

7.01.58 Intraoperative Neurophysiologic Monitoring			
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Section:	7.0 Surgery	Page:	Page 1 of 33

## Policy Statement

- I. 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:
  - A. Spinal
  - B. Intracranial
  - C. Vascular procedures
  - D. Epilepsy ablation
- II. Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered **medically necessary** in individuals undergoing **either** of the following:
  - A. High-risk thyroid or parathyroid surgery, including:
    1. Total thyroidectomy
    2. Repeat thyroid or parathyroid surgery
    3. Surgery for cancer
    4. Thyrotoxicosis
    5. Retrosternal or giant goiter
    6. Thyroiditis
  - B. Anterior cervical spine surgery associated with **any** of the following increased risk situations:
    1. 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
    2. Multilevel anterior cervical discectomy and fusion
    3. Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve
- III. 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**.
- IV. Intraoperative monitoring of visual-evoked potentials is considered **investigational**.
- V. 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**.
- VI. Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered **investigational**.

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

## Policy Guidelines

**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.

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

See the [Codes table](#) for details.

## 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.

### Summary of Evidence

For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve who receive intraoperative neurophysiologic monitoring, the evidence includes a large randomized controlled trial (RCT) and systematic reviews. Relevant outcomes are morbid events, functional outcomes, and quality of life. The strongest evidence on neurophysiologic monitoring derives from a RCT of 1000 patients undergoing thyroid surgery. This RCT found a significant reduction in recurrent laryngeal nerve injury in patients at high-risk for injury. High-risk in this trial was defined as surgery for cancer, thyrotoxicosis, retrosternal or giant goiter, or thyroiditis. The high-risk category may also include patients with prior thyroid or parathyroid surgery or total thyroidectomy. A low volume of surgeries might also contribute to a higher risk for recurrent laryngeal nerve injury. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing anterior cervical spine surgery and are at high-risk of injury to the recurrent laryngeal nerve who receive intraoperative neurophysiologic monitoring, the evidence includes 3 systematic reviews of case series and cohort studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. Two of the 3 analyses compared the risk of nerve injury using intraoperative neurophysiologic monitoring with no intraoperative neurophysiologic monitoring and found no statistically significant 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 systematic review of mainly nonrandomized comparative

studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. The systematic review found less recurrent laryngeal nerve palsy with intraoperative neurophysiologic monitoring but conclusions are limited by the design of the included studies. Current evidence is not sufficiently robust to determine whether neurophysiologic monitoring reduces recurrent laryngeal nerve injury in patients undergoing esophageal surgery. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing surgery proximal to a peripheral nerve who receive intraoperative neurophysiologic monitoring, the evidence includes case series and a controlled cohort study. Relevant outcomes are morbid events, functional outcomes, and quality of life. Surgical guidance with peripheral intraoperative neurophysiologic monitoring and the predictive ability of monitoring of peripheral nerves have been reported. No prospective comparative studies were identified that assessed whether outcomes are improved with neurophysiologic monitoring. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing spinal instrumentation requiring screws or distraction who receive intraoperative neurophysiologic monitoring, the evidence includes systematic reviews of nonrandomized studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. The available evidence suggests that intraoperative neurophysiologic monitoring has high sensitivity and specificity for detecting neurologic deficits. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

### **Additional Information**

#### **2017 Input**

Clinical input was sought to help determine whether the use of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve for individuals undergoing cervical spine surgery would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, clinical input was received from 5 specialty society-level responses while this policy was under review in 2017.

For individuals undergoing cervical spine surgery who receive intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve, clinical input supports this use provides a clinically meaningful improvement in net health outcome and indicates this use is consistent with generally accepted medical practice in a subgroup of appropriately selected patients. The following patient selection criteria are based on clinical expert opinion and information from clinical study populations:

- 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.

Further details from clinical input are included in Appendix 1.

### **Related Policies**

- Vestibular Function Testing

### **Benefit Application**

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member

health services 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 law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

## 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 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 are described below.

#### 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 monitoring has been used for surgery on lesions near the optic chiasm. However, VEPs are very difficult to interpret due to their sensitivity to anesthesia, temperature, and blood pressure.

