

7.01.58 Intraoperative Neurophysiologic Monitoring			
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Section:	7.0 Surgery	Page:	Page 1 of 31

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 may be considered **medically necessary** for protection of the spinal cord where work is performed in close proximity to the cord, as in the placement or removal of old hardware or where there have been numerous interventions.
- III. Intraoperative neurophysiologic monitoring may be considered **medically necessary** during **any** of the following procedures:
 - A. Surgery for acoustic neuroma congenital auricular lesions or cranial based lesions
 - B. Surgery for middle ear and mastoid regions (i.e., cholesteatoma surgery, chronic otitis media surgery, and mastoid surgery)
 - C. Surgical excision of neuromas of the facial nerve
 - D. Microvascular decompression of the facial nerve for hemifacial spasm
- IV. 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
- V. 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**.
- VI. Intraoperative monitoring of visual-evoked potentials is considered **investigational**.

- VII. 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**.
- VIII. Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered **investigational**.

Note: These policy statements refer only to use of these techniques as part of intraoperative monitoring. Other clinical applications of these techniques, such as visual-evoked potentials and electromyography (EMG), are not considered in this policy.

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

Policy Guidelines

Intraoperative neurophysiologic monitoring, including somatosensory-evoked potentials and motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography of cranial nerves, electroencephalography, and electrocorticography, has broad acceptance, particularly for spine surgery and open abdominal aorta aneurysm repairs. Therefore, this evidence review focuses on monitoring of the recurrent laryngeal nerve during neck surgeries and monitoring of peripheral nerves.

Constant communication among the surgeon, neurophysiologist, and anesthetist is required for safe and effective intraoperative neurophysiologic monitoring.

Coding

There are specific CPT codes for this service:

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

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

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

- **95865:** Needle electromyography; larynx
- **95867:** Needle electromyography; cranial nerve supplied muscle(s), unilateral
- **95868:** Needle electromyography; cranial nerve supplied muscles, bilateral
- **95907:** Nerve conduction studies; 1-2 studies
- **95908:** Nerve conduction studies; 3-4 studies
- **95909:** Nerve conduction studies; 5-6 studies
- **95910:** Nerve conduction studies; 7-8 studies
- **95911:** Nerve conduction studies; 9-10 studies
- **95912:** Nerve conduction studies; 11-12 studies
- **95913:** Nerve conduction studies; 13 or more studies
- **95925:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs

- **95926:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
- **95927:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
- **95928:** Central motor evoked potential study (transcranial motor stimulation); upper limbs
- **95929:** Central motor evoked potential study (transcranial motor stimulation); lower limbs
- **95930:** Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
- **95938:** Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
- **95939:** Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs
- **95955:** Electroencephalogram (EEG) during nonintracranial surgery (e.g., carotid surgery)

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

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

Description

Intraoperative neurophysiologic monitoring describes a variety of procedures used to monitor the integrity of neural pathways during high-risk neurosurgical, orthopedic, and vascular surgeries. It involves the detection of electrical signals produced by the nervous system in response to sensory or electrical stimuli to provide information about the functional integrity of neuronal structures. This evidence review does not address established neurophysiologic monitoring (i.e., somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography of cranial nerves, electroencephalography, electrocorticography), during spinal, intracranial, or vascular procedures.

Related Policies

- N/A

Benefit Application

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

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

Regulatory Status

A number of EEG and EMG monitors have been cleared for marketing by the FDA through the 510(k) process.

FDA product code: GWQ.

