

<b>7.01.58</b>	<b>Intraoperative Neurophysiologic Monitoring</b>		
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<b>Section:</b>	7.0 Surgery	<b>Page:</b>	Page 1 of 32

### Policy Statement

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 **any** of the following procedures:

- I. Spinal
- II. Intracranial
- III. Vascular procedures
- IV. Epilepsy ablation

Intraoperative neurophysiologic monitoring may be considered **medically necessary** for protection of the spinal cord where work is performed in close proximity to the cord, as in the placement or removal of old hardware or where there have been numerous interventions.

Intraoperative neurophysiologic monitoring may be considered **medically necessary** during **any** of the following procedures:

- I. Surgery for acoustic neuroma congenital auricular lesions or cranial based lesions
- II. Surgery for middle ear and mastoid regions (i.e., cholesteatoma surgery, chronic otitis media surgery, and mastoid surgery)
- III. Surgical excision of neuromas of the facial nerve
- IV. Microvascular decompression of the facial nerve for hemifacial spasm

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

- I. High-risk thyroid or parathyroid surgery, including:
  - A. Total thyroidectomy
  - B. Repeat thyroid or parathyroid surgery
  - C. Surgery for cancer
  - D. Thyrotoxicosis
  - E. Retrosternal or giant goiter
  - F. Thyroiditis
- II. Anterior cervical spine surgery associated with **any** of the following increased risk situations:
  - A. 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
  - B. Multilevel anterior cervical discectomy and fusion
  - C. 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 (FDA), intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered **investigational**.

Intraoperative electromyography (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 electromyography (EMG), are not considered in this policy.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## 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.

### Coding

There are specific CPT codes for this service:

- **95940:** Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)
- **95941:** Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure)

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

Codes 95940 and 95941 would be reported in conjunction with the code(s) for the testing performed, i.e., reported with any of the following CPT procedure codes (not an inclusive list):

- **95865:** Needle electromyography; larynx
- **95867:** Needle electromyography; cranial nerve supplied muscle(s), unilateral
- **95868:** Needle electromyography; cranial nerve supplied muscles, bilateral
- **95907:** Nerve conduction studies; 1-2 studies
- **95908:** Nerve conduction studies; 3-4 studies
- **95909:** Nerve conduction studies; 5-6 studies
- **95910:** Nerve conduction studies; 7-8 studies
- **95911:** Nerve conduction studies; 9-10 studies
- **95912:** Nerve conduction studies; 11-12 studies
- **95913:** Nerve conduction studies; 13 or more studies
- **95925:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
- **95926:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
- **95927:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
- **95928:** Central motor evoked potential study (transcranial motor stimulation); upper limbs
- **95929:** Central motor evoked potential study (transcranial motor stimulation); lower limbs
- **95930:** Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report

- **95938**: Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
- **95939**: Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs
- **95955**: Electroencephalogram (EEG) during nonintracranial surgery (e.g., carotid surgery)

**Effective January 1, 2021**, the following CPT code has been **deleted**:

- **92585**: Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive

The Centers for Medicare & Medicaid Services (CMS) also established a new HCPCS code for this type of monitoring:

- **G0453**: Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)

## 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.

## Related Policies

- N/A

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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

### 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 include:

#### 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 & Electrodagnostic Medicine.<sup>1-7</sup> Therefore, this evidence review focuses on monitoring of the recurrent laryngeal nerve during neck and esophageal surgeries and monitoring of peripheral nerves.

**Literature Review**

Early literature focused on intraoperative monitoring of cranial and spinal nerves. This evidence review focuses on more recently investigated techniques, including monitoring of the recurrent laryngeal nerve and peripheral nerves.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

**Recurrent Laryngeal Nerve Monitoring During Thyroid or Parathyroid Surgery  
Clinical Context and Therapy Purpose**

The purpose of intraoperative neurophysiologic monitoring is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as surgery without neurophysiologic monitoring, in patients who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve.

The question addressed in this evidence review is: Does recurrent laryngeal nerve monitoring improve the net health outcome in patients undergoing thyroid or parathyroid surgery and at high risk of injury to the recurrent laryngeal nerve?

The following PICO was used to select literature to inform this review.

**Populations**

The relevant population of interest is individuals who are undergoing thyroid or parathyroid surgery and at high risk of injury to the recurrent laryngeal nerve.

**Interventions**

The therapy being considered is intraoperative neurophysiologic monitoring.

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.

Patients who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve are actively managed by endocrine surgeons, neurosurgeons, and primary care providers in a surgical setting.

### **Comparators**

Comparators of interest include surgery without neurophysiologic monitoring. This operation is managed by endocrine surgeons in a surgical setting.

### **Outcomes**

The general outcomes of interest are morbid events, functional outcomes, and quality of life.

The existing literature evaluating intraoperative neurophysiologic monitoring as a treatment for patients who are undergoing thyroid or parathyroid surgery and at high risk of injury to the recurrent laryngeal nerve has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### **Systematic Reviews**

Henry et al (2017) reported on a systematic review of meta-analyses published up to February 2017 that compared intraoperative neurophysiologic monitoring with direct recurrent laryngeal nerve visualization by assessing rates of vocal fold palsy.<sup>8</sup> Reviewers included 8 meta-analyses of RCTs or observational studies (prospective or retrospective) and selected the best evidence based on the Jadad algorithm. The 8 meta-analyses differed significantly in the literature search methodology, databases included, the inclusion of quality assessment, and most did not include a study quality assessment. Pisanu et al (2014) was found to be the highest-quality meta-analysis<sup>9</sup>; it showed no statistically significant reductions in recurrent laryngeal nerve injury between procedures using intraoperative neurophysiologic monitoring versus direct recurrent laryngeal nerve visualization. However, reviewers also noted that recent developments in intraoperative neurophysiologic monitoring technology such as continuous vagal intraoperative neurophysiologic monitoring and staged thyroidectomy might provide additional benefits, which were out of the scope of their systematic review and need to be further assessed in prospective multicenter trials.

Sun et al (2017) reported on a meta-analysis of recurrent laryngeal nerve injury during thyroid surgery with or without intraoperative neurophysiologic monitoring.<sup>10</sup> Included were 2 prospective cohort studies and 7 retrospective cohort studies. Results are summarized in Tables 1 and 2. Intraoperative neurophysiologic monitoring was associated with a reduction in overall and permanent recurrent laryngeal nerve palsy in thyroid reoperations. Limitations included small sample sizes and study heterogeneity.

Pardal-Refoyo and Ochoa-Sangrador (2016) reported on a systematic review of recurrent laryngeal nerve injury during total thyroidectomy with or without intraoperative neurophysiologic monitoring.<sup>11</sup> Included were 1 large (N=1000) and 1 small (N=23) RCT and 52 case series that estimated the risk to the recurrent laryngeal nerve. Twenty-nine studies used recurrent laryngeal nerve monitoring and 25 did not. Results are summarized in Tables 1 and 2. The observed differences in the subgroup analysis were imprecise because the number of observed instances of paralysis was very low.