### **Motor-Evoked Potentials**

Motor-evoked potentials 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:

- EEG monitoring has been widely used to monitor cerebral ischemia secondary to carotid cross-clamping during a carotid endarterectomy. EEG monitoring may identify those patients who would benefit from the use of a vascular shunt during the procedure to restore adequate cerebral perfusion. Conversely, shunts, which have an associated risk of iatrogenic complications, may be avoided in those patients with a normal EEG activity. Carotid endarterectomy may be done with the patient under local anesthesia so that monitoring of cortical function can be directly assessed.
- Electrocorticography is the recording of EEG activity directly from a surgically exposed cerebral cortex. Electrocorticography is typically used to define the sensory cortex and map the critical limits of a surgical resection. Electrocorticography recordings have been most

frequently used to identify epileptogenic regions for resection. In these applications, electrocorticography does not constitute monitoring, per se.

Intraoperative neurophysiologic monitoring, including somatosensory-evoked potentials and motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, EMG of cranial nerves, EEG, and electrocorticography, has broad acceptance, particularly for spine surgery and open abdominal aorta aneurysm repairs. These indications have long been considered the standard of care, as evidenced by numerous society guidelines, including those from the American Academy of Neurology, American Clinical Neurophysiology Society, American Association of Neurological Surgeons, Congress of Neurologic Surgeons, and American Association of Neuromuscular & Electrodiagnostic Medicine.<sup>1,2,3,4,5,6</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. Randomized controlled trials 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 individuals who are undergoing thyroid or parathyroid surgery and are 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.

### ***Comparators***

Comparators of interest include surgery without neurophysiologic monitoring.

### ***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**

Cozzi et al (2023) reported on a systematic review of 164 studies that reported on intraoperative neurophysiologic monitoring during thyroid surgery.<sup>7</sup> The combined rates of temporary and permanent recurrent laryngeal nerve injury were 3.15% and 0.422%, respectively, for all procedures. For cases where intraoperative neurophysiologic monitoring was used, these rates were 3.29% and 0.409%, and for cases without monitoring, the rates were 3.16% and 0.463%, respectively. The pooled rates of temporary recurrent laryngeal nerve injury were 2.48% for intermittent intraoperative neurophysiologic monitoring and 2.913% for continuous intraoperative neurophysiologic monitoring; for definitive injury rates, the pooled rates were 0.395% and 0.40%, respectively. Authors noted that pooled rates had largely overlapping 95% confidence intervals (CI), and concluded that intraoperative neurophysiologic monitoring does not affect the temporary or definitive recurrent laryngeal nerve injury rate following thyroidectomy.

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 to 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 to 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 to 23 patients)	Meta-analyses	NR
<b>Cozzi et al (2023)<sup>7</sup></b>	Up to Jan 2023	<ul style="list-style-type: none"> <li>12 RCTs</li> <li>80 prospective cohort studies</li> <li>72 were prospective case series</li> </ul>	Studies reporting incidence of RLN complications after thyroid surgery	42,015 procedures with 73,325 nerves at risk	<ul style="list-style-type: none"> <li>RCTs</li> <li>Prospective cohort</li> <li>Case series</li> </ul>	1 year or more

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
Pardal-Refoyo and Ochoa-Sangrador (2016) <sup>11</sup>			
ARR (95% CI)	2.75% (NR) <sup>a</sup>	NR	NR
NNT (95% CI)	364 (NR) <sup>a</sup>	NR	NR
I <sup>2</sup> (p)	8% (NR) <sup>a</sup>	NR	NR
	Overall RLN Palsy		
Sun et al (2017) <sup>10</sup>			
With IONM	4.69%	3.98% <sup>b</sup>	1.26% <sup>b</sup>
Without IONM	9.27%	6.63% <sup>b</sup>	2.78% <sup>b</sup>
RR (95% CI)	0.434 (0.206 to 0.916)	0.607 (0.270 to 1.366)	0.426 (0.196 to 0.925)



Study	Risk of Bilateral RLN Paralysis	Transient RLN Palsy	Permanent RLN Palsy
NNT (95% CI)	NR	NR <sup>b</sup>	NR <sup>b</sup>
I <sup>2</sup> (p)	70.2% (.029)	67.4% <sup>b</sup> (.227)	13.7% <sup>b</sup> (.031)
Cozzi et al (2023) <sup>7</sup>			
With IONM	NR	3.29% (95% CI, 2.69% to 3.95%)	0.409% (95% CI, 0.302% to 0.532%)
Without IONM	NR	3.16% (95% CI, 2.54% to 3.86%)	0.463% (95% CI, 0.339% to 0.607%)

