Intraoperative Neurophysiologic Monitoring

Description

Intraoperative neurophysiologic monitoring describes a variety of procedures 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. This evidence review does not address established neurophysiologic monitoring (i.e., somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography of cranial nerves, electroencephalography, electrocorticography), during spinal, intracranial, or vascular procedures.

OBJECTIVE

The objective of this evidence review is to determine whether neurophysiologic monitoring improves the net health outcome in patients during surgeries that could damage their recurrent laryngeal nerve or peripheral nerves. 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 electromyography, are not considered in this policy.
POLICY STATEMENT

Intraoperative neurophysiologic monitoring, which includes somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography 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
  - 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 monitors approved by the U.S. Food and Drug Administration, intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered investigational.

Intraoperative electromyography 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 electromyography, are not considered in this policy.

POLICY GUIDELINES

Intraoperative neurophysiologic 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 among the surgeon, neurophysiologist, and anesthetist is 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).

Intraoperative neurophysiologic monitoring is considered reimbursable as a separate service only when a licensed health care practitioner, other than the operating surgeon, interprets the monitoring. The monitoring is performed by a health care practitioner or technician who is in attendance in the operating room throughout the procedure.

Coding for intraoperative monitoring uses time-based codes; they are not based on the number (single vs. multiple) of modalities used.

FDA REGULATORY STATUS

A number of EEG and EMG monitors have been cleared for marketing by the FDA through the 510(k) process. FDA product code: GWQ.

Intraoperative neurophysiologic monitoring of motor-evoked potentials using transcranial magnetic stimulation does not have the FDA approval.

RATIONALE

Summary of Evidence

For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve who receive intraoperative neurophysiologic monitoring, the evidence includes a large randomized controlled trial (RCT) and systematic reviews. Relevant outcomes are morbid events, functional outcomes, and quality of life. The strongest evidence on neurophysiologic monitoring derives from a RCT of 1000 patients undergoing thyroid surgery. This RCT found a significant reduction in recurrent laryngeal nerve injury in patients at high-risk for injury. High-risk in this trial 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 might also contribute to a higher risk for recurrent laryngeal nerve injury. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing anterior cervical spine surgery and are at high-risk of injury to the recurrent laryngeal nerve who receive intraoperative neurophysiologic monitoring, the evidence includes systematic reviews of case series and cohort studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. The evidence on the use of intraoperative neurophysiologic monitoring to reduce recurrent laryngeal nerve injury during cervical spinal surgery includes a 2017 systematic review and a meta-analysis. Of the 10 studies assessed in the systematic review, 2 compared the risk of nerve injury with use of intraoperative neurophysiologic monitoring versus no intraoperative neurophysiologic monitoring and found no difference. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing esophageal surgery who receive intraoperative neurophysiologic monitoring, the evidence includes a nonrandomized comparative study. Relevant outcomes are morbid events, functional outcomes, and quality of life. One nonrandomized comparative study on surgery for esophageal cancer was identified. Interpretation of this study is confounded because only those patients who had visual identification of the nerve underwent neurophysiologic monitoring. Current evidence is not sufficiently robust to determine whether neurophysiologic monitoring reduces recurrent laryngeal nerve injury in patients undergoing surgery for esophageal cancer. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing surgery proximal to a peripheral nerve who receive intraoperative neurophysiologic monitoring, 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 intraoperative neurophysiologic monitoring and the predictive ability of monitoring of peripheral nerves have been reported. No prospective comparative studies were identified that assessed whether outcomes are improved with neurophysiologic monitoring. The evidence is insufficient to determine.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in "Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines issued by these entities.
In 2012, the American Academy of Neurology (AAN) published an assessment of intraoperative neurophysiologic monitoring, with an evidence-based guideline update by the AAN and ACNS (2012).1,2 The 1990 assessment indicated that monitoring requires a team approach with a well-trained physician-neurophysiologist to provide or supervise monitoring. Electroencephalogram (EEG) monitoring is used during carotid endarterectomy or for other similar situations in which cerebral blood flow is at high risk. Electroencephalography from surgically exposed cortex can help to define the optimal limits of surgical resection or identify regions of greatest impairment, while sensory cortex somatosensory-evoked potentials can help to localize the central fissure and motor cortex. Auditory-evoked potentials, along with cranial nerve monitoring can be used during posterior fossa neurosurgical procedures. Spinal cord somatosensory-evoked potentials are frequently used to monitor the spinal cord during orthopedic or neurosurgical procedures around the spinal cord, or cross-clamping of the thoracic aorta. Electromyographic monitoring during procedures near the roots and peripheral nerves can be used to warn of excessive traction or other impairment of motor nerves. At the time of the 1990 assessment, motor-evoked potentials were considered investigational by many neurophysiologists. The 2012 update, which was endorsed by the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), concluded that the available evidence supported intraoperative neurophysiologic monitoring using somatosensory-evoked potentials or motor-evoked potentials when conducted under the supervision of a clinical neurophysiologist experienced with intraoperative neurophysiologic monitoring. Evidence was insufficient to evaluate intraoperative neurophysiologic monitoring when conducted by technicians alone or by an automated device.