**Table 1. Characteristics of Systematic Reviews**

Study	Dates	Trials	Participants	N (Range)	Design	Duration
<b>Pardal-Refoyo and Ochoa-Sangrador (2016)<sup>11</sup></b>	1987-2013	<ul style="list-style-type: none"> <li>• 2 RCTs</li> <li>• 52 case series</li> </ul>	Studies reporting incidence of RLN paralysis after single-stage total thyroidectomy through open cervicotomy	30,922 (23-2546 patients)	<ul style="list-style-type: none"> <li>• RCTs</li> <li>• Case series</li> </ul>	NR
<b>Sun et al (2017)<sup>10</sup></b>	Up to Aug 2016	9	Studies reporting incidence of RLN complications after thyroid surgery	2436 nerves at risk (1109 with IONM, 1327 without IONM)	Prospective and retrospective cohort studies	NR
<b>Henry et al (2017)<sup>8</sup></b>	Up to Feb 2017	8 meta-analyses	Meta-analyses of RCTs and non-RCTs comparing IONM with direct visualization for RLNs during thyroidectomy	8 meta-analyses (6-23 patients)	Meta-analyses	NR

IONM: intraoperative neurophysiologic monitoring; NR: not reported; RCT: randomized controlled trial; RLN: recurrent laryngeal nerve.

**Table 2. Results of Systematic Reviews**

Study	Risk of Bilateral RLN Paralysis	Transient RLN Palsy	Permanent RLN Palsy
<b>Pardal-Refoyo and Ochoa-Sangrador (2016)<sup>11</sup></b>			
<b>ARR (95% CI)</b>	2.75% (NR) <sup>a</sup>	NR	NR
<b>NNT (95% CI)</b>	364 (NR) <sup>a</sup>	NR	NR
<b>I2 (p)</b>	8% <sup>a</sup> (NR)	NR	NR
Overall RLN Palsy			
<b>Sun et al (2017)<sup>10</sup></b>			
<b>With IONM</b>	4.69%	3.98% <sup>b</sup>	1.26% <sup>b</sup>
<b>Without IONM</b>	9.27%	6.63% <sup>b</sup>	2.78% <sup>b</sup>
<b>RR (95% CI) (p)</b>	0.434 (0.206 to 0.916) (0.029)	0.607 (0.270 to 1.366) (0.227) <sup>b</sup>	0.426 (0.196 to 0.925) (0.031) <sup>b</sup>
<b>NNT (95% CI)</b>	NR	NR <sup>b</sup>	NR <sup>b</sup>
<b>I2 (p)</b>	70.2% (NR)	67.4% <sup>b</sup> (NR)	13.7% <sup>b</sup> (NR)

ARR: absolute risk reduction; CI: confidence interval; IONM: intraoperative neurophysiologic monitoring; NNT: number needed to treat; NR: not reported; RLN: recurrent laryngeal nerve; RR: relative risk.

<sup>a</sup> Sample size of 11947 patients.

<sup>b</sup> Sample of 7 studies.

### Randomized Controlled Trials

Barczynski et al (2009) reported results of the largest RCT evaluating recurrent laryngeal nerve monitoring as summarized in Tables 3 and 4.<sup>12</sup> Recurrent laryngeal nerve monitoring was performed with electrodes on the vocal muscles through the cricothyroid ligament, which may not be the method currently used in the United States in high-risk patients, defined as those undergoing surgery for cancer, thyrotoxicosis, retrosternal or giant goiter, or thyroiditis. The prevalence of transient recurrent laryngeal nerve paresis was 2.9% lower in patients who had recurrent laryngeal nerve monitoring (p=0.011) compared with those who received visual identification only. In low-risk patients, there was no significant difference in recurrent laryngeal nerve injury rates between monitoring and no monitoring. Notably, high-risk patients with prior thyroid or parathyroid surgery were excluded from this trial. A benefit of recurrent laryngeal nerve monitoring was also shown in patients undergoing high-risk total thyroidectomy.<sup>13</sup>

**Table 3. Summary of Key Trial Characteristics**

Study	Countries	Sites	Dates	Participants	Active	Comparator
<b>Barczynski et al (2009)<sup>12</sup></b>	Poland	1	2006-2007	Patients undergoing bilateral neck surgery	500	500



**Table 4. Summary of Key RCT Results**

Study	RLN Injury	RLN Paresis	Permanent RLN Palsy
<b>Barczynski et al (2009)<sup>12</sup></b>			
RLN visualization alone, n/N	8/500	NR	NR
RLN visualization plus monitoring, n/N	NR	NR	NR
<b>ARR (95% CI) (p)</b>	2.3% (NR) (0.007)	1.9% (NR) (0.011)	0.4% (NR) (NS)
<b>NNT (95% CI)</b>	NR	NR	NR

ARR: absolute risk reduction; CI: confidence interval; NNT: number needed to treat; NR: not reported; NS: not significant; RCT: randomized controlled trial; RLN: recurrent laryngeal nerve.

### **Section Summary: Recurrent Laryngeal Nerve Monitoring During Thyroid or Parathyroid Surgery**

The evidence on the use of intraoperative neurophysiologic monitoring in reducing recurrent laryngeal nerve injury includes a large RCT and systematic reviews assessing thyroid and parathyroid surgery. The strongest evidence derives from an RCT of 1,000 patients undergoing thyroid surgery. This RCT found minimal effect of intraoperative neurophysiologic monitoring overall but 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.

### **Recurrent Laryngeal Nerve Monitoring During Cervical Spine Surgery**

#### **Clinical Context and Therapy Purpose**

The purpose of intraoperative neurophysiologic monitoring is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as surgery without neurophysiologic monitoring, in patients who are undergoing anterior cervical spine surgery and are at high risk of injury to the recurrent laryngeal nerve.

The question addressed in this evidence review is: Does recurrent laryngeal nerve monitoring improve the net health outcome in patients undergoing anterior cervical spine surgery and at high risk of injury to the recurrent laryngeal nerve?

The following PICO was used to select literature to inform this review.

#### **Populations**

The relevant population of interest is individuals who are undergoing anterior cervical spine surgery and at high risk of injury to the recurrent laryngeal nerve.

#### **Interventions**

The therapy being considered is intraoperative neurophysiologic monitoring.

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.

Patients who are undergoing anterior cervical spine surgery and at high risk of injury to the recurrent laryngeal nerve are actively managed by neurosurgeons, orthopedic surgeons, and primary care providers in an inpatient surgical setting.

#### **Comparators**

Comparators of interest include surgery without neurophysiologic monitoring. This operation is managed by neurosurgeons, orthopedic surgeons, and primary care providers in an inpatient surgical setting.

## Outcomes

The general outcomes of interest are morbid events, functional outcomes, and quality of life.

The existing literature evaluating intraoperative neurophysiologic monitoring as a treatment for patients who are undergoing anterior cervical spine surgery and at high risk of injury to the recurrent laryngeal nerve has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

## Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Systematic Reviews

Ajiboye et al (2017) reported on the results of a systematic review that included 10 studies (N =26,357 patients).<sup>14</sup> All studies were of low methodologic quality but had a low risk of bias. Only studies that compared the risk of nerve injury using intraoperative neurophysiologic monitoring with no intraoperative neurophysiologic monitoring were included. Based on data from these 2 studies, there was no statistically significant difference in the risk of neurologic injury with or without intraoperative neurophysiologic monitoring (odds ratio [OR], 0.726; 95% confidence interval [CI], 0.287 to 1.833; p=0.498) ( Tables 5 and 6).