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=.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 Randomized Controlled Trial Characteristics**

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

**Table 4. Summary of Key Randomized Controlled Trial Results**

Study	RLN Injury	RLN Paresis	Permanent RLN Palsy
Barczynski et al (2009) <sup>12</sup>			
RLN visualization alone, n/N	8/500	NR	NR
RLN visualization plus monitoring, n/N	NR	NR	NR
ARR (95% CI) (p)	2.3% (NR) (.007)	1.9% (NR) (.011)	0.4% (NR) (NS)

ARR: absolute risk reduction; CI: confidence interval; NR: not reported; NS: not significant; 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 a 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 individuals who are undergoing anterior cervical spine surgery and are 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.

### ***Comparators***

Comparators of interest include surgery without neurophysiologic monitoring.

### ***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).<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% CI, 0.287 to 1.833; p=.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), 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;  $p=.4584$ ), and sensitivity analysis, which included only 2 studies, had a pooled OR of 0.199 (95% CI, 0.038 to 1.035;  $p=.055$ ). 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
Ajiboye et al (2017) <sup>14</sup>	
OR <sup>a,b</sup> (95% CI)	0.726 (0.287 to 1.833)
I <sup>2</sup> (p)	0% (.44)
Erwood et al (2016) <sup>15</sup>	
Estimate <sup>c</sup> (95% CI)	0.14 (0.10 to 0.19)
I <sup>2</sup> (p)	10.7% (NR)
Daniel et al (2018) <sup>16</sup>	
OR <sup>a</sup> (95% CI)	0.72 (0.71 to 1.79)
I <sup>2</sup> (p)	NR (.4584)

CI: confidence interval; NR: not reported; OR: odds ratio.

<sup>a</sup> Risk of neurologic injury after spine surgery with or without intraoperative neurophysiologic monitoring.

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

<sup>c</sup> Overall rate of recurrent laryngeal nerve injury.

### 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 3 systematic reviews. Two of the 3 analyses compared the risk of nerve injury using intraoperative neurophysiologic monitoring with no intraoperative neurophysiologic monitoring and found no statistically significant 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 individuals who are undergoing esophageal surgery.

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.

**Comparators**

Comparators of interest include surgery without neurophysiologic monitoring.

**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****Systematic Review**

Chen et al (2023) conducted a systematic review on the efficacy of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during esophagectomy (Tables 7 and 8).<sup>17</sup> Ten studies that compared intraoperative neurophysiologic monitoring to no monitoring during esophagectomy with mediastinal lymph node dissection were included. Table 9 summarizes the results of the analysis. Intraoperative neurophysiologic monitoring significantly reduced the incidence of recurrent laryngeal nerve palsy (OR, 0.32; 95% CI, 0.19 to 0.54;  $p < .0001$ ;  $I^2 = 42\%$ ) and increased the number of mediastinal lymph nodes dissected (weighted mean difference, 4.26; 95% CI, 1.63 to 6.89;  $p = .002$ ;  $I^2 = 49\%$ ). However, there were no significant differences in total operation time or hospital length of stay. Limitations include a significant publication bias ( $p = .02$ ), lack of randomization in all but 1 study, use of historical control groups in some studies, and small sample sizes.

**Table 7. Comparison of Trials/Studies Included in Systematic Review**

Study	Chen et al (2023) <sup>17</sup>
Komatsu et al (2022) <sup>18</sup>	●
Huang et al (2022) <sup>19</sup>	●
Zhao et al (2022) <sup>20</sup>	●
Yuda et al (2022) <sup>21</sup>	●
Takeda et al (2020) <sup>22</sup>	●
Fujimoto et al (2021) <sup>23</sup>	●
Kobayashi et al (2018) <sup>24</sup>	●
Zhu et al (2018) <sup>25</sup>	●
Hikage et al (2017) <sup>26</sup>	●
Zhong et al (2014) <sup>27</sup>	●

**Table 8. Systematic Review Characteristics**

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Chen et al (2023) <sup>17</sup>	2014-2022	10	Patients with esophageal malignancy undergoing esophagectomy with mediastinal lymph node dissection	949 (16 to 142)	1 RCT, 9 nonrandomized studies	NR

NR: not reported; RCT: randomized controlled trial.

