literature search was performed through October 8, 2019.

Summary of Evidence

There is no gold standard technology for currently measuring cerebral perfusion. While angiography might be considered the gold standard, this test is not routinely performed; rather a variety of noninvasive tests are used to determine the need for angiography. Transcranial Doppler (TCD) is the most commonly performed noninvasive test; however, in the published literature, the diagnostic performance of the cerebral thermal perfusion probe was correlated to xenon-enhanced CT scan (Xe-CT), since this test also provides an absolute measure of cerebral blood flow. The impact of the test on the management of the patient primarily focuses on triaging the patient to various treatment strategies of increasing complexity. For example, in the instance of subarachnoid hemorrhage (SAH), assessment of cerebral perfusion may dictate whether or not the patient requires more aggressive therapy, including the invasive procedures of angiography and angiogram. Finally, the ability of an implanted cerebral infusion probe creates the unique opportunity of providing continuous real time data. The ultimate health outcomes are the morbidity and mortality related to the underlying event, i.e., residual neurologic defects or death.

In the FDA Summary of Safety and Effectiveness of the QFlow 500™ Perfusion Monitoring System, the manufacturer indicates that the device is essentially similar to other perfusion monitors. Measurement of perfusion using thermistors is an established and accepted technology. However, the technical challenge of the cerebral perfusion probe is related to the necessity of distinguishing between thermal conduction and convection. Data analysis of the QFlow 500™ device relies on data reduction algorithms to make this distinction. An additional issue of technical feasibility is the ability to accurately place the probe in the area of vascular interest such that the cerebral perfusion is measured in the critical area. Vasospasm may not be predictably associated with the area of SAH, and may even occur contralateral to the bleed. This aspect of technical feasibility is not specifically addressed in the published literature.

There are minimal published data regarding the diagnostic performance of the cerebral perfusion probe. As noted above, Vajkoczy studied the correlation of the probe compared to xenon-enhanced CT scan. The microprobe was implanted subcortically into 16 brain-injured patients, and cerebral blood flow was assessed simultaneously with the thermal perfusion probe and xenon-enhanced CT scans. The 2 values were highly correlated (R= 0.89). However, it should be noted that the probe was implanted contralateral to the vascular area of interest, and thus, in this validation study, was not intended to provide clinically relevant information. Aside from a correlation with a gold standard, diagnostic performance is based on sensitivity, specificity, and positive and negative predictive values for the presence, absence, or severity of vasospasm, which in turn depend on cut off values to distinguish between a positive and negative test. There is minimal discussion of these diagnostic parameters in the published literature. For example, the availability of continuous monitoring, compared to monitoring with episodic TCD, creates the possibility of assessing the evolution and severity of vasospasm, in contrast to its presence or absence. Cut off values are important to determine when vasospasm is clinically relevant in order to guide treatment decisions.

No published studies were identified that used data from a cerebral thermal perfusion probe to guide treatment decisions. Thome et al used a thermal perfusion probe as a technique for intraoperative monitoring in 20 patients undergoing aneurysm surgery that required temporary arterial occlusion. However, it does not appear that treatment decisions were based on probe data. Vajkoczy et al used a thermal diffusion probe in 14 patients with high grade SAH treated operatively, implanting 2 probes in the vascular territories deemed at highest risk for developing vasospasm. Again, treatment decisions were not based on data from the cerebral perfusion probe.

There are inadequate data to permit scientific conclusions concerning the effect of the technology on health outcomes, and whether or not the use of a cerebral thermal perfusion probe results in an improvement in the net health outcome.

Two small studies were identified that used a thermal diffusion probe for experimental monitoring of cerebral blood flow following traumatic brain injury or subarachnoid hemorrhage. One was a case study and the other was a study with 8 patients. No studies were identified that would alter the coverage statement of this policy.

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.

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)

PREVIOUS CODING:

CPT Codes:

0077T	Implanting and securing cerebral thermal perfusion probe, including twist or burr hole, to measure absolute cerebral tissue perfusion

REFERENCES:

1. Barth M, Capelle HH, et al. Effects of the selective endothelin A (ER(A)) receptor antagonist Clazosentan on cerebral perfusion and cerebral oxygenation following severe subarachnoid hemorrhage – preliminary results from a randomized clinical series. Acta Neurochir 2007; 149(9): 911-918.
2. Blue Cross Blue Shield Association. Monitoring of regional cerebral blood flow using an implanted cerebral thermal perfusion probe. Medical Policy Reference Manual, March 2008.
3. Jaeger M, Soehle M and Meixensberger J. Brain tissue oxygen (PtiO2): A clinical comparison of two monitoring devices. Acta Neurochir Suppl 2005; 95: 79-81. (Abstract)
4. Thome, C., Vajkoczy, P., Horn, P., & et al. Continuous monitoring of regional cerebral blood flow during temporary arterial occlusion in aneurysm surgery. J Neurosurg 2001; 95:402-11.
5. U.S. Food and Drug Administration. 510(k) Summary of Safety and Effectiveness: QFlow™ 500 Perfusion Monitoring System, May 2002. //www.fda.gov.
6. U.S. Food and Drug Administration. 510(k) Summary for CMA Cerebral Tissue Monitoring System. October 2002, //www.fda.gov.
7. Vajkoczy, P., Horn, P., Thome, C., & et al. Regional cerebral blood flow monitoring in the diagnosis of delayed ischemia following aneurismal subarachnoid hemorrhage. J Neurosurg 2003; 98:1227-1234.
8. Vajkoczy, R., Roth, H., Horn, P., & et al. Continuous monitoring of regional cerebral blood flow; experimental and clinical validation of a novel thermal diffusion microprobe. J Neurosurg 2000; 93:265-74.

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