Erwood et al (2016) reported on the results of a meta-analysis that summarized the relative rate of recurrent laryngeal nerve injury following revision anterior cervical discectomy and fusion.<sup>15</sup> The meta-analysis did not report recurrent laryngeal nerve injury rate with intraoperative neurophysiologic monitoring versus without intraoperative neurophysiologic monitoring. Based on pooled data from 3 prospective cohort studies and 5 retrospective series (N =238 patients), reviewers reported an overall recurrent laryngeal nerve injury rate of 14.1% (95% CI, 9.8% to 19.1%)( Tables 5 and 6).

Daniel et al (2018) published a literature review and meta-analysis evaluating intraoperative neurophysiologic monitoring during spinal operative surgical procedures.<sup>16</sup> Six retrospective studies, published between 2006 and 2016, with a total of 335,458 patients (range, 74 to 231,067) were included. Pooled OR for neurological events with and without intraoperative neurophysiologic monitoring was 0.72 (95% CI, 0.71 to 1.79; p=0.4584), and sensitivity analysis, which included only 2 studies, had a pooled OR of 0.199 (95% CI, 0.038 to 1.035; p=0.055). The review was limited by the lack of prospective studies, by only 3 of the included studies being considered to have high methodological quality assessment, and by many heterogeneous spinal procedures with different rates of neurological events and wide CIs being included.

**Table 5. Characteristics of Systematic Reviews**

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Ajiboye et al (2017) <sup>14</sup>	NR	10	Studies reporting IONM use for ACSS	26,357 (16 to 22,768)	9 retrospective, 1 prospective	NR
Erwood et al (2016) <sup>15</sup>	1998-2015	8	Studies reporting reoperative ACSS for RLN	238 (13 to 63)	5 prospective, 3 retrospective	2 wk to 24 mo
Daniel et al (2018) <sup>16</sup>	2006-2016	6	Studies reporting IONM use for spinal surgical procedures	335,458 (74 to 231,067)	2 cohort, 4 retrospective	NR

ACSS: anterior cervical spine surgery; IONM: intraoperative neurophysiologic monitoring; NR: not reported; RLN: recurrent laryngeal nerve.

**Table 6. Results of Systematic Reviews**

Study	Risk of Neurologic Injury
<b>Ajiboye et al (2017)<sup>14</sup></b>	
OR (95% CI) (p) <sup>a</sup>	0.726 (0.287 to 1.833) (0.44) <sup>b</sup>
NNT (95% CI)	NR
I2 (p)	0% (NR)
<b>Erwood et al (2016)<sup>15</sup></b>	
Estimate (95% CI) (p) <sup>a</sup>	0.14 (0.10 to 0.19)
NNT (95% CI)	NR
I2 (p)	10.7% (NR)
<b>Daniel et al (2018)<sup>16</sup></b>	
OR (95% CI) (p)	0.72 (0.71 to 1.79) (0.4584)

CI: confidence interval; NNT: number needed to treat; NR: not reported; OR: odds ratio.

<sup>a</sup> Risk of neurologic injury after anterior cervical discectomy and fusion with or without intraoperative neurophysiologic monitoring.

<sup>b</sup> Included 2 studies.

### Section Summary: Recurrent Laryngeal Nerve Monitoring During Cervical Spine Surgery

The evidence on the use of intraoperative neurophysiologic monitoring in reducing recurrent laryngeal nerve injury during cervical spinal surgery includes a 2017 systematic review and a meta-analysis. Of the 10 studies included in the systematic review, 2 compared the risk of nerve injury using intraoperative neurophysiologic monitoring with no intraoperative neurophysiologic monitoring and found no difference.

### Recurrent Laryngeal Nerve Monitoring During Esophageal Surgery

#### Clinical Context and Therapy Purpose

The purpose of intraoperative neurophysiologic monitoring is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as surgery without neurophysiologic monitoring, in patients who are undergoing esophageal surgery.

The question addressed in this evidence review is: Does recurrent laryngeal nerve monitoring improve the net health outcome in patients undergoing esophageal surgery during surgeries that could damage their recurrent laryngeal nerve?

The following PICO was used to select literature to inform this review.

#### Populations

The relevant population of interest is individuals who are undergoing esophageal surgery.

#### Interventions

The therapy being considered is intraoperative neurophysiologic monitoring.

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.

Patients who are undergoing esophageal surgery are actively managed by neurosurgeons, thoracic surgeons, and primary care providers in a surgical setting.

#### Comparators

Comparators of interest include surgery without neurophysiologic monitoring. This operation is managed by thoracic surgeons and primary care providers in a surgical setting.

## Outcomes

The general outcomes of interest are morbid events, functional outcomes, and quality of life.

The existing literature evaluating intraoperative neurophysiologic monitoring as a treatment for patients who are undergoing esophageal surgery has varying lengths of follow-up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

## Study Selection Criteria

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Nonrandomized Comparative Study

Zhong et al (2014) published a comparative study from Asia evaluating recurrent laryngeal nerve monitoring during surgery for esophageal cancer.<sup>17</sup> One hundred fifteen patients with esophageal cancer were enrolled in this prospective study. In 54 patients, the left recurrent laryngeal nerve was found and underwent monitoring. In the remainder (n=61), the recurrent laryngeal nerve was not located. No recurrent laryngeal nerve injury was reported during surgery in either group, but 6 (10%) of 61 patients who did not receive monitoring had notable recurrent laryngeal nerve injury identified postoperatively. It is unclear whether the difference in outcomes was due to monitoring or to the inability to identify the recurrent laryngeal nerve during surgery.

### Section Summary: Recurrent Laryngeal Nerve Monitoring During Esophageal Surgery

One nonrandomized comparative study on surgery for esophageal cancer was identified. Interpretation of this study is confounded because only the patients who had visual identification of the nerve underwent intraoperative neurophysiologic monitoring. Current evidence does not support conclusions on whether intraoperative neurophysiologic monitoring reduces recurrent laryngeal nerve injury in patients undergoing surgery for esophageal cancer.

## Monitoring Peripheral Nerves

### Clinical Context and Therapy Purpose

The purpose of intraoperative neurophysiologic monitoring is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as surgery without neurophysiologic monitoring, in patients who are undergoing surgery proximal to a peripheral nerve.

The question addressed in this evidence review is: Does neurophysiologic monitoring improve the net health outcome in patients during surgeries that could damage their peripheral nerves?

The following PICO was used to select literature to inform this review.

### Populations

The relevant population of interest is individuals who are undergoing surgery proximal to a peripheral nerve.

### Interventions

The therapy being considered is intraoperative neurophysiologic monitoring.

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.

Patients who are undergoing surgery proximal to a peripheral nerve are actively managed by neurosurgeons and primary care providers in an inpatient surgical setting.