**Table 9. Systematic Review Results**

Study	Recurrent laryngeal nerve palsy	Number of mediastinal lymph nodes dissected	Total operation time	Length of hospital stay
Chen et al (2023) <sup>17</sup>				
949	949	340	452	568
Odds ratio (95% CI)	0.32 (0.19 to 0.54)	4.26 <sup>a</sup> (1.63 to 6.89)	-12.33 <sup>a</sup> (-33.94 to 9.28)	-2.07 <sup>a</sup> (-6.61 to 2.46)
P (p)	42% (<.0001)	49% (.002)	59% (0.26)	56% (.37)

CI: confidence interval.

<sup>a</sup> Weighted mean difference.

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

One systematic review of 10 studies (mostly nonrandomized) on esophageal surgery was identified. Intraoperative neurophysiologic monitoring reduced recurrent laryngeal nerve injury in the combined analysis, but well-designed studies are needed to confirm these results.

### 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 individuals who are undergoing surgery proximal to a peripheral nerve.

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.

#### *Comparators*

Comparators of interest include surgery without neurophysiologic monitoring.

#### *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>28</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 monitoring. Kneist et al (2013) also reported on erectile function following low anterior rectal resection in a pilot study with 17 patients.<sup>29</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>30</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>31</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>32,33,34</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.

### Spinal Instrumentation Requiring Screws or Distraction

#### 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 individuals who are undergoing spinal instrumentation requiring screws or distraction.

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

### ***Populations***

The relevant population of interest is individuals who are undergoing spinal instrumentation requiring screws or distraction.

### ***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.

### ***Comparators***

Comparators of interest include surgery without neurophysiologic monitoring.

### ***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 spinal instrumentation requiring screws or distraction 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**

Reddy et al (2022) conducted a systematic review and meta-analysis of 13 studies that used intraoperative triggered electromyographic monitoring to detect early malposition of screws during instrumentation of the lumbar spine.<sup>35</sup> The electromyographic alarm trigger varied from 5 mA to 11 mA among studies. Among the 2236 patients in the analysis, postoperative neurologic deficit occurred in 3.04%. The proportion of patients who developed postoperative neurologic deficit but did not reach the alarm threshold during surgery was 13.28%. The sensitivity and specificity of intraoperative triggered electromyographic monitoring were 49% and 88%, respectively.

Thirumala et al (2017) conducted a systematic review of the diagnostic accuracy of intraoperative transcranial motor evoked potentials to detect neurologic deficit during idiopathic scoliosis correction surgery.<sup>36</sup> Twelve studies were included (none randomized) that represented 2102 patients with idiopathic scoliosis. The alarm criteria for significant change in motor evoked potentials ranged among studies from 50% to 80% decrease in amplitude. Neurologic deficits occurred in 1.38% of patients. Among the 95 patients with a motor evoked potential change that indicated a new neurologic deficit, 38 (40%) had reversible deficits and 33 (34.7%) had irreversible deficits. Sensitivity and specificity of intraoperative monitoring were 91% and 96%, respectively ( $P=89\%$ ).

Table 10. Comparison of Trials/Studies Included in Systematic Reviews

Study	Reddy et al (2022) <sup>35</sup>	Thirumala et al (2017) <sup>36</sup>
Alemo et al (2010) <sup>37</sup>	●	
Bindal et al (2007) <sup>38</sup>	●	
Bose et al (2002) <sup>39</sup>	●	
Clements et al (1996) <sup>40</sup>	●	
Darden et al (1996) <sup>41</sup>	●	
Luo et al (2012) <sup>42</sup>	●	
Maguire et al (1995) <sup>43</sup>	●	
Papadopoulos et al (2005) <sup>44</sup>	●	
Sutter et al (2007) <sup>45</sup>	●	
Welch et al (1997) <sup>46</sup>	●	
Wood et al (2010) <sup>47</sup>	●	
Wood et al (2014) <sup>48</sup>	●	
Melachuri et al (2021) <sup>49</sup>	●	
Accadbled et al (2006) <sup>50</sup>		●
Eggspuehler et al (2007) <sup>51</sup>		●
El-Hawary et al (2006) <sup>52</sup>		●
Feng et al (2012) <sup>53</sup>		●
Kundnani et al (2010) <sup>54</sup>		●
Lo et al (2008) <sup>55</sup>		●
Luk et al (2001) <sup>56</sup>		●
MacDonald et al (2007) <sup>57</sup>		●
Noonan et al (2002) <sup>58</sup>		●
Pastorelli et al (2011) <sup>59</sup>		●
Pereon et al (1998) <sup>60</sup>		●
Schwartz et al (2007) <sup>61</sup>		●