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

Rationale

Background

Intraoperative Neurophysiologic Monitoring

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

Sensory-Evoked Potentials

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

Somatosensory-Evoked Potentials

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

Brainstem Auditory-Evoked Potentials

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

Visual-Evoked Potentials

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

Motor-Evoked Potentials

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

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

Electromyogram Monitoring and Nerve Conduction Velocity Measurements

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

Electroencephalogram Monitoring

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

- 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.¹⁻⁷ 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Recurrent Laryngeal Nerve Monitoring During Thyroid or Parathyroid Surgery

Clinical Context and Therapy Purpose

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

The 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

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.⁷ 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-analysis⁸; 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.⁹ 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.¹⁰ 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
Pardal-Refoyo and Ochoa-Sangrador (2016)¹⁰	1987-2013	<ul style="list-style-type: none"> 2 RCTs 52 case series 	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"> RCTs Case series 	NR
Sun et al (2017)⁹	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
Henry et al (2017)⁷	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

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)¹⁰			
ARR (95% CI)	2.75% (NR) ^a	NR	NR
NNT (95% CI)	364 (NR) ^a	NR	NR
I ² (p)	8% (NR) ^a	NR	NR
	Overall RLN Palsy		
Sun et al (2017)⁹			
With IONM	4.69%	3.98% ^b	1.26% ^b
Without IONM	9.27%	6.63% ^b	2.78% ^b
RR (95% CI)	0.434 (0.206 to 0.916)	0.607 (0.270 to 1.366)	0.426 (0.196 to 0.925)
NNT (95% CI)	NR	NR ^b	NR ^b
I ² (p)	70.2% (.029)	67.4% ^b (.227)	13.7% ^b (.031)

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.

^a Sample size of 11947 patients.

^b 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 4.¹¹ 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.¹²

Table 3. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Active	Comparator
Barczynski et al (2009)¹¹	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) ¹¹			
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; NNT: number needed to treat; 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 patients 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).¹³ All studies were of low methodologic quality but had a low risk of bias. Only studies that compared the risk of nerve injury using intraoperative neurophysiologic monitoring with no intraoperative neurophysiologic monitoring were included. Based on data from these 2 studies, there was no statistically significant difference in the risk of neurologic injury with or without intraoperative neurophysiologic monitoring (odds ratio [OR], 0.726; 95% confidence interval [CI], 0.287 to 1.833; $p=.498$) (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.¹⁴ 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.¹⁵ 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) ¹³	NR	10	Studies reporting IONM use for ACSS	26,357 (16 to 22,768)	9 retrospective, 1 prospective	NR
Erwood et al (2016) ¹⁴	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) ¹⁵	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) ¹³	
OR ^{a,b} (95% CI)	0.726 (0.287 to 1.833)
I ² (p)	0% (.44)
Erwood et al (2016) ¹⁴	
Estimate ^c (95% CI)	0.14 (0.10 to 0.19)
I ² (p)	10.7% (NR)
Daniel et al (2018) ¹⁵	
OR ^a (95% CI)	0.72 (0.71 to 1.79)

Study	Risk of Neurologic Injury
I ² (p)	NR (.4584)

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

^a Risk of neurologic injury after spine surgery with or without intraoperative neurophysiologic monitoring.

^b Included 2 studies.

^c 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).¹⁶ 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) ¹⁶
Komatsu et al (2022) ¹⁷ ,	●
Huang et al (2022) ¹⁸ ,	●
Zhao et al (2022) ¹⁹ ,	●
Yuda et al (2022) ²⁰ ,	●
Takeda et al (2020) ²¹ ,	●
Fujimoto et al (2021) ²² ,	●
Kobayashi et al (2018) ²³ ,	●
Zhu et al (2018) ²⁴ ,	●
Hikage et al (2017) ²⁵ ,	●
Zhong et al (2014) ²⁶ ,	●

Table 8. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Chen et al (2023) ¹⁶ ,	2014-2022	10	Patients with esophageal malignancy undergoing esophagectomy with mediastinal lymph node dissection	949 (16-142)	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) ¹⁶ ,				
949	949	340	452	568
Odds ratio (95% CI)	0.32 (0.19 to 0.54)	4.26 ^a (1.63 to 6.89)	-12.33 ^a (-33.94 to 9.28)	-2.07 ^a (-6.61 to 2.46)
I^2 (p)	42% (<.0001)	49% (.002)	59% (0.26)	56% (.37)

CI: confidence interval.