### **Comparators**

Comparators of interest include surgery without neurophysiologic monitoring. This operation is managed by neurosurgeons and primary care providers in an inpatient surgical setting.

### **Outcomes**

The general outcomes of interest are morbid events, functional outcomes, and quality of life.

The existing literature evaluating intraoperative neurophysiologic monitoring as a treatment for patients who are undergoing surgery proximal to a peripheral nerve has varying lengths of follow up. While studies described below all reported at least 1 outcome of interest, longer follow-up was necessary to fully observe outcomes.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

### **Review of Evidence**

#### **Case-Control Study**

Kneist et al (2013) assessed monitoring peripheral nerves during surgery in a case-control study of 30 patients.<sup>18</sup> In patients undergoing total mesorectal excision, impaired anorectal function was observed in 1 (7%) of 15 patients who had intraoperative neurophysiologic monitoring compared with 6 (40%) of 15 without. Kneist et al (2013) also reported on erectile function following low anterior rectal resection in a pilot study with 17 patients.<sup>19</sup> In this study, the combined intraoperative measurement of the bladder and internal anal sphincter innervation was a strong predictor of postoperative erectile function, with a sensitivity of 90%, specificity of 86%, positive predictive value of 90%, and negative predictive value of 86%. The possibility of intervention during surgery was not addressed.

#### **Case Series**

Clarkson et al (2011) described the use of intraoperative nerve recording for suspected brachial plexus root avulsion.<sup>20</sup> Included in this retrospective review were 25 consecutive patients who underwent intraoperative nerve recording during surgery for unilateral brachial plexus injury. Of 55 roots thought to be avulsed preoperatively, 14 (25%) were found to be intact using intraoperative nerve recording. Eleven of them were then used for reconstruction, of which 9 (82%) had a positive functional outcome. Electrophysiologic monitoring has also been reported to guide selective rhizotomy for glossopharyngeal neuralgia in a series of 8 patients.<sup>21</sup>

Use of intraoperative neurophysiologic monitoring of peripheral nerves has also been reported in patients undergoing orthopedic procedures, including tibial/fibular osteotomies, hip arthroscopy for femoroacetabular impingement, and shoulder arthroplasty.<sup>22,23,24</sup>

**Section Summary: Monitoring Peripheral Nerves**

Surgical guidance with peripheral intraoperative neurophysiologic monitoring has been reported in case series and 1 case-control study. Other case series have reported on the predictive ability of monitoring of peripheral nerves. No prospective comparative studies identified have assessed whether outcomes are improved with neurophysiologic monitoring.

**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 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**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

**Clinical Input From Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate



reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

### **2017 Input**

In response to requests from Blue Cross Blue Shield Association, clinical input on intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve for individuals undergoing cervical spine surgery was received from 5 specialty society-level response in 2017.

Based on the evidence and independent clinical input, the clinical input supports that the following indication provides a clinically meaningful improvement in the net health outcome and is consistent with generally accepted medical practice:

- Use of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve for individuals undergoing cervical spine surgery with:
  - 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; and
  - preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve

### **2014 Input**

In response to requests from Blue Cross Blue Shield Association, input was received from 5 physician specialty societies (7 responses) and 2 academic medical centers in 2014. Input agreed that intraoperative neurophysiologic monitoring with somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography of cranial nerves, electroencephalography, or electrocorticography might be medically necessary during spinal, intracranial, or vascular procedures. There was general agreement that intraoperative neurophysiologic monitoring of visual-evoked potentials and motor-evoked potentials using transcranial magnetic stimulation is investigational. Input was mixed on whether intraoperative neurophysiologic monitoring of peripheral nerves would be considered medically necessary. Some reviewers recommended monitoring some peripheral nerves during spinal surgery (e.g., nerve roots, percutaneous pedicle screw placement, lateral transpsoas approach to the lumbar spine). Other reviewers suggested using intraoperative neurophysiologic monitoring during resection of peripheral nerve tumors or surgery around the brachial plexus or facial/cranial nerves.

### **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 that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American Academy of Neurology**

In 1990 (updated 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).<sup>12</sup> 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. Electrocorticography 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 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.<sup>25</sup> 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 quadriparesis 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)."

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.<sup>26</sup> They stated that intraoperative neurophysiologic monitoring, especially motor evoked potential, "is a reliable diagnostic tool for assessment of spinal cord integrity during surgery" (Level 1 evidence). Intraoperative motor evoked potentials may also "predict recovery in traumatic cervical spinal cord injury." However, AANS and Congress of Neurological Surgeons found no evidence that such monitoring provides a therapeutic benefit. The statement also recommends that intraoperative neurophysiologic monitoring should be used when the operating surgeon believes it is warranted for diagnostic value, such as with "deformity correction, spinal instability, spinal cord compression, intradural spinal cord lesions, and when in proximity to peripheral nerves or roots." In addition, they recommend spontaneous and evoked electromyography "for minimally invasive lateral retroperitoneal transpoas approaches to the lumbar spine" and during pedicle screw insertion.

### **American Association of Neuromuscular & Electrodiagnostic Medicine**

In 2017, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) updated their position statement on electrodiagnostic medicine.<sup>7</sup> 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.<sup>4</sup> Guideline 11A included the following statement<sup>27</sup>:

"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 (i.e., 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.<sup>16</sup> 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 or facial nerve.<sup>28</sup>

### 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.<sup>29</sup> 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."<sup>30</sup> 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."<sup>31</sup>

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 7.

**Table 7. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<b>NCT03773120</b>	Effectiveness of Intraoperative Neuromonitoring of the External Branch of the Superior Laryngeal Nerve During Thyroid Surgery	126	Dec 2021
<b>NCT01630785</b>	Retrospective Data Analysis of Neurophysiological Data for Intraoperative or Epilepsy Monitoring	5000	Dec 2025
<b>Unpublished</b>			
<b>NCT01585727</b>	Continuous Intraoperative Monitoring of the Pelvic Autonomic Nerves During Total Mesorectal Excision (TME) for the Prevention of Urogenital and Anorectal Dysfunction in Patients With Rectal Cancer (NEUROS)	188	Dec 2018 (updated 02/27/19)

NCT: national clinical trial.

## Appendix 1

### Appendix 1: Clinical Input

In 2017, clinical input was sought for intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve to determine whether monitoring improves health outcomes when used during cervical spine surgery.