In 2012, the AAN published a model policy on principles of coding for intraoperative neurophysiologic monitoring and testing.25 The background section of this document provides the following information on the value of intraoperative neurophysiologic monitoring in averting neural injuries during surgery:

1. "Value of EEG Monitoring in Carotid Surgery. Carotid occlusion, incident to carotid endarterectomies, poses a high-risk for cerebral hemispheric injury. Electroencephalogram (EEG) monitoring is capable of detecting cerebral ischemia, a serious prelude to injury. Studies of continuous monitoring established the ability of electroencephalogram EEG to correctly predict risks of postoperative deficits after a deliberate, but necessary, carotid occlusion as part of the surgical procedure. The surgeon can respond to adverse EEG events by raising blood pressure, implanting a shunt, adjusting a poorly functioning shunt, or performing other interventions.

2. Multicenter Data in Spinal Surgeries. An extensive multicenter study conducted in 1995 demonstrated that [intraoperative neurophysiologic monitoring] using [sensory-evoked potentials] reduced the risk of paraplegia by 60% in spinal surgeries. The incidence of false negative cases, wherein an operative complication occurred without having been detected by the monitoring procedure, was small: 0.06%.

3. Technology Assessment of Monitoring in Spinal Surgeries. A technology assessment by the McGill University Health Center...reviewed 11 studies and concluded that spinal [intraoperative neurophysiologic monitoring] is capable of substantially reducing injury in surgeries that pose a risk to spinal cord integrity. It recommended combined sensory-evoked potentials/motor-evoked potential monitoring, under the presence or constant availability of a monitoring physician, for all cases of spinal surgery for which there is a risk of spinal cord injury.

4. Value of Combined Motor and Sensory Monitoring. Numerous studies of post-surgical paraparesis and quadriaparesis have shown that both sensory-evoked potentials and motor-evoked potential monitoring had predicted adverse outcomes in a timely fashion. The timing of the predictions allowed the surgeons the opportunity to intervene and prevent adverse outcomes. The 2 different techniques (sensory-evoked potentials and motor-evoked potential) monitor different spinal cord tracts. Sometimes, one of the techniques cannot be used for practical purposes, for anesthetic reasons, or because of preoperative absence of signals in those pathways. Thus, the decision about which of these techniques to use needs to be tailored to the individual patient's circumstances.

5. Protecting the Spinal Cord from Ischemia during Aortic Procedures. Studies have shown that [intraoperative neurophysiologic monitoring] accurately predicts risks for spinal cord ischemia associated with clamping the aorta or ligating segmental spinal arteries. [Intraoperative neurophysiologic monitoring] can assess whether the spinal cord is tolerating the degree of relative ischemia in these procedures. The surgeon can then respond by raising blood pressure, implanting a shunt, re-implanting segmental vessels, draining spinal fluid, or through other interventions...

6. Value of EMG [electromyogram] monitoring. Selective posterior rhizotomy in cerebral palsy significantly reduces spasticity, increases range of motion, and improves functional skills. Electromyography during this procedure can assist in selecting specific dorsal roots to transect. Electromyogram (EMG) can also be used in peripheral nerve procedures that pose a risk of injuries to nerves...

7. Value of Spinal Monitoring using somatosensory-evoked potentials and motor-evoked potentials. According to a recent review of spinal monitoring using somatosensory-evoked potential and motor-evoked potentials by the Therapeutics and Technology Assessment Subcommittee of AAN and ACNS, [intraoperative neurophysiologic monitoring] is established as effective to predict an increased risk of the adverse outcomes of paraparesis, paraplegia, and quadriplegia in spinal surgery (4 Class I and 7 Class II studies). Surgeons and other members of the operating team should be alerted to the increased risk of severe adverse neurologic outcomes in patients with important [intraoperative neurophysiologic monitoring] changes (Level A)."

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The AAN model policy also offered guidance on personnel and monitoring standards for intraoperative neurophysiologic monitoring and somatosensory-evoked potential.

