

Protocol

Intraoperative Neurophysiologic Monitoring

(70158)

Medical Benefit		Effective Date: 10/01/17	Next Review Date: 05/19
Preauthorization	No	Review Dates: 03/13, 05/13, 05/14, 05/15, 05/16, 05/17, 07/17, 05/18	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • Who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve	Interventions of interest are: • Intraoperative neurophysiologic monitoring	Comparators of interest are: • Surgery without neurophysiologic monitoring	Relevant outcomes include: • Morbid events • Functional outcomes • Quality of life
Individuals: • Who are undergoing anterior cervical spine surgery and are at high risk of injury to the recurrent laryngeal nerve	Interventions of interest are: • Intraoperative neurophysiologic monitoring	Comparators of interest are: • Surgery without neurophysiologic monitoring	Relevant outcomes include: • Morbid events • Functional outcomes • Quality of life
Individuals: • Who are undergoing esophageal surgery	Interventions of interest are: • Intraoperative neurophysiologic monitoring	Comparators of interest are: • Surgery without neurophysiologic monitoring	Relevant outcomes include: • Morbid events • Functional outcomes • Quality of life
Individuals: • Who are undergoing surgery proximal to a peripheral nerve	Interventions of interest are: • Intraoperative neurophysiologic monitoring	Comparators of interest are: • Surgery without neurophysiologic monitoring	Relevant outcomes include: • Morbid events • Functional outcomes • Quality of life

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 protocol 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.

SUMMARY OF EVIDENCE

For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve (RLN) who receive IONM, 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 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 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. A qualitative systematic review found moderate evidence that monitoring endotracheal cuff pressure reduced the incidence of vocal cord palsy, but there was insufficient data to recommend the routine use of electromyography. 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.

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. 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 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.

In 2017, clinical input was also supportive of IONM of the RLN during 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 RLN pathology, when there is residual function of the RLN.

POLICY

Intraoperative neurophysiologic monitoring, which includes somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography (EMG) of cranial nerves, electroencephalography (EEG), and electrocorticography (ECoG), 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 of 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 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 protocol.

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 protocol 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.

Intraoperative monitoring is considered a separate service only when a licensed healthcare practitioner, other than the operating surgeon, interprets the monitoring. The provision/monitoring of the sensory procedure is performed by a healthcare practitioner or technician who is in attendance in the operating room throughout the procedure.

Intraoperative monitoring performed remotely would be provided in conjunction with the healthcare provider who is providing/monitoring the sensory test in the operating room, by the remote physician whose attention is directed solely on one patient. Those providing the intraoperative monitoring services must have the proper training to do so whether providing real-time review and interpretation on-site versus remote.

BACKGROUND

INTRAOPERATIVE NEUROPHYSIOLOGIC MONITORING

The principal goal of IONM is identification of nervous system impairment on the assumption that prompt intervention will prevent permanent deficits. Correctable factors at surgery include circulatory disturbance, excess compression from retraction, bony structures, hematomas, or mechanical stretching. The technology is continuously evolving with refinements in equipment and analytic techniques, including recording, with several patients monitored under the supervision of a physician who is outside the operating room.

The different methodologies of monitoring are described next.

Sensory-Evoked Potentials

Sensory-evoked potential (SEP) describes the responses of the sensory pathways to sensory or electrical stimuli. Intraoperative monitoring of SEPs is used to assess the functional integrity of central nervous system (CNS) pathways during surgeries that put the spinal cord or brain at risk for significant ischemia or traumatic injury. The basic principles of SEP monitoring involve identification of a neurologic region at risk, selection and stimulation of a nerve that carries a signal through the at-risk region, and recording and interpretation of the signal at certain standardized points along the pathway. Monitoring of SEPs is commonly used during the following procedures: carotid endarterectomy, brain surgery involving vasculature, surgery with distraction compression or ischemia of the spinal cord and brainstem, and acoustic neuroma surgery. SEPs can be further broken down into the following categories by type of stimulation used.

Somatosensory-Evoked Potentials

Somatosensory-evoked potentials (SSEPs) are cortical responses elicited by peripheral nerve stimulations. Peripheral nerves, such as the median, ulnar, or tibial nerves, are typically stimulated, but, in some situations, the spinal cord may be stimulated directly. Recording is done either cortically or at the level of the spinal cord above the surgical procedure. Intraoperative monitoring of SSEPs is most commonly used during orthopedic or neurologic surgery to prompt intervention to reduce surgically induced morbidity and/or to monitor the level of anesthesia. One of the most common indications for SSEP monitoring is in patients undergoing corrective surgery for scoliosis. In this setting, SSEP monitors the status of the posterior column pathways and thus does not reflect ischemia in the anterior (motor) pathways. Several different techniques are commonly used, including stimulation of a relevant peripheral nerve with monitoring from the scalp, from interspinous ligament needle electrodes, or from catheter electrodes in the epidural space.

