BlueCross BlueShield Federal Employee Program.

FEP 7.01.58 Intraoperative Neurophysiologic Monitoring

Effective Date: July 15, 2018 **Related Policies:** None

Intraoperative Neurophysiologic Monitoring

Description

Intraoperative neurophysiologic monitoring (IONM) 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 (ie, 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.

FDA REGULATORY STATUS

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

IONM of MEPs using transcranial magnetic stimulation does not have FDA approval.

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).

RATIONALE

Summary of Evidence

For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the RLN 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 derives from a randomized controlled trial of 1000 patients undergoing thyroid surgery. This randomized controlled trial found a significant reduction in RLN 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 RLN 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 and are at high risk of injury to the RLN 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. The evidence on the use of IONM to reduce RLN injury during cervical spinal surgery includes a 2017 systematic review and a meta-analysis. Of the 10 studies assessed in the systematic review, two compared the risk of nerve injury with use of IONM vs no IONM and found no difference. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are undergoing esophageal surgery who receive IONM, 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 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 proximal 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 have 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

The 2012 position statement on electrophysiologic neurophysiologic monitoring (IONM) during routine spinal surgery by the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), updated in 2014, has stated that IONM may assist in diagnosing neurologic injury.[5] 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 taken by AANS and CNS indicated that routine use of IONM is neither warranted nor recommended, although IONM 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. In the 2014 update, AANS and CNS found no evidence that would conflict with their previous recommendations for IONM for lumbar fusion.[6,24] The societies found no evidence that IONM can prevent injury to the nerve roots. They found limited evidence that IONM 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.

American Association of Neuromuscular & Electrodiagnostic Medicine

A 2014 position statement on somatosensory-evoked potentials (SSEPs) from the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) has indicated that intraoperative sensory-evoked potentials (SEPs) have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts.[7] AANEM stated that intraoperative SEP monitoring is indicated for select spine surgeries in which there is a risk of additional nerve root or spinal cord injury. Indications for SEP

monitoring may include, but are not limited to, complex, extensive, or lengthy procedures, and when mandated by hospital policy. However, intraoperative SEP 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 IONM.[4] Guideline 11A included the following statement[25]:

> "The monitoring team should be under the direct supervision of a physician with training and experience in NIOM [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 NIOM data. The monitoring physician should be present in the operating room or have access to NIOM 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 monitoring physician must be available to be in the operating room, and 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 Academy of Neurology

The American Academy of Neurology (AAN) published an assessment of IONM in 1990, with an evidence-based guideline update in 2012 by the AAN and ACNS.[1,2] The 1990 assessment indicated that monitoring requires a team approach with a well-trained physician-neurophysiologist to provide or supervise monitoring. Electroencephalography (EEG) monitoring is used during carotid endarterectomy or for other similar situations in which cerebral blood flow is at high risk. Electrocorticography from surgically exposed cortex can help to define the optimal limits of a surgical resection or identify regions of greatest impairment, while sensory cortex SSEPs 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 SSEPs 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 (EMG) 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 (MEPs) were considered investigational by many neurophysiologists. The 2012 update, which was endorsed by AANEM, concluded that the available evidence supported IONM using SSEPs or MEPs when conducted under the supervision of a clinical neurophysiologist experienced with IONM. Evidence was insufficient to evaluate IONM when conducted by technicians alone or by an automated device.

AAN published a model policy on principles of coding for IONM and testing in 2012.[26] The background section of this document provides the following information on the value of IONM 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. EEG monitoring is capable of detecting cerebral ischemia, a serious prelude to injury. Studies of continuous monitoring established the ability of 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 IOM [intraoperative neurophysiologic monitoring] using SEP 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 IOM is capable of substantially reducing injury in surgeries that pose a risk to spinal cord integrity. It recommended combined SEP/MEP 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 quadriparesis have shown that both SEP and MEP 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 two different techniques (SEP and MEP) 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 IOM accurately predicts risks for spinal cord ischemia associated with clamping the aorta or ligating segmental spinal arteries. IOM 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 [electromyography] 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. EMG can also be used in peripheral nerve procedures that pose a risk of injuries to nerves.
7. Value of Spinal Monitoring using SSEP and MEPs. According to a recent review of spinal monitoring using SSEP and MEPs by the Therapeutics and Technology Assessment Subcommittee of AAN and ACNS, IOM 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 IOM changes (Level A)."

The AAN model policy also offered guidance on personnel and monitoring standards for IONM and SSEP.

American Society of Neurophysiological Monitoring

In 2013, the American Society of Neurophysiological Monitoring published practice guidelines on the supervising professional on IONM.[3] The Society's 2013 position statement on intraoperative MEP monitoring indicated that MEPs are an established practice option for cortical and subcortical mapping and for monitoring during surgeries risking motor injury in the brain, brainstem, spinal cord or facial nerve.[27]

National Institute for Health and Care Excellence

A 2008 guidance from the National Institute for Health and Care Excellence on IONM during thyroid surgery found no major safety concerns.[28] In terms of efficacy, IONM 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 (MS) 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."[29] Coverage determinations for other modalities were not identified.

For 2013, the CMS Physician Fee Schedule Final Rule 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, CMS 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."[30]

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POLICY HISTORY

Date	Action	Description

December 2011	New Policy	
March 2013	Update Policy	Policy updated with literature review; references added and reordered; policy statements unchanged.
September 2014	Update Policy	Policy updated with literature review, references 10-14, 16-18, 22, 24, and 25 added; policy statements unchanged.
September 2015	Update Policy	Policy updated with literature review; references 12, 13, 15, and 22 added; policy statements unchanged.
June 2017	Update Policy	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 “Intraoperative Neurophysiologic Monitoring.”
June 2018	Update Policy	Policy updated with literature review through February 23, 2018; references 8, 10, and 14 added; references 6-7 updated. Policy statements unchanged.