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<b>Preauthorization</b>	No	<b>Review Dates:</b> 03/13, 05/13, 05/14, 05/15, 05/16, 05/17, 07/17, 05/18, 05/19, 05/20, 05/21, 05/22	

**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.*

**RELATED PROTOCOL**

Vestibular Function Testing

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>Who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Intraoperative neurophysiologic monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Surgery without neurophysiologic monitoring</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Morbid events</li> <li>Functional outcomes</li> <li>Quality of life</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are undergoing anterior cervical spine surgery and are at high risk of injury to the recurrent laryngeal nerve</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Intraoperative neurophysiologic monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Surgery without neurophysiologic monitoring</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Morbid events</li> <li>Functional outcomes</li> <li>Quality of life</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are undergoing esophageal surgery</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Intraoperative neurophysiologic monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Surgery without neurophysiologic monitoring</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Morbid events</li> <li>Functional outcomes</li> <li>Quality of life</li> </ul>
Individuals: <ul style="list-style-type: none"> <li>Who are undergoing surgery proximal to a peripheral nerve</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>Intraoperative neurophysiologic monitoring</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>Surgery without neurophysiologic monitoring</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>Morbid events</li> <li>Functional outcomes</li> <li>Quality of life</li> </ul>

**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 informa-

tion 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 who receive intraoperative neurophysiologic monitoring, the evidence includes a large randomized controlled trial 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 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 that the technology results in an improvement in the net health outcome.

### 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 intraoperative neurophysiologic monitoring is the 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 potentials describe the responses of the sensory pathways to sensory or electrical stimuli. Intraoperative monitoring of sensory-evoked potentials is used to assess the functional integrity of central nervous system pathways during surgeries that put the spinal cord or brain at risk for significant ischemia or traumatic injury. The basic principles of sensory-evoked potential 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 interpreting the signal at certain standardized points along the pathway. Monitoring of sensory-evoked potentials is commonly used in 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. Sensory-evoked potentials can be further categorized by type of stimulation used, as follows.

#### Somatosensory-Evoked Potentials

Somatosensory-evoked potentials 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. The recording is done either cortically or at the level of the spinal cord above the surgical procedure. Intraoperative monitoring of somatosensory-evoked potentials 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 somatosensory-evoked potential monitoring is in patients undergoing corrective surgery for scoliosis. In this setting, somatosensory-evoked potential 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 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 brainstem auditory-evoked potentials 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. Visual-evoked potential (VEP) monitoring has been used for surgery on lesions near the optic chiasm. However, visual-evoked potentials (VEPs) are very difficult to interpret due to their sensitivity to anesthesia, temperature, and blood pressure.

#### Motor-Evoked Potentials

Motor-evoked potentials are recorded from muscles following direct or transcranial electrical stimulation of motor cortex or pulsed magnetic stimulation provided using 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. Motor-evoked potentials, 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 the FDA for this use.

Multimodal intraoperative neurophysiologic monitoring, in which more than 1 technique is used, most commonly with somatosensory-evoked potentials and motor-evoked potentials, has also been described.

#### Electromyogram Monitoring and Nerve Conduction Velocity Measurements

Electromyogram (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 sensory-evoked potentials but the purpose is similar, to verify that the neural pathway is intact.

#### Electroencephalogram Monitoring

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

- Electroencephalogram (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 activity. Carotid endarterectomy may be done with the patient under local anesthesia so that monitoring of cortical function can be directly assessed.
- Electrocorticography is the recording of EEG activity directly from a surgically exposed cerebral cortex. Electrocorticography is typically used to define the sensory cortex and map the critical limits of a surgical resection. Electrocorticography recordings have been most frequently used to identify epileptogenic regions for resection. In these applications, electrocorticography does not constitute monitoring, per se.

Intraoperative neurophysiologic monitoring, including somatosensory-evoked potentials and motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, EMG of cranial nerves, EEG, and electrocorticography, has broad acceptance, particularly for spine surgery and open abdominal aorta aneurysm repairs. These indications have long been considered the 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.<sup>1-7</sup> 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 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.

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