FEP 7.01.58 Intraoperative Neurophysiologic Monitoring

Description
Intraoperative neurophysiologic monitoring (IONM) describes a variety of procedures that have been used to monitor the integrity of neural pathways during high-risk neurosurgical, orthopedic, and vascular surgeries. It involves the detection of electrical signals produced by the nervous system in response to sensory or electrical stimuli to provide information about the functional integrity of neuronal structures.

FDA REGULATORY STATUS
A number of electroencephalography and electromyography monitors have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA product code: GWQ. Intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation does not have FDA approval.

POLICY STATEMENT
Intraoperative monitoring, which includes somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography (EMG) of cranial nerves, electroencephalography, and electrocorticography, may be considered medically necessary during spinal, intracranial, or vascular procedures.

Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered medically necessary in patients undergoing:

- high risk thyroid or parathyroid surgery, including:
  - total thyroidectomy
  - repeat thyroid or parathyroid surgery
  - surgery for cancer
  - thyrotoxicosis
  - retrosternal or giant goiter
  - thyroiditis

- anterior cervical spine surgery associated with any of the following increased risk situations:
  - prior anterior cervical surgery, particularly revision anterior cervical discectomy and fusion, revision surgery through a scarred surgical field, reoperation for pseudarthrosis or revision for failed fusion
  - multilevel anterior cervical discectomy and fusion
  - time consuming anterior cervical discectomy and fusion (eg, tumor)

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- preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve.

Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during anterior cervical spine surgery not meeting the criteria above or during esophageal surgeries is considered investigational.

Intraoperative monitoring of visual-evoked potentials is considered investigational.

Due to the lack of U.S. Food and Drug Administration approval, intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered investigational.

Intraoperative EMG and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered not medically necessary.

Note: These policy statements refer only to use of these techniques as part of intraoperative monitoring. Other clinical applications of these techniques, such as visual-evoked potentials and EMG, are not considered in this policy.

POLICY GUIDELINES

Intraoperative monitoring including somatosensory-evoked potentials and motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography of cranial nerves, electroencephalography, and electrocorticography has broad acceptance, particularly for spine surgery and open abdominal aorta aneurysm repairs. Therefore, this evidence review focuses on monitoring of the recurrent laryngeal nerve during neck surgeries and monitoring of peripheral nerves. Constant communication between surgeon, neurophysiologist, and anesthetist are required for safe and effective intraoperative neurophysiologic monitoring.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who are undergoing thyroid or parathyroid surgery who are at high risk of injury to the recurrent laryngeal nerve who receive IONM, the evidence includes a large RCT and systematic reviews. Relevant outcomes are morbid events, functional outcomes, and quality of life. The strongest evidence on neurophysiologic monitoring is from an RCT of 1000 patients undergoing thyroid surgery. This RCT found a significant reduction in RLN injury in patients at high risk for injury. High risk in this study was defined as surgery for cancer, thyrotoxicosis, retrosternal or giant goiter, or thyroiditis. The high risk category may also include patients with prior thyroid or parathyroid surgery or total thyroidectomy. A low volume of surgeries may also contribute to a higher risk for recurrent laryngeal nerve injury. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. For individuals who are undergoing anterior cervical spine surgery who are at high risk of injury to the recurrent laryngeal nerve who receive IONM, the evidence includes systematic reviews of case series and cohort studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. A qualitative systematic review found moderate evidence that monitoring the endotracheal cuff pressure reduced the incidence of vocal cord palsy, but there was insufficient data to recommend the routine use of EMG. A 2016 meta-analysis found a high rate of RLN injury following revision anterior cervical discectomy and fusion, but the magnitude of the problem with current surgical procedures is uncertain. No studies were identified that evaluated whether IONM reduces RLN injury in anterior cervical spine surgeries. The evidence is insufficient to determine the effects of the technology on health outcomes.
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For individuals who are undergoing esophageal surgery who are at high risk of injury to the recurrent laryngeal nerve who receive IONM, the evidence includes a non-randomized comparative study. Relevant outcomes are morbid events, functional outcomes, and quality of life. One non-randomized comparative study on surgery for esophageal cancer was identified. This study is confounded because only the patients who had visual identification of the nerve underwent neurophysiologic monitoring. There is insufficient evidence to evaluate whether neurophysiologic monitoring reduces RLN injury in patients undergoing surgery for esophageal cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are undergoing surgery in proximity to a peripheral nerve who receive IONM, the evidence includes case series and a controlled cohort study. Relevant outcomes are morbid events, functional outcomes, and quality of life. Surgical guidance with peripheral IONM and the predictive ability of monitoring of peripheral nerves has been reported. No prospective comparative studies were identified that assessed whether outcomes are improved with neurophysiologic monitoring. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Association of Neurological Surgeons and Congress of Neurological Surgeons
A 2012 position statement on electrophysiologic monitoring during routine spinal surgery by the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) stated that intraoperative electrophysiologic monitoring during spinal surgery may assist in diagnosing neurologic injury. However, AANS and CNS found no evidence that such monitoring either (1) reduces the incidence of neurologic injury or (2) mitigates the severity of it. The position offered by AANS and CNS is that routine use of intraoperative electrophysiologic monitoring is neither warranted nor recommended, although intraoperative electrophysiologic monitoring should be performed if the diagnostic information gained is of value, particularly in high-risk cases such as deformity, gross instability, navigation through or around peripheral nerves, or intramedullary procedures.

A 2014 guideline update from AANS and CNS found no evidence that would conflict with their previous recommendations for intraoperative monitoring for lumbar fusion. The societies found no evidence that intraoperative monitoring can prevent injury to the nerve roots. They found limited evidence that intraoperative monitoring can indicate a medial pedicle breach by a pedicle screw, but once a nerve root injury has taken place, changing the direction of the screw does not alter the outcome.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

EEG monitoring “may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted.” Coverage determinations for other modalities were not identified.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
31. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Electroencephalographic monitoring During Surgical Procedures Involving the Cerebral Vasculature (160.8). http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=77&ncdver=2&CovSelection=National&KeyWord=monitoring&KeyWordLookUp=Title&KeyWordLookUp=Title&KeyWordSearchType=And&KeyWordSearchType=And&KeyWordSearchType=And&KeyWordSearchType=And&KeyWordSearchType=And&KeyWordSearchType=And&KeyWordSearchType=And&KeyWordSearchType=And&bc=gAAAAACAAAAA&. Accessed March, 2015.

POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review; references added and reordered; policy statements unchanged.</td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, references 10-14, 16-18, 22, 24, and 25 added; policy statements unchanged.</td>
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<tr>
<td>September 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 12, 13, 15, and 22 added; policy statements unchanged.</td>
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<tr>
<td>June 2017</td>
<td>Revise Policy</td>
<td>Policy updated with literature review through October 11, 2016; references added and some references removed. New clinical input obtained in 2017 is added regarding cervical spine surgery. Intraoperative monitoring is considered medically necessary for high risk thyroid and anterior cervical spine surgeries. Title changed to “Intraoperative Neurophysiologic Monitoring.”</td>
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