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

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy #  00150
Original Effective Date:  01/31/2005
Archived Date:  02/15/2012

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers monitoring of regional cerebral perfusion using an implanted cerebral thermal perfusion probe to be investigational.*

**Background/Overview**

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 (SAH). 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. 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 (computed tomography) CT scans, (positron emission tomography) 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 labeled indication for the device is as follows:
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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. Monitoring buried muscle or esophagus following free muscle transfer or esophageal free muscle transfer or esophageal reconstruction, and
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.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
The QFlow 500 Perfusion Monitoring System is a cerebral thermal perfusion probe that received clearance through the 510(k) process in 2002.

Rationale/Source
Evaluation of a diagnostic technology typically consists of three steps:
1. Evaluation of the technical performance of the test; and
2. Diagnostic performance of the test in comparison to a gold standard, and
3. Evaluation of the impact on the clinical management of the patient and a determination of whether the changes in clinical management based on the test result in an improvement of overall health outcomes.

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 is used to determine the need for angiography. 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...
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the patient to various treatment strategies of increasing complexity. For example, in the instance of 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.

Technical Feasibility
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.

Diagnostic Performance of the Test
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 two 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.

Impact of Test on the Management of Patient
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No published studies were identified that used data from a cerebral thermal perfusion probe to guide treatment decisions. Thome and colleagues 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 and colleagues used a thermal diffusion probe in 14 patients with high grade SAH treated operatively, implanting two 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.

A literature search from 2005 through October 2006 identified two small studies (one case report and one study with eight patients) that used a thermal diffusion probe for experimental monitoring of cerebral blood flow following traumatic brain injury or subarachnoid hemorrhage. No studies were identified that would prompt reevaluation of the policy statement.

A literature search from October 2006 through 2008 was conducted and one new study was identified. A thermal diffusion probe was used for experimental monitoring of regional cerebral blood flow following subarachnoid hemorrhage in 12 patients at one institution. The monitoring was conducted alongside the treatment protocol of a phase IIa study of a drug to prevent vasospasm among patients with subarachnoid hemorrhage and was not used to guide treatment. Data are insufficient to change the current coverage statement.

References

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Policy History

Original Effective Date: 01/31/2005
12/07/2004 Medical Director review
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01/31/2005 Managed Care Advisory Council approval
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
01/10/2007 Medical Director review
01/17/2007 Medical Policy Committee approval. Coverage eligibility unchanged.
01/07/2009 Medical Director review
01/14/2009 Medical Policy Committee approval. Coverage eligibility unchanged.
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01/20/2010 Medical Policy Implementation Committee approval. Coverage eligibility unchanged. Coding revision
01/06/2011 Medical Policy Committee review

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01/19/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012 Medical Policy Committee review. Recommend archiving policy.
02/15/2012 Medical Policy Implementation Committee approval. Archived.
Next Scheduled Review Date: Archived Medical Policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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   2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. reference to federal regulations.

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