#### Respondents

Clinical input was provided by the following medical specialty societies (listed alphabetically):

- American Academy of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS)
- American Academy of Orthopaedic Surgeons and North American Spine Society (AAOS/NASS combined response)
- American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS)

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by the specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street®. However, participation in the clinical input process by a special society and/or physician member designated by the specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

#### Clinical Input Ratings

**Appendix Table 1. Respondent Profile**

Specialty Society		
No.	Name of Organization	Clinical Specialty
1	American Academy of Neurological Surgeons / Congress of Neurological Surgeons	Neurosurgery
2	American Academy of Otolaryngology-Head and Neck Surgery	Otolaryngology, Head and Neck Surgery
3	American Academy of Orthopaedic Surgeons / North American Spine Society	Orthopaedic Surgery, Spine Disorders

**Appendix Table 2. Respondent Conflict of Interest Disclosure**

No.	1. Research support related to the topic where clinical input is being sought	2. Positions, paid or unpaid, related to the topic where clinical input is being sought	3. Reportable, more than \$1000, healthcare-related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	4. Reportable, more than \$350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought
No.	Yes/No Explanation	Yes/No Explanation	Yes/No Explanation	Yes/No Explanation
1	No	No	No	No
2	3 No1 Yes1 NR Triological Society Career Development Award recipient. Topic of research is the study of laryngeal motor neuropathy	4 No1 NR	4 No1 NR	4 No1 NR

No.	1. Research support related to the topic where clinical input is being sought	2. Positions, paid or unpaid, related to the topic where clinical input is being sought	3. Reportable, more than \$1000, healthcare-related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought	4. Reportable, more than \$350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought
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through the evaluation of transcranial magnetic stimulation-evoked myogenic potentials

**No. Conflict of Interest Policy Statement**

**3** The North American Spine Society (NASS) employs rigorous checks and balances to ensure that its comments and recommendations on payors' coverage policies/clinical evidence reports are scientifically sound and unbiased. These checks and balances include requiring all individuals involved in drafting, reviewing, revising and approving the comments to disclose any conflicts of interest he or she may have. Using an evidence-based approach when possible, the multi-disciplinary team works together to develop the comments which requires multiple levels of review. The individuals who provide the final reviews and approvals are further required to divest themselves of most financial interests in any medical industry-related concerns. For more information on NASS' Level 1 disclosure policy, please visit [NASS website](#).

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.

NR: not reported.

### Clinical Input Responses

No.	Yes/No	Explanation
1	Yes	<p>A meta-analysis by Erwood from 2016 was performed to determine the rate of recurrent laryngeal nerve injuries after recurrent ACDF's. They report a rate of recurrent laryngeal nerve injury after reoperative ACDF of 14.1% (95% confidence interval [CI] 9.8%-19.1%). This number is much greater than what is reported for routine ACDF's, and as such we must take into account that monitoring of the recurrent laryngeal nerve may be indicated in patients undergoing revision ACDF procedures. Tan et al (2014 Spine J) also confirm that there is significant evidence that revision ACDF increase the risk of laryngeal palsy. An article from Dimopoulos (2009) reviewed the role of laryngeal intraoperative electromyography (IEMG) in predicting the development of postoperative recurrent laryngeal nerve palsy in patients undergoing anterior cervical discectomy and fusion (ACDF). They found significantly increased IEMG activity in patients with previous surgical intervention, patients undergoing multilevel procedures, long-lasting procedures, and cases in which self-retained retractors were used. They therefore conclude that IEMG can provide real-time information and can potentially minimize the risk of operative recurrent laryngeal nerve injury. Refs:</p> <ul style="list-style-type: none"> <li>• Erwood MS, Hadley MN, Gordon AS, et al. Recurrent laryngeal nerve injury following reoperative anterior cervical discectomy and fusion: a meta-analysis. J Neurosurg Spine. 2016 Aug;25(2):198-204. PMID: 27015129</li> <li>• Tan TP, Govindarajulu AP, Massicotte EM, et al. Vocal cord palsy after anterior cervical spine surgery: a qualitative systematic review. Spine J. 2014 Jul 1; 14(7):1332-42. PMID: 24632183</li> <li>• Dimopoulos VG, Chung I, Lee GP, et al. Quantitative estimation of the recurrent laryngeal nerve irritation by employing spontaneous intraoperative electromyographic monitoring during anterior cervical discectomy and fusion. J Spinal Disord Tech. 2009 Feb;22(1):1-7. PMID: 19190427</li> </ul>
2	Yes	<p>1. Revision surgery through a scarred surgical field</p> <ul style="list-style-type: none"> <li>o Beutler WJ, Sweeney CA, Connolly PJ. Recurrent laryngeal nerve injury with anterior cervical spine surgery risk with laterality of surgical approach. Spine (Phila Pa 1976). 2001 Jun 15; 26(12):1337-42. PMID: 11426148</li> </ul>



No.	Yes/No	Explanation
		<ul style="list-style-type: none"> <li>o Dimopoulos VG, Chung I, Lee GP, et al. Quantitative estimation of the recurrent laryngeal nerve irritation by employing spontaneous intraoperative electromyographic monitoring during anterior cervical discectomy and fusion. J Spinal Disord Tech. 2009 Feb;22(1):1-7. PMID: 19190427</li> </ul>
2.		<p>Preexisting recurrent laryngeal nerve pathology</p> <ul style="list-style-type: none"> <li>o Jung A, Schramm J, Lehnerdt K, et al. Recurrent laryngeal nerve palsy during anterior cervical spine surgery: a prospective study. J Neurosurg Spine. 2005 Feb;2(2):123-7. PMID: 15739522</li> <li>o Paniello RC, Martin-Bredahl KJ, Henkener LJ, et al. Preoperative laryngeal nerve screening for revision anterior cervical spine procedures. Ann Otol Rhinol Laryngol. 2008 Aug; 117(8):594-7. PMID: 18771076</li> </ul>
3.		<p>Lower level cervical spine surgery:</p> <ul style="list-style-type: none"> <li>o Apfelbaum RI, Kriskovich MD, Haller JR. On the incidence, cause, and prevention of recurrent laryngeal nerve palsies during anterior cervical spine surgery. Spine (Phila Pa 1976). 2000 Nov 15; 25(22):2906-12. PMID: 11074678</li> <li>o Razfar A, Sadr-Hosseini SM, Rosen CA, et al. Prevention and management of dysphonia during anterior cervical spine surgery. Laryngoscope. 2012 Oct; 122(10):2179-83. PMID: 22898808</li> </ul>
4.		<p>Right-sided approach:</p> <ul style="list-style-type: none"> <li>o While most approaches are done from the left, some surgeons do prefer a right sided approach. There is a known incidence of non-recurrent laryngeal nerve on the right of ~1% (Kamani D, Potenza AS, Cernea CR, et al. The nonrecurrent laryngeal nerve: anatomic and electrophysiologic algorithm for reliable identification. Laryngoscope. 2015 Feb;125(2):503-8. PMID: 25042210). Dissection on this side, without monitoring, almost certainly results in right recurrent laryngeal nerve injury. Review of 16 cases of vocal fold paralysis at a single institution showed 15/16 were secondary to right sided approach (Netterville JL, Koriwchak MJ, Winkle M, et al. Vocal fold paralysis following the anterior approach to the cervical spine. Ann Otol Rhinol Laryngol. 1996 Feb; 105(2):85-91. PMID: 8659941).</li> </ul>
3	Yes	Increased risk for injury to the recurrent laryngeal nerve have been found in patients with prior anterior cervical surgery as well as patients undergoing re-operation for pseudarthrosis or failed fusion.

- For each situation you described in Question 1:
  - o Please fill in the first column of the table below with each indication you reported.
  - o Please respond YES or NO whether the use of intraoperative neurophysiologic monitoring would be expected to **improve health outcomes** by reducing nerve injury and postoperative morbidity.
  - o Please use the 1 to 5 scale outlined below to indicate your level of confidence that there is adequate evidence that supports your conclusions.