**American Association of Neurological Surgeons and Congress of Neurological Surgeons**

In 2018, the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons updated their position statement on intraoperative neurophysiologic monitoring during routine spinal surgery. The recommendations indicated that intraoperative sensory-evoked potentials have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts. The AANEM stated that intraoperative sensory-evoked potential monitoring is indicated for select spine surgeries in which there is a risk of additional nerve root or spinal cord injury. Indications for sensory-evoked potential monitoring may include, but are not limited to, complex, extensive, or lengthy procedures, and when mandated by hospital policy. However, intraoperative sensory-evoked potential monitoring may not be indicated for routine lumbar or cervical root decompression.

**American Association of Neuromuscular & Electrodiagnostic Medicine**

In 2017, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) updated their position statement on electrodiagnostic medicine. The recommendations indicated that intraoperative sensory-evoked potentials have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts. The AANEM stated that intraoperative sensory-evoked potential monitoring is indicated for select spine surgeries in which there is a risk of additional nerve root or spinal cord injury. Indications for sensory-evoked potential monitoring may include, but are not limited to, complex, extensive, or lengthy procedures, and when mandated by hospital policy. However, intraoperative sensory-evoked potential monitoring may not be indicated for routine lumbar or cervical root decompression.

**American Clinical Neurophysiology Society**

In 2009, the American Clinical Neurophysiology Society (ACNS) recommended standards for intraoperative neurophysiologic monitoring. Guideline 11A included the following statement:

"The monitoring team should be under the direct supervision of a physician with training and experience in neurophysiologic intraoperative monitoring. The monitoring physician should be licensed in the state and privileged to interpret neurophysiologic testing in the hospital in which the surgery is being performed. He/she is responsible for real-time interpretation of neurophysiologic intraoperative monitoring data. The monitoring physician should be present in the operating room or have access to intraoperative neurophysiologic monitoring data in real-time from a remote location and be in communication with the staff in the operating room. There are many methods of remote monitoring, however any method used must conform to local and national protected health information guidelines. The specifics of this availability (ie, types of surgeries) should be decided by the hospital credentialing committee. In order to devote the needed attention, it is recommended that the monitoring physician interpret no more than three cases concurrently."

**American Society of Neurophysiological Monitoring**

In 2018, the American Society of Neurophysiological Monitoring (ASNM) published practice guidelines for the supervising professional on intraoperative neurophysiologic monitoring. The ASNM (2013) position statement on intraoperative motor-evoked potential monitoring indicated that motor-evoked potentials are an established practice option for cortical and subcortical mapping and monitoring during surgeries risking motor injury in the brain, brainstem, spinal cord, and facial nerve.

**National Institute for Health and Care Excellence**

In 2008, a guidance from the National Institute for Health and Care Excellence on intraoperative neurophysiologic monitoring during thyroid surgery found no major safety concerns. Regarding efficacy, intraoperative neurophysiologic monitoring was indicated as helpful "in performing more complex operations such as reoperative surgery and operations on large thyroid glands."

**U.S. Preventive Services Task Force Recommendations**

Not applicable.
Medicare National Coverage

The Centers for Medicare & Medicaid Services has indicated that 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.

The Centers for Medicare & Medicaid Services Physician Fee Schedule Final Rule (2013) discussed payment of neurophysiologic monitoring. The rule states that CPT code 95940, which is reported when a physician monitors a patient directly, is payable by Medicare. CPT code 95941, which is used for remote monitoring, was made invalid for submission to Medicare.

In the Final Rule, the Centers established a HCPCS G code (see Policy Guidelines section) for reporting physician monitoring performed from outside of the operating room (nearby or remotely). HCPCS code G0453 "may be billed only for undivided attention by the monitoring physician to a single beneficiary [1:1 technologist to oversight physician billing], and not for simultaneous attention by the monitoring physician to more than one patient."

REFERENCES


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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

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<td>Replace policy</td>
<td>Policy updated with literature review; references added and reordered; policy statements unchanged.</td>
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<td>September 2014</td>
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<td>Policy updated with literature review; references 10-14, 16-18, 22, 24, and 25 added; policy statements unchanged.</td>
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<td>Policy updated with literature review through October 11, 2016; references added and some references removed. Intraoperative monitoring is considered medically necessary for high risk thyroid and anterior cervical spine surgeries. Title changed to &quot;Intraoperative Neurophysiologic Monitoring.&quot;</td>
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<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 23, 2018; references 8, 10, and 14 added; references 6-7 updated. Policy statements unchanged.</td>
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<td>June 2019</td>
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<td>Policy updated with literature review through February 18, 2019; references added. Policy statements unchanged.</td>
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