^a 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.²⁷ 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.²⁸ 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.²⁹ 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.³⁰

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.^{31,32,33}

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.³⁴ 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%. 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.³⁵ 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 ($I^2=89\%$).

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

Study	Reddy et al (2022) ³⁴	Thirumala et al (2017) ³⁵
Alemo et al (2010) ³⁶	●	
Bindal et al (2007) ³⁷	●	
Bose et al (2002) ³⁸	●	
Clements et al (1996) ³⁹	●	
Darden et al (1996) ⁴⁰	●	
Luo et al (2012) ⁴¹	●	
Maguire et al (1995) ⁴²	●	
Papadopoulos et al (2005) ⁴³	●	
Sutter et al (2007) ⁴⁴	●	
Welch et al (1997) ⁴⁵	●	
Wood et al (2010) ⁴⁶	●	
Wood et al (2014) ⁴⁷	●	
Melachuri et al (2021) ⁴⁸	●	
Accadbled et al (2006) ⁴⁹		●
Eggspuehler et al (2007) ⁵⁰		●
El-Hawary et al (2006) ⁵¹		●
Feng et al (2012) ⁵²		●
Kundnani et al (2010) ⁵³		●
Lo et al (2008) ⁵⁴		●
Luk et al (2001) ⁵⁵		●
MacDonald et al (2007) ⁵⁶		●
Noonan et al (2002) ⁵⁷		●
Pastorelli et al (2011) ⁵⁸		●
Pereon et al (1998) ⁵⁹		●
Schwartz et al (2007) ⁶⁰		●

Table 11. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Reddy et al (2022) ³⁴	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

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Thirumala et al (2017) ³⁵	1998-2012	12	Patients undergoing idiopathic scoliosis correction surgery	2915 (25-1121)	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) ³⁴				
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) ³⁵				
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 cohort studies have evaluated the effect of intraoperative neurophysiologic monitoring during spinal procedures requiring instrumentation. Some of these studies reported measures of accuracy. For example, Murphy et al (2022) conducted a retrospective evaluation of 169 patients who underwent spinal surgery with intraoperative neurophysiologic monitoring.⁶¹ Signal changes occurred in 45 patients (26.6%). Of the 21 patients whose signals did not improve before the end of the procedure, none developed postoperative neurologic deficits. The rate of false positives was 38% and false negatives was 1.8%.

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.⁶² 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. 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.⁴⁴ 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. 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.

Supplemental Information

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2017 Input

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.

2014 Input

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

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology

In 1990 (updated in 2012), the American Academy of Neurology (AAN) published an assessment of intraoperative neurophysiologic monitoring, with an evidence-based guideline update by the AAN and the American Clinical Neurophysiology Society (ACNS) in 2012 (guideline last reaffirmed on October 17, 2020).^{1,2} The 1990 assessment indicated that monitoring requires a team approach with a well-trained physician-neurophysiologist to provide or supervise monitoring. Electroencephalogram (EEG) monitoring is used during carotid endarterectomy or for other similar situations in which

cerebral blood flow is at high risk. Electrocorticography from surgically exposed cortex can help to define the optimal limits of surgical resection or identify regions of greatest impairment, while sensory cortex somatosensory-evoked potentials can help to localize the central fissure and motor cortex. Auditory-evoked potentials, along with cranial nerve monitoring can be used during posterior fossa neurosurgical procedures. Spinal cord somatosensory-evoked potentials are frequently used to monitor the spinal cord during orthopedic or neurosurgical procedures around the spinal cord, or cross-clamping of the thoracic aorta. Electromyographic monitoring during procedures near the roots and peripheral nerves can be used to warn of excessive traction or other impairment of motor nerves. At the time of the 1990 assessment, motor-evoked potentials were considered investigational by many neurophysiologists. The 2012 update, which was endorsed by the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), concluded that the available evidence supported intraoperative neurophysiologic monitoring using somatosensory-evoked potentials or motor-evoked potentials when conducted under the supervision of a clinical neurophysiologist experienced with intraoperative neurophysiologic monitoring. Evidence was insufficient to evaluate intraoperative neurophysiologic monitoring when conducted by technicians alone or by an automated device.