Table 11. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Reddy et al (2022) <sup>35</sup>	1995–2020	13	Adults (≥18 years) undergoing elective lumbar spine surgery with screws not due to trauma or tumor	2236 (16 to 1179)	Prospective and retrospective cohorts	Ranged from immediately postoperative to 6 months
Thirumala et al (2017) <sup>36</sup>	1998–2012	12	Patients undergoing idiopathic scoliosis correction surgery	2915 (25 to 1121)	Prospective and retrospective cohorts	Ranged from immediately postoperative to 3 months

Table 12. Systematic Review Results

Study	Postoperative neurologic deficits	Sensitivity	Specificity	Odds ratio of stimulation predicting postoperative neurologic deficit
Reddy et al (2022) <sup>35</sup>				
2236	2236	2236	2236	2236
Pooled effect (95% CI)	3.04%	0.49 (0.36 to 0.63)	0.88 (0.80 to 0.93)	2.32 (1.37 to 3.26)
Thirumala et al (2017) <sup>36</sup>				
2102	2102	2102	2102	2102
Pooled effect (95% CI)	1.38%	0.91 (0.34 to 1.00)	0.95 (0.92 to 0.98)	250.42 (10.87 to 5766.62)

CI: confidence interval.

### Observational Studies

Numerous large cohort studies (N>1000) have evaluated the effect of intraoperative neurophysiologic monitoring during spinal procedures requiring instrumentation. Some of these studies reported measures of accuracy. For example, Tsirikos et al (2020) studied a cohort of 1155



patients who underwent spinal deformity surgery using somatosensory evoked potentials and transcranial electrical motor evoked potentials.<sup>62</sup> No patients had postoperative neurologic deficits and there were no false negative events. Rates of true positive events, transient true positive events, and transient false positive events were 0.17%, 0.69%, and 0.69%, respectively. The sensitivity of the multimodal intraoperative monitoring technique was 100%, specificity was 99.3%, positive predictive value was 55.6%, and negative predictive value was 100%.

Sutter et al (2007) conducted a prospective study of 1017 patients who underwent multimodal intraoperative monitoring during spinal surgery.<sup>45</sup> Monitoring techniques included sensory spinal evoked potentials, cortical evoked potentials, electromyographic monitoring, and motor evoked potentials. True negative cases occurred in 935 (91.9%) patients, false negative cases occurred in 8 (0.79%) patients, true positive cases occurred in 66 (6.5%) patients, and false positive cases occurred in 8 (0.79%) patients. The specificity and sensitivity of multimodal intraoperative monitoring were 99% and 89%, respectively.

### Section Summary: Spinal Instrumentation Requiring Screws or Distraction

Two systematic reviews and numerous observational studies have concluded that intraoperative neurophysiologic monitoring has high sensitivity and specificity in detecting neurologic deficits. Various surgical settings that require spinal instrumentation have been studied, including lumbar surgery and scoliosis correction surgery.

## Appendix 1

### Appendix 1: Clinical Input 2017 Input

#### Objective

Clinical input was sought to help determine whether the use of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve for individuals undergoing cervical spine surgery would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice.

#### 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 a 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 review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a specialty society and/or physician member designated by a 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

Specialty Society		
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	1 Yes = Triological Society Career Development Award recipient. Topic of research is the study of laryngeal motor neuropathy through the evaluation of transcranial magnetic stimulation-evoked myogenic potentials	4 No1 NR		4 No1 NR		4 No1 NR	
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 <a href="#">NASS website</a> .							

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	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)