No.	Fill in the blanks below with each indication you reported in Question 1	Yes/No	Confidence				
			Low Confidence	2	Intermediate Confidence	4	High Confidence
			1	2	3	4	5
1	Revision anterior cervical discectomy and fusion	Yes					X
1	Multilevel anterior cervical discectomy and fusion	Yes			X		
1	Time consuming anterior cervical discectomy and fusion (e.g., tumor)	Yes			X		
2	Revision surgery through a scarred surgical field	Yes					X
2	Preexisting recurrent laryngeal nerve pathology	Yes				X	
2	Lower level cervical spine surgery	Yes		X			
2	Right-sided approach	Yes	X				
3	Prior anterior cervical surgery	Yes			X		
3	Reoperation for pseudarthrosis or revision for failed fusion	Yes			X		

- For each situation you described in Question 1:
  - Please fill in the first column of the table below with each indication you reported.
  - Please respond YES or NO whether this clinical use is in accordance with generally accepted medical practice.
  - Please use the 1 to 5 scale outlined below to indicate your level of confidence that this **clinical use is in accordance with generally accepted medical practice**.

No.	Fill in the blanks below with each indication you reported in Question 1	Yes/No	Low Confidence		Intermediate Confidence		High Confidence	
			1	2	3	4	5	
1	Revision anterior cervical discectomy and fusion	Yes					X	
1	Multilevel anterior cervical discectomy and fusion	Yes		X				
1	Time consuming anterior cervical discectomy and fusion (e.g., tumor)	Yes		X				
2	Revision surgery through a scarred surgical field	Yes						X
2	Preexisting recurrent laryngeal nerve pathology	No			X			
2	Lower level cervical spine surgery	No			X			
2	Right-sided approach	Yes	X					
3	Prior anterior cervical surgery	No					X	
3	Reoperation for pseudarthrosis or revision for failed fusion	No					X	

- Additional comments and/or any citations supporting your clinical input on the clinical use of intraoperative neurophysiologic monitoring in patients undergoing cervical spine surgery.

#### No. Additional Comments

- |   |  |
|---|--|
| 1 | <p>We feel that it is generally at the surgeon's discretion whether neurophysiologic monitoring of the recurrent laryngeal nerve is indicated in patients undergoing cervical spine surgery. As referenced above, for monitoring of the recurrent laryngeal nerve, there are certain circumstances where this nerve is at much higher risk of injury, and perhaps monitoring of this nerve may play a role in preventing injuries to it.</p> <p>On the broader topic of general intraoperative neurophysiologic monitoring in patients undergoing cervical spine surgery, the AANS has made guidelines as follows:</p> <ul style="list-style-type: none"> <li>• Multimodality intraoperative monitoring (IOM), including somatosensory evoked potentials and motor evoked potentials recording during spinal cord/spinal column surgery is a reliable and valid diagnostic adjunct to assess spinal cord integrity and is recommended if utilized for this purpose.</li> <li>• Motor evoked potential recordings are superior to somatosensory-evoked potential recordings during spinal cord/spinal column surgery as diagnostic adjuncts for assessment of spinal cord integrity and are recommended if utilized for this purpose.               <ul style="list-style-type: none"> <li>○ somatosensory-evoked potential recordings during spinal cord/spinal column surgery are reliable and valid diagnostic adjuncts to describe spinal cord integrity and are recommended if utilized for this purpose.</li> </ul> </li> </ul> |
| 2 | <ul style="list-style-type: none"> <li>• Revision surgery through a scarred surgical field:               <ul style="list-style-type: none"> <li>○ Beutler WJ, Sweeney CA, Connolly PJ. Recurrent laryngeal nerve injury with anterior cervical spine surgery risk with laterality of surgical approach. Spine (Phila Pa 1976). 2001 Jun 15; 26(12):1337-42. PMID: 11426148</li> <li>○ Dimopoulos VG, Chung I, Lee GP, et al. Quantitative estimation of the recurrent laryngeal nerve irritation by employing spontaneous intraoperative electromyographic monitoring during anterior cervical discectomy and fusion. J Spinal Disord Tech. 2009 Feb;22(1):1-7. PMID: 191904275.</li> </ul> </li> <li>• Preexisting recurrent laryngeal nerve pathology</li> </ul>  |

**No. Additional Comments**

- Jung A, Schramm J, Lehnerdt K, et al. Recurrent laryngeal nerve palsy during anterior cervical spine surgery: a prospective study. *J Neurosurg Spine*. 2005 Feb;2(2):123-7. PMID: 15739522
- Paniello RC, Martin-Bredahl KJ, Henkener LJ, et al. Preoperative laryngeal nerve screening for revision anterior cervical spine procedures. *Ann Otol Rhinol Laryngol*. 2008 Aug; 117(8):594-7. PMID: 18771076
- Preexisting recurrent laryngeal nerve pathology:
  - If there is a pre-existing injury to the recurrent laryngeal nerve and there is no nerve function it would seem that monitoring that side has no value. If the included definition of recurrent laryngeal nerve pathology was partial and not complete there would be value in monitoring the affected nerve. However, if they are talking about the contralateral recurrent laryngeal nerve that was currently working well, the answer should be high confidence and monitored in every situation.
  - Monitoring the contralateral recurrent laryngeal nerve in the presence of ipsilateral pathology would be yes with high confidence. However, monitoring the already damaged recurrent laryngeal nerve would not be valuable as described above.
- Lower level cervical spine surgery
  - Apfelbaum RI, Kriskovich MD, Haller JR. On the incidence, cause, and prevention of recurrent laryngeal nerve palsies during anterior cervical spine surgery. *Spine (Phila Pa 1976)*. 2000 Nov 15; 25(22):2906-12. PMID: 11074678
  - Razfar A, Sadr-Hosseini SM, Rosen CA, et al. Prevention and management of dysphonia during anterior cervical spine surgery. *Laryngoscope*. 2012 Oct; 122(10):2179-83. PMID: 22898808
  - Ebraheim NA, Lu J, Skie M, et al. Vulnerability of the recurrent laryngeal nerve in the anterior approach to the lower cervical spine. *Spine (Phila Pa 1976)*. 1997 Nov 15; 22(22):2664-7. PMID: 9399453

**3** While there is little evidence to support the use of intraoperative monitoring of the recurrent laryngeal nerve during primary anterior cervical spine surgery, it has been well-studied in soft-tissue surgery of the neck, including thyroidectomy. Given the increased difficulty, scarring and aberrant anatomy sometimes associated with revision anterior cervical surgery, we extrapolate from the available literature that monitoring of the recurrent laryngeal nerve may increase patient safety in these revision situations. Thus, each case and use of monitoring would be up to the surgeons' discretion.

- Is there any evidence missing from the attached draft review of evidence?