In 2012, the AAN published a model policy on principles of coding for intraoperative neurophysiologic monitoring and testing (last amended July 31, 2018).⁶³ The background section of this document provides the following information on the value of intraoperative neurophysiologic monitoring in averting neural injuries during surgery:

1. "Value of EEG Monitoring in Carotid Surgery. Carotid occlusion, incident to carotid endarterectomies, poses a high-risk for cerebral hemispheric injury. Electroencephalogram (EEG) monitoring is capable of detecting cerebral ischemia, a serious prelude to injury. Studies of continuous monitoring established the ability of electroencephalogram EEG to correctly predict risks of postoperative deficits after a deliberate, but necessary, carotid occlusion as part of the surgical procedure. The surgeon can respond to adverse EEG events by raising blood pressure, implanting a shunt, adjusting a poorly functioning shunt, or performing other interventions.
2. Multicenter Data in Spinal Surgeries. An extensive multicenter study conducted in 1995 demonstrated that [intraoperative neurophysiologic monitoring] using [sensory-evoked potentials] reduced the risk of paraplegia by 60% in spinal surgeries. The incidence of false negative cases, wherein an operative complication occurred without having been detected by the monitoring procedure, was small: 0.06%.
3. Technology Assessment of Monitoring in Spinal Surgeries. A technology assessment by the McGill University Health Center...reviewed 11 studies and concluded that spinal [intraoperative neurophysiologic monitoring] is capable of substantially reducing injury in surgeries that pose a risk to spinal cord integrity. It recommended combined sensory-evoked potentials/motor-evoked potential monitoring, under the presence or constant availability of a monitoring physician, for all cases of spinal surgery for which there is a risk of spinal cord injury.
4. Value of Combined Motor and Sensory Monitoring. Numerous studies of post-surgical paraparesis and quadriparesis have shown that both sensory-evoked potentials and motor-evoked potential monitoring had predicted adverse outcomes in a timely fashion. The timing of the predictions allowed the surgeons the opportunity to intervene and prevent adverse outcomes. The 2 different techniques (sensory-evoked potentials and motor-evoked potential) monitor different spinal cord tracts. Sometimes, one of the techniques cannot be used for practical purposes, for anesthetic reasons, or because of preoperative absence of signals in those pathways. Thus, the decision about which of these techniques to use needs to be tailored to the individual patient's circumstances.
5. Protecting the Spinal Cord from Ischemia during Aortic Procedures. Studies have shown that [intraoperative neurophysiologic monitoring] accurately predicts risks for spinal cord ischemia associated with clamping the aorta or ligating segmental spinal arteries. [Intraoperative neurophysiologic monitoring] can assess whether the spinal cord is tolerating the degree of relative ischemia in these procedures. The surgeon can then respond by raising

blood pressure, implanting a shunt, re-implanting segmental vessels, draining spinal fluid, or through other interventions...

6. Value of EMG [electromyogram] monitoring. Selective posterior rhizotomy in cerebral palsy significantly reduces spasticity, increases range of motion, and improves functional skills. Electromyography during this procedure can assist in selecting specific dorsal roots to transect. Electromyogram (EMG) can also be used in peripheral nerve procedures that pose a risk of injuries to nerves...
7. Value of Spinal Monitoring using somatosensory-evoked potentials and motor-evoked potentials. According to a recent review of spinal monitoring using somatosensory-evoked potential and motor-evoked potentials by the Therapeutics and Technology Assessment Subcommittee of AAN and ACNS, [intraoperative neurophysiologic monitoring] is established as effective to predict an increased risk of the adverse outcomes of paraparesis, paraplegia, and quadriplegia in spinal surgery (4 Class I and 7 Class II studies). Surgeons and other members of the operating team should be alerted to the increased risk of severe adverse neurologic outcomes in patients with important [intraoperative neurophysiologic monitoring] changes (Level A)."