No.	Yes/No	Explanation
		<p>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. <i>J Neurosurg Spine</i>. 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. <i>Spine J</i>. 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. <i>J Spinal Disord Tech</i>. 2009 Feb;22(1):1-7. PMID: 19190427</li> </ul>
2	Yes	<ol style="list-style-type: none"> <li>1. 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. <i>Spine (Phila Pa 1976)</i>. 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. <i>J Spinal Disord Tech</i>. 2009 Feb;22(1):1-7. PMID: 19190427</li> </ul> </li> <li>2. Preexisting recurrent laryngeal nerve pathology <ul style="list-style-type: none"> <li>○ Jung A, Schramm J, Lehnerdt K, et al. Recurrent laryngeal nerve palsy during anterior cervical spine surgery: a prospective study. <i>J Neurosurg Spine</i>. 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. <i>Ann Otol Rhinol Laryngol</i>. 2008 Aug; 117(8):594-7. PMID: 18771076</li> </ul> </li> <li>3. Lower level cervical spine surgery: <ul style="list-style-type: none"> <li>○ Apfelbaum RI, Kriskovich MD, Haller JR. On the incidence, cause, and prevention of recurrent laryngeal nerve palsies during anterior cervical spine surgery. <i>Spine (Phila Pa 1976)</i>. 2000 Nov 15; 25(22):2906-12. PMID: 11074678.</li> <li>○ Razfar A, Sadr-Hosseini SM, Rosen CA, et al. Prevention and management of dysphonia during anterior cervical spine surgery. <i>Laryngoscope</i>. 2012 Oct; 122(10):2179-83. PMID: 22898808</li> </ul> </li> <li>4. Right-sided approach: <ul style="list-style-type: none"> <li>○ 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. <i>Laryngoscope</i>. 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. <i>Ann Otol Rhinol Laryngol</i>. 1996 Feb; 105(2):85-91. PMID: 8659941).</li> </ul> </li> </ol>
3	Yes	<p>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.</p>

- 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 the use of intraoperative neurophysiologic monitoring would be expected to **improve health outcomes** by reducing nerve injury and postoperative morbidity.
- 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	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	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	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,

**No. Additional Comments**

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.

On the broader topic of general intraoperative neurophysiologic monitoring in patients undergoing cervical spine surgery, the AANS has made guidelines as follows:

- 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.
- 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.
  - 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.

- 2
  - Revision surgery through a scarred surgical field:
    - 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
    - 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.
  - Preexisting recurrent laryngeal nerve pathology
    - 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
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>JBSJ</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, 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.</li> </ul> </li> <li>• Eggspuehler et al, <i>Eur Spine J</i>, 2007 (Eggspuehler A, Sutter MA, Grob D, et al. Multimodal intraoperative monitoring (MIOM) during cervical spine surgical procedures in 246 patients. <i>Eur Spine J</i>. 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. <i>J Neurosurg Spine</i>. 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, <i>Spine</i>, 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. <i>Spine (Phila Pa 1976)</i>. 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% (ie, five of six alerts were false positive).</li> <li>○ Class I: TcMEPs superior to somatosensory-evoked potential. oClass 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. <i>J Neurosurg Spine</i>. 2016 Aug;25(2):198-204. PMID: 27015129</li> </ul>



No.	Yes/No	Citations of Missing Evidence
		<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. <i>Spine (Phila Pa 1976)</i>. 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. <i>J Spinal Disord Tech</i>. 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. <i>J Neurosurg Spine</i>. 2005 Feb;2(2):123-7. PMID: 15739522</li> <li>• Paniello RC, Martin-Bredahl KJ, Henkenner LJ, et al. Preoperative laryngeal nerve screening for revision anterior cervical spine procedures. <i>Ann Otol Rhinol Laryngol</i>. 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. <i>Laryngoscope</i>. 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. <i>Spine (Phila Pa 1976)</i>. 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. <i>Laryngoscope</i>. 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. <i>J Neurosurg</i>. 1999 Oct; 91(2 Suppl):170-4. PMID: 10505500</li> <li>• Kamani D, Potenza AS, Cernea CR, et al. The nonrecurrent laryngeal nerve: anatomic and electrophysiologic algorithm for reliable identification. <i>Laryngoscope</i>. 2015 Feb;125(2):503-8. PMID: 25042210</li> <li>• Mehra S, Heineman TE, Cammisa FP Jr, et al. Factors predictive of voice and swallowing outcomes after anterior approaches to the cervical spine. <i>Otolaryngol Head Neck Surg</i>. 2014 Feb; 150(2):259-65. PMID: 24367048</li> <li>• Nettekville JL, Koriwchak MJ, Winkle M, et al. Vocal fold paralysis following the anterior approach to the cervical spine. <i>Ann Otol Rhinol Laryngol</i>. 1996 Feb; 105(2):85-91. PMID: 8659941</li> <li>• Zeng JH, Li XD, Deng L, et al. Lower cervical levels: Increased risk of early dysphonia following anterior cervical spine surgery. <i>Clin Neurol Neurosurg</i>. 2016 Oct; 149:118-21. PMID: 27513980</li> </ul>
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 anesthetist

## Coding

*The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.*

Type	Code	Description
CPT®	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

Type	Code	Description
	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.
06/01/2022	Annual review. Policy statement, guidelines and literature updated.

