Scott&White HEALTH PLAN
PART OF BAYLOR SCOTT & WHITE HEALTH

MEDICAL COVERAGE POLICY

SERVICE:	**Regional Cerebral Blood Flow via Implanted Cerebral Thermal Perfusion Probe**
Policy Number:	**058**
Effective Date:	**12/01/2019**
Last Review:	**09/26/2019**
Next Review Date:	**09/26/2020**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus 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 (EOC) or Summary Plan Description (SPD) 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 Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan 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. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

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 without proven benefit and thus not medically necessary.

OVERVIEW: The brain uses approximately 20% of available oxygen for normal function, which means that tight regulation of blood flow (Cerebral Blood Flow [CBF]) and oxygen delivery is critical for survival. Ischemic brain injury occurs when CBF is insufficient to meet metabolic demand, which can be caused by acute neurological disorders (i.e., head injury, subarachnoid hemorrhage, or following neurosurgery.) (See https://www.ncbi.nlm.nih.gov/books/NBK53082/).

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, , 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.

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 QFlow 500 perfusion monitoring systemTM 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.

In 2016 a new probe called the NeMo Probe was evaluated in pigs. It is a multiparametric brain tissue probe that was developed in Zurich, Switzerland. The NeMo Probe was developed to monitor Intracranial pressure (ICP) and brain temperature monitoring and for determination of cerebral hemodynamis and oxygenation. "Whereas parameters of oxyhemoglobin and deoxyhemoglobin are measured continuously with near-infrared spectroscopy (NIRS), cerebral hemodynamic monitoring is based on a combined NIRS and indocyanine green (ICG) dye dilution method. After intravenous injection of ICG, the NeMo Probe facilitates serial measurements of the mean transit time of the dye (ICG), cerebral blood volume (CBV), and CBF."

Previous studies were conducted that showed that ICG administration followed by near=infrared light exposure is safe when applied for CBF monitoring in animals with disrupted blood –brain barrier. They have also shown proof of concept of NIRS-ICG method in patients with acute brain injury.

This study was conducted, by the authors, to evaluate the performance of the newly developed NeMo Probe compared with the existing QFlow 500 Probe in an experimental pig model allowing for stardardized alterations of arterial blood pressure and oxygenation. Flow 500 Probe into the subcortical white matter. Parallel measurements were recorded during (1) baseline, (2) hypotension, (3) hypertension, and (4) hyperventilation. Thereafter, protocol points 1 through 4 were repeated once. The results demonstrated poor agreement between absolute CBF values obtained by the 2 methods.

This experiment showed that the CBF NeMo vs. CBF QFlow indicated that the NeMo Probe underread the QFlow 500 Probe. The findings clearly demonstrated that absolute CBF values obtained by the NeMo Probe cannot be interpreted as equivalent to those of the QFlow 500 Probe. Reliable trending ability of CBF is an important issue for the clinical routine to guide therapy, whether it is detection of secondary ischemic events or guidance of therapeutic interventions.

"This preliminary study demonstrates that absolute CBF values measured with the NeMo Probe cannot be interpreted as equivalent to the values measured by the existin QFlow 500 Probe. On the other hand, the NeMo Probe offers acceptable trending ability during standardized changes in blood pressure and ventilation parameters, as well as acceptable reproducibility of measurement values from repeated measurements under comparable physiological conditions. Future clinical studies with multimodal neuromonitoring are warranted to evaluate the NeMo Probe in the setting of acute brain injury." (See https://academic.oup.com/neurosurgery/article/79/6/905/2837408/Evaluation-of-a-New-Brain-Tissue-Probe-for?searchresult=1).

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.

CPT Codes:	
CPT Not Covered:	61107 – Twist drill hole(s) for subdural, intracerebrak. Or ventricular puncture; for implanting ventricular catheter, pressure recording device, or other intracerebral monitoring device 61210 – Burr hole(s); for implanting ventricular catheter, reservoir, EED electrode(s), pressure recording device, or other cerebral monitoring device (separate procedure) 0042T – Cerebral perfusion analysis using computed tomography with contrast administration, including post-processing of parametric maps with determination of cerebral blood flow, cerebral blood volume, and mean transit time.
ICD-10 codes:	
ICD-10 Not covered:	G00.0 – G09 - Inflammatory disease of the central nervous system G11.0 – G13.8 – Systematic atrophies primarily affecting the central nervous system

	G30.0 – G32.8 – Other degenerative diseases of the nervous system G45.0 – G45.9- Transient cerebral ischemic attacks and related syndromes G46.0 – G46.8- Vascular syndromes of brain in cerebrovascular diseases G90.01 – G99.2 – Other disorders of the nervous system I60.0 – I60.9 – Nontraumatic subarachnoid hemorrhage I67.0-I67.9 – Other cerebrovascular diseases S02.0xx – S02.413- Fracture of skull and facial bones, with or without intracranial injury S06.0x0 – S06.9x9 – Intracranial injury excluding those with skull fracture

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

POLICY HISTORY:

Status	Date	Action
New	12/6/2010	New policy
Reviewed	6/6/2011	Reviewed.
Reviewed	12/6/2011	No changes
Reviewed	11/15/2012	No changes
Reviewed	11/14/2013	No changes.
Reviewed	11/6/2014	No changes.
Reviewed	10/22/2015	No changes.
Reviewed	10/27/2016	No changes.
Reviewed	09/26/2017	Reviewed. Overview, codes and references updated
Reviewed	07/03/2018	No changes.
Reviewed	09/26/2019	No changes.

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.

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4. Jaeger, M., Soehle, M., et. al. Correlation of continuously monitored regional cerebral blood flow and brain tissue oxygen. Acta Neurochirurgica (Wien) (2005) 147(1):51-6.
5. Barth, M., Capelle, H.H., et al, Effects of the selective endothelin A (ET A) receptor antagonist clazosentan on c perfusion and cerebral oxygenation following severe subarachnoid hemmorhage – preliminary results from a randomized clinical series. Acta Neurochir (Wien) 2007; 149 (9):911-8.

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11. Seule, M, Isaak, R, Sanchez-Porras, R, et.al, Evaluation of a New Brain Tissue Probe for Cerebral Blood Flow Monitoring in an Experimental Pig Model, Neurosurgery: Volume 79, Number 6, December 2016. May be accessed online at https://academic.oup.com/neurosurgery/article/79/6/905/2837408/Evaluation-of-a-New-Brain-Tissue-Probe-for?searchresult=1 Last accessed 9/22/2017.
12. Tasneem N, Samaniego EA, Pieper C, et al. Brain multimodality monitoring: A new tool in neurocritical care of comatose patients. Crit Care Res Pract. 2017;2017:6097265.