Brainstem Auditory-Evoked Potentials

Brainstem auditory-evoked potentials (BAEPs) are generated in response to auditory clicks and can define the functional status of the auditory nerve. Surgical resection of a cerebellopontine angle tumor, such as an acoustic neuroma, places the auditory nerves at risk, and BAEPs have been extensively used to monitor auditory function during these procedures.

Visual-Evoked Potentials

Visual-evoked potentials (VEPs) with light flashes are used to track visual signals from the retina to the occipital cortex. VEP monitoring has been used for surgery on lesions near the optic chiasm. However, VEPs are very difficult to interpret due to their sensitivity to anesthesia, temperature, and blood pressure.

Motor-Evoked Potentials

Motor-evoked potentials (MEPs) are recorded from muscles following direct or transcranial electrical stimulation of motor cortex or by pulsed magnetic stimulation provided by a coil placed over the head. Peripheral motor responses (muscle activity) are recorded by electrodes placed on the skin at prescribed points along the motor pathways. MEPs, especially when induced by magnetic stimulation, can be affected by anesthesia. The Digitimer electrical cortical stimulator received U.S. Food and Drug Administration (FDA) premarket approval in 2002. Devices for transcranial magnetic stimulation have not been approved by FDA for this use.

Multimodal IONM, in which more than one technique is used, most commonly with SSEPs and MEPs, has also been described.

Electromyogram Monitoring and Nerve Conduction Velocity Measurements

Electromyography (EMG) monitoring and nerve conduction velocity measurements can be performed in the operating room and may be used to assess the status of the cranial or peripheral nerves (e.g., to identify the extent of nerve damage before nerve grafting or during resection of tumors). For procedures with a risk of vocal cord paralysis due to damage to the recurrent laryngeal nerve (i.e., during carotid artery, thyroid, parathyroid, goiter, or anterior cervical spine procedures), monitoring of the vocal cords or vocal cord muscles has been performed. These techniques may also be used during procedures proximal to the nerve roots and peripheral nerves to assess the presence of excessive traction or other impairment. Surgery in the region of cranial nerves can be monitored by electrically stimulating the proximal (brain) end of the nerve and recording via EMG activity in the facial or neck muscles. Thus, monitoring is done in the direction opposite that of SEPs, but the purpose is similar—to verify that the neural pathway is intact.

Electroencephalogram Monitoring

Spontaneous electroencephalography (EEG) monitoring can also be used during surgery and can be subdivided as follows:

- EEG monitoring has been widely used to monitor cerebral ischemia secondary to carotid cross-clamping during a carotid endarterectomy. EEG monitoring may identify those patients who would benefit from the use of a vascular shunt during the procedure to restore adequate cerebral perfusion. Conversely, shunts, which have an associated risk of iatrogenic complications, may be avoided in those patients with a normal EEG. Carotid endarterectomy may be done with the patient under local anesthesia so that monitoring of cortical function can be directly assessed.
- Electrocorticography (ECoG) is the recording of the EEG directly from a surgically exposed cerebral cortex. ECoG is typically used to define the sensory cortex and map the critical limits of a surgical resection. ECoG recordings have been most frequently used to identify epileptogenic regions for resection. In these applications, ECoG does not constitute monitoring, per se.

Intraoperative neurophysiologic monitoring, including SSEPs and MEPs using transcranial electrical stimulation, BAEPs, EMG of cranial nerves, EEG, and ECoG, has broad acceptance, particularly for spine surgery and open abdominal aorta aneurysm repairs. These indications have long been considered standard of care, as evidenced by numerous society guidelines, including those from the American Academy of Neurology, American Clinical Neurophysiology Society, American Association of Neurological Surgeons, Congress of Neurologic Surgeons, and American Association of Neuromuscular & Electrodiagnostic Medicine.¹⁻⁷ Therefore, this protocol focuses on monitoring of the recurrent laryngeal nerve during neck and esophageal surgeries and monitoring of peripheral nerves.

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

RELATED PROTOCOL

Vestibular Function Testing

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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