**No. Yes/No Citations of Missing Evidence**

- | No. | Yes/No | Citations of Missing Evidence   |
|-----|--------|---|
| 1   | Yes    | <ul style="list-style-type: none"> <li>• In 2010 Fehlings et al offered a systematic review of the literature on intraoperative neurophysiologic monitoring recordings during spinal surgery. They screened 103 articles and reviewed 32 that met rigid inclusion criteria. The authors concluded that "high level" medical evidence supports the use of IOM as a sensitive and specific means to monitor spinal cord function and integrity and to detect intraoperative neurological injury during spinal surgery. (Fehlings MG, Brodke DS, Norvell DC, et al. The evidence for intraoperative neurophysiological monitoring in spine surgery: does it make a difference? <i>Spine (Phila Pa 1976)</i>. 2010 Apr 20; 35(9 Suppl):S37-46. PMID: 20407350)</li> <li>• May et al, <i>JNS</i>, 1996 (May DM, Jones SJ, Crockard HA. Somatosensory evoked potential monitoring in cervical surgery: identification of pre- and intraoperative risk factors associated with neurological deterioration. <i>J Neurosurg</i>. 1996 Oct; 85(4):566-73. PMID: 8814157.)           <ul style="list-style-type: none"> <li>○ Case series of somatosensory-evoked potential monitoring in 191 cervical spine procedures (24 for trauma). Broad spectrum of cervical pathology. I somatosensory-evoked potential changes were noted in 33 cases while 10 patients had new neurological deficits post-surgery. Sensitivity was 99% but specificity low, 27%. False positives exceeded true positives 3:1.</li> </ul> </li> <li>• Hilibrand et al, <i>JBJS</i>, 2004 (Hilibrand AS, Schwartz DM, Sethuraman V, et al. Comparison of transcranial electric motor and somatosensory evoked potential monitoring during cervical spine surgery. <i>J Bone Joint Surg Am</i>. 2004 Jun; 86-A(6):1248-53. PMID: 15173299.)           <ul style="list-style-type: none"> <li>○ Retrospective review of 427 cervical spine procedures for broad-spectrum pathology monitored with somatosensory-evoked potential and TcMEP,</li> </ul> </li> </ul> |

No.	Yes/No	Citations of Missing Evidence
		<p>comparing both modalities to neurological outcome. I TcMEP sensitivity and specificity were 100%. somatosensory-evoked potential was 100% specific but only 25% sensitive. TcMEPs superior to somatosensory-evoked potentials to detect motor tract deficits.</p> <ul style="list-style-type: none"> <li>• Eggspuehler et al, Eur Spine J, 2007 (Eggspuehler A, Sutter MA, Grob D, et al. Multimodal intraoperative monitoring (MIOM) during cervical spine surgical procedures in 246 patients. Eur Spine J. 2007 Nov; 16 Suppl 2:S209-15. PMID: 17610090.) <ul style="list-style-type: none"> <li>○ Prospective series of 246 patients undergoing cervical spine surgery with multimodal IOM. I Multimodal IOM sensitivity and specificity were 83% and 99%. Only 7 cases were performed for fracture/ instability.</li> </ul> </li> <li>• Kelleher MO, Tan G, Sarjeant R, et al. Predictive value of intraoperative neurophysiological monitoring during cervical spine surgery: a prospective analysis of 1055 consecutive patients. J Neurosurg Spine. 2008 Mar;8(3):215-21. PMID: 18312072. <ul style="list-style-type: none"> <li>○ Prospective series of 1055 cervical spine procedures performed with multimodal intraoperative monitoring (IOM). I/II somatosensory-evoked potential (n=1055) was 52% sensitive and 100% specific while TcMEP (n=26) was 100% sensitive and 96% specific in predicting new post-op deficits. True comparison of monitoring modalities not offered.</li> </ul> </li> <li>• Kim et al, Spine, 2007 (Kim DH, Zaremski J, Kwon B, et al. Risk factors for false positive transcranial motor evoked potential monitoring alerts during surgical treatment of cervical myelopathy. Spine (Phila Pa 1976). 2007 Dec 15;32(26):3041-6. PMID: 18091499.) <ul style="list-style-type: none"> <li>○ Retrospective series of 52 consecutive patients undergoing surgery for cervical myelopathy with somatosensory-evoked potential and TcMEP monitoring. I/II TcMEP sensitivity and specificity were 100% and 90% vs. 0% and 100% for somatosensory-evoked potential. TcMEP positive predictive value was 17% (i.e., five of six alerts were false positive).</li> <li>○ Class I: TcMEPs superior to somatosensory-evoked potential.</li> <li>○ Class II: Limited to small CSM population.</li> </ul> </li> </ul>
2	Yes	<ul style="list-style-type: none"> <li>• Erwood MS, Hadley MN, Gordon AS, et al. Recurrent laryngeal nerve injury following reoperative anterior cervical discectomy and fusion: a meta-analysis. J Neurosurg Spine. 2016 Aug;25(2):198-204. PMID: 27015129</li> <li>• Beutler WJ, Sweeney CA, Connolly PJ. Recurrent laryngeal nerve injury with anterior cervical spine surgery risk with laterality of surgical approach. Spine (Phila Pa 1976). 2001 Jun 15; 26(12):1337-42. PMID: 11426148</li> <li>• Dimopoulos VG, Chung I, Lee GP, et al. Quantitative estimation of the recurrent laryngeal nerve irritation by employing spontaneous intraoperative electromyographic monitoring during anterior cervical discectomy and fusion. J Spinal Disord Tech. 2009 Feb;22(1):1-7. PMID: 19190427</li> <li>• Jung A, Schramm J, Lehnerdt K, et al. Recurrent laryngeal nerve palsy during anterior cervical spine surgery: a prospective study. J Neurosurg Spine. 2005 Feb;2(2):123-7. PMID: 15739522</li> <li>• Paniello RC, Martin-Bredahl KJ, Henkener LJ, et al. Preoperative laryngeal nerve screening for revision anterior cervical spine procedures. Ann Otol Rhinol Laryngol. 2008 Aug; 117(8):594-7. PMID: 18771076</li> <li>• Razfar A, Sadr-Hosseini SM, Rosen CA, et al. Prevention and management of dysphonia during anterior cervical spine surgery. Laryngoscope. 2012 Oct; 122(10):2179-83. PMID: 22898808</li> <li>• Apfelbaum RI, Kriskovich MD, Haller JR. On the incidence, cause, and prevention of recurrent laryngeal nerve palsies during anterior cervical spine surgery. Spine (Phila Pa 1976). 2000 Nov 15; 25(22):2906-12. PMID: 11074678</li> <li>• Kriskovich MD, Apfelbaum RI, Haller JR. Vocal fold paralysis after anterior cervical spine surgery: incidence, mechanism, and prevention of injury. Laryngoscope. 2000 Sep; 110(9):1467-73. PMID: 10983944</li> <li>• Jellish WS, Jensen RL, Anderson DE, et al. Intraoperative electromyographic assessment of recurrent laryngeal nerve stress and pharyngeal injury during anterior cervical spine surgery with Caspar instrumentation. J Neurosurg. 1999 Oct; 91(2 Suppl):170-4. PMID: 10505500</li> </ul>

No.	Yes/No	Citations of Missing Evidence
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3	No	