Effective Date	Action
06/01/2023	Annual review. Policy statement and literature review updated.
07/01/2024	Annual review. Policy statement, guidelines and literature review updated.
06/01/2025	Annual review. No change to policy statement. Literature review updated.

## Definitions of Decision Determinations

**Healthcare Services:** For the purpose of this Medical Policy, Healthcare Services means procedures, treatments, supplies, devices, and equipment.

**Medically Necessary:** Healthcare 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 of California, are: (a) consistent with Blue Shield of California 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 member; 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 or Experimental:** Healthcare Services which do not meet ALL of the following five (5) elements are considered investigational or experimental:

- A. The technology must have final approval from the appropriate government regulatory bodies.
  - This criterion applies to drugs, biological products, devices and any other product or procedure that must have final approval to market from the U.S. Food and Drug Administration ("FDA") or any other federal governmental body with authority to regulate the use of the technology.
  - Any approval that is granted as an interim step in the FDA's or any other federal governmental body's regulatory process is not sufficient.
  - The indications for which the technology is approved need not be the same as those which Blue Shield of California is evaluating.
- B. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
  - The evidence should consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the body of studies and the consistency of the results are considered in evaluating the evidence.
  - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence, or a convincing argument based on established medical facts that such measurement or alteration affects health outcomes.
- C. The technology must improve the net health outcome.
  - The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- D. The technology must be as beneficial as any established alternatives.
  - The technology should improve the net health outcome as much as, or more than, established alternatives.
- E. The improvement must be attainable outside the investigational setting.
  - When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy Criteria C and D.

## Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

For medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

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: 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 member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p><b>Intraoperative Neurophysiologic Monitoring 7.01.58</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. 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: <ol style="list-style-type: none"> <li>A. Spinal</li> <li>B. Intracranial</li> <li>C. Vascular procedures</li> <li>D. Epilepsy ablation</li> </ol> </li> <li>II. Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered <b>medically necessary</b> in individuals undergoing <b>either</b> of the following: <ol style="list-style-type: none"> <li>A. High-risk thyroid or parathyroid surgery, including: <ol style="list-style-type: none"> <li>1. Total thyroidectomy</li> <li>2. Repeat thyroid or parathyroid surgery</li> <li>3. Surgery for cancer</li> <li>4. Thyrotoxicosis</li> <li>5. Retrosternal or giant goiter</li> <li>6. Thyroiditis</li> </ol> </li> <li>B. Anterior cervical spine surgery associated with <b>any</b> of the following increased risk situations: <ol style="list-style-type: none"> <li>1. 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</li> <li>2. Multilevel anterior cervical discectomy and fusion</li> </ol> </li> </ol> </li> </ol>	<p><b>Intraoperative Neurophysiologic Monitoring 7.01.58</b></p> <p><b>Policy Statement:</b></p> <ol style="list-style-type: none"> <li>I. 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: <ol style="list-style-type: none"> <li>A. Spinal</li> <li>B. Intracranial</li> <li>C. Vascular procedures</li> <li>D. Epilepsy ablation</li> </ol> </li> <li>II. Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered <b>medically necessary</b> in individuals undergoing <b>either</b> of the following: <ol style="list-style-type: none"> <li>A. High-risk thyroid or parathyroid surgery, including: <ol style="list-style-type: none"> <li>1. Total thyroidectomy</li> <li>2. Repeat thyroid or parathyroid surgery</li> <li>3. Surgery for cancer</li> <li>4. Thyrotoxicosis</li> <li>5. Retrosternal or giant goiter</li> <li>6. Thyroiditis</li> </ol> </li> <li>B. Anterior cervical spine surgery associated with <b>any</b> of the following increased risk situations: <ol style="list-style-type: none"> <li>1. 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</li> <li>2. Multilevel anterior cervical discectomy and fusion</li> </ol> </li> </ol> </li> </ol>



POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>3. Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve</p> <p>III. 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>IV. Intraoperative monitoring of visual-evoked potentials is considered <b>investigational</b>.</p> <p>V. 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>VI. Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered <b>investigational</b>.</p>	<p>3. Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve</p> <p>III. 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>IV. Intraoperative monitoring of visual-evoked potentials is considered <b>investigational</b>.</p> <p>V. 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>VI. Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered <b>investigational</b>.</p>