Important note
Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Monitoring of Regional Cerebral Blood Flow (CBF) Using an Implanted Cerebral Thermal Perfusion Probe

PRIOR AUTHORIZATION: Not applicable.

POLICY: SWHP considers monitoring cerebral blood flow using an implanted cerebral perfusion probe experimental and investigational and is not a covered benefit.

OVERVIEW: Assessment of cerebral perfusion may be a 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, 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 five 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 only 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 thermal perfusion probe has been investigated that has the additional advantage of being able to provide continuous bedside monitoring. In contrast to techniques that can assess the entire brain (e.g., TCD), the thermal perfusion probe will assess regional CBF. The QFlow 500 Perfusion Monitoring SystemTM is a cerebral thermal perfusion probe that received U.S. Food and Drug Administration (FDA) clearance through the 510(k) process in 2002. The labeled indication for the device is as follows:

“The QFlowTM 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.”

This 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.

Monitoring regional CBF using an implanted cerebral thermal perfusion probe is not supported by evidence in the peer-reviewed medical literature that:

• permits conclusions on the effect of regional cerebral thermal perfusion probe monitoring on health outcomes.
• demonstrates an improvement in net health outcome through use of regional cerebral thermal perfusion probe monitoring
• demonstrates that use of regional cerebral thermal perfusion probe monitoring is as beneficial as established alternatives.

MANDATES: None.

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

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CMS: There are no NCDs or LCDs related to this coverage.

Regional Cerebral Blood Flow via Implanted Cerebral Thermal Perfusion Probe.
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POLICY HISTORY:

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REFERENCES:
The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.