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## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical and/or consultation notes including:
  - Reason for the need for monitoring, including but not limited to the type of procedure planned

### Post Service (in addition to the above, please include the following):

- Results/reports of tests performed
- Operative report, including the following:
  - The type of procedure that required monitoring
  - Indication of constant communication between surgeon, neurophysiologist, and anesthesiologist

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	92585	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive ( <b>Deleted code effective 1/1/2021</b> )
	95829	Electrocorticogram at surgery (separate procedure)
	95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days
	95865	Needle electromyography; larynx
	95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
	95868	Needle electromyography; cranial nerve supplied muscles, bilateral
	95907	Nerve conduction studies; 1-2 studies
	95908	Nerve conduction studies; 3-4 studies
	95909	Nerve conduction studies; 5-6 studies
	95910	Nerve conduction studies; 7-8 studies
	95911	Nerve conduction studies; 9-10 studies
	95912	Nerve conduction studies; 11-12 studies
	95913	Nerve conduction studies; 13 or more studies
	95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
	95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
	95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
	95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs
	95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs
	95930	Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
	95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs	
95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)	
95941	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure)	
95955	Electroencephalogram (EEG) during non-intracranial surgery (e.g., carotid surgery)	
HCPCS	G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby), per patient, (attention directed exclusively to one patient) each 15 minutes (list in addition to primary procedure)

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
09/27/2013	BCBSA Medical Policy adoption
03/07/2014	Coding and Administrative Update
07/31/2015	Coding update
08/01/2016	Policy title change from Intraoperative Neurophysiologic Monitoring Policy revision with position change
07/01/2017	Policy title change from Intraoperative Neurophysiologic Monitoring (Sensory-Evoked Potentials, Motor-Evoked Potentials, EEG Monitoring) Policy revision without position change
02/01/2018	Coding update
06/01/2018	Policy revision without position change
02/01/2019	Coding update
06/01/2019	Policy revision without position change
06/01/2020	Annual review. No change to policy statement. Literature review updated.
01/01/2021	Coding update.
06/01/2021	Annual review. No change to policy statement. Policy guidelines and literature updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

**Appendix A**

<b>POLICY STATEMENT</b> <b>(No changes)</b>	
<b>BEFORE</b>	<b>AFTER</b>
<p><b>Intraoperative Neurophysiologic Monitoring 7.01.58</b></p> <p><b>Policy Statement:</b>                      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 <b>medically necessary</b> during <b>any</b> of the following procedures:</p> <ol style="list-style-type: none"> <li>I. Spinal</li> <li>II. Intracranial</li> <li>III. Vascular procedures</li> <li>IV. Epilepsy ablation</li> </ol> <p>Intraoperative neurophysiologic monitoring may be considered <b>medically necessary</b> for protection of the spinal cord where work is performed in close proximity to the cord, as in the placement or removal of old hardware or where there have been numerous interventions.</p> <p>Intraoperative neurophysiologic monitoring may be considered <b>medically necessary</b> during <b>any</b> of the following procedures:</p> <ol style="list-style-type: none"> <li>I. Surgery for acoustic neuroma congenital auricular lesions or cranial based lesions</li> <li>II. Surgery for middle ear and mastoid regions (i.e., cholesteatoma surgery, chronic otitis media surgery, and mastoid surgery)</li> <li>III. Surgical excision of neuromas of the facial nerve</li> <li>IV. Microvascular decompression of the facial nerve for hemifacial spasm</li> </ol> <p>Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered <b>medically necessary</b> in patients undergoing <b>either</b> of the following:</p> <ol style="list-style-type: none"> <li>I. High-risk thyroid or parathyroid surgery, including:                             <ol style="list-style-type: none"> <li>A. Total thyroidectomy</li> <li>B. Repeat thyroid or parathyroid surgery</li> </ol> </li> </ol>	<p><b>Intraoperative Neurophysiologic Monitoring 7.01.58</b></p> <p><b>Policy Statement:</b>                      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 <b>medically necessary</b> during <b>any</b> of the following procedures:</p> <ol style="list-style-type: none"> <li>I. Spinal</li> <li>II. Intracranial</li> <li>III. Vascular procedures</li> <li>IV. Epilepsy ablation</li> </ol> <p>Intraoperative neurophysiologic monitoring may be considered <b>medically necessary</b> for protection of the spinal cord where work is performed in close proximity to the cord, as in the placement or removal of old hardware or where there have been numerous interventions.</p> <p>Intraoperative neurophysiologic monitoring may be considered <b>medically necessary</b> during <b>any</b> of the following procedures:</p> <ol style="list-style-type: none"> <li>I. Surgery for acoustic neuroma congenital auricular lesions or cranial based lesions</li> <li>II. Surgery for middle ear and mastoid regions (i.e., cholesteatoma surgery, chronic otitis media surgery, and mastoid surgery)</li> <li>III. Surgical excision of neuromas of the facial nerve</li> <li>IV. Microvascular decompression of the facial nerve for hemifacial spasm</li> </ol> <p>Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered <b>medically necessary</b> in patients undergoing <b>either</b> of the following:</p> <ol style="list-style-type: none"> <li>I. High-risk thyroid or parathyroid surgery, including:                             <ol style="list-style-type: none"> <li>A. Total thyroidectomy</li> <li>B. Repeat thyroid or parathyroid surgery</li> </ol> </li> </ol>

**POLICY STATEMENT**

**(No changes)**

BEFORE	AFTER
<p>C. Surgery for cancer                      D. Thyrotoxicosis                      E. Retrosternal or giant goiter                      F. Thyroiditis</p> <p>II. Anterior cervical spine surgery associated with <b>any</b> of the following increased risk situations:</p> <p>A. 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</p> <p>B. Multilevel anterior cervical discectomy and fusion</p> <p>C. Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve</p> <p>Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during anterior cervical spine surgery not meeting the criteria above or during esophageal surgeries is considered <b>investigational</b>.</p> <p>Intraoperative monitoring of visual-evoked potentials is considered <b>investigational</b>.</p> <p>Due to the lack of monitors approved by the U.S. Food and Drug Administration (FDA), intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered <b>investigational</b>.</p> <p>Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered <b>not medically necessary</b>.</p> <p><b>Note:</b> 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 (EMG), are not considered in this policy.</p>	<p>C. Surgery for cancer                      D. Thyrotoxicosis                      E. Retrosternal or giant goiter                      F. Thyroiditis</p> <p>II. Anterior cervical spine surgery associated with <b>any</b> of the following increased risk situations:</p> <p>A. 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</p> <p>B. Multilevel anterior cervical discectomy and fusion</p> <p>C. Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve</p> <p>Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during anterior cervical spine surgery not meeting the criteria above or during esophageal surgeries is considered <b>investigational</b>.</p> <p>Intraoperative monitoring of visual-evoked potentials is considered <b>investigational</b>.</p> <p>Due to the lack of monitors approved by the U.S. Food and Drug Administration (FDA), intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered <b>investigational</b>.</p> <p>Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered <b>not medically necessary</b>.</p> <p><b>Note:</b> 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 (EMG), are not considered in this policy.</p>