The AAN model policy also offered guidance on personnel and monitoring standards for intraoperative neurophysiologic monitoring and somatosensory-evoked potential.

American Association of Neurological Surgeons and Congress of Neurological Surgeons

In 2018, the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons updated their position statement on intraoperative neurophysiologic monitoring during routine spinal surgery.⁶⁴ They stated that intraoperative neurophysiologic monitoring, especially motor evoked potential, "is a reliable diagnostic tool for assessment of spinal cord integrity during surgery" (Level 1 evidence). Intraoperative motor evoked potentials may also "predict recovery in traumatic cervical spinal cord injury." However, AANS and Congress of Neurological Surgeons found no evidence that such monitoring provides a therapeutic benefit. The statement also recommends that intraoperative neurophysiologic monitoring should be used when the operating surgeon believes it is warranted for diagnostic value, such as with "deformity correction, spinal instability, spinal cord compression, intradural spinal cord lesions, and when in proximity to peripheral nerves or roots." In addition, they recommend spontaneous and evoked electromyography "for minimally invasive lateral retroperitoneal transpsoas approaches to the lumbar spine" and during screw insertion. In 2014, the same organizations published guidance on electrophysiological monitoring for lumbar fusion procedures.⁶⁵ The authors concluded that there was a lack of high quality studies and that routine intraoperative monitoring during lumbar fusion could not be recommended. Evidence regarding the efficacy of intraoperative monitoring to recover nerve function or affect the outcome of surgery.

American Association of Neuromuscular & Electrodiagnostic Medicine

In 2023, the AANEM updated their position statement on electrodiagnostic medicine.⁵ The recommendations indicated that intraoperative sensory-evoked potentials have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts. The AANEM stated that intraoperative somatosensory-evoked potential monitoring is indicated for select spine surgeries in which there is a risk of additional nerve root or spinal cord injury. Indications for somatosensory-evoked potential monitoring may include, but are not limited to, complex, extensive, or lengthy procedures, and when mandated by hospital policy. However, intraoperative somatosensory-evoked potential monitoring may not be indicated for routine lumbar or cervical root decompression.

American Clinical Neurophysiology Society

In 2009, the ACNS recommended standards for intraoperative neurophysiologic monitoring.⁴ Guideline 11A included the following statement⁶⁶:

"The monitoring team should be under the direct supervision of a physician with training and experience in neurophysiologic intraoperative monitoring. The monitoring physician should be licensed in the state and privileged to interpret neurophysiologic testing in the hospital in which the

surgery is being performed. He/she is responsible for real-time interpretation of neurophysiologic intraoperative monitoring data. The monitoring physician should be present in the operating room or have access to intraoperative neurophysiologic monitoring data in real-time from a remote location and be in communication with the staff in the operating room. There are many methods of remote monitoring, however any method used must conform to local and national protected health information guidelines. The specifics of this availability (ie, types of surgeries) should be decided by the hospital credentialing committee. In order to devote the needed attention, it is recommended that the monitoring physician interpret no more than three cases concurrently."

American Head and Neck Society

In 2022, the American Head and Neck Society Endocrine Surgery Section and the International Neural Monitoring Study Group published a clinical review of intraoperative nerve monitoring during pediatric thyroid surgery.⁶⁷ The review stated that intraoperative neurophysiologic monitoring can be considered in all pediatric thyroid surgeries. Procedures for which monitoring may be most beneficial include: total thyroidectomy, hemithyroidectomy in which the contralateral vocal cord is paralyzed, and reoperative surgeries.

American Society of Neurophysiological Monitoring

In 2018, the American Society of Neurophysiological Monitoring (ASNM) published practice guidelines for the supervising professional on intraoperative neurophysiologic monitoring.¹⁵ The ASNM (2013) position statement on intraoperative motor-evoked potential monitoring indicated that motor-evoked potentials are an established practice option for cortical and subcortical mapping and monitoring during surgeries risking motor injury in the brain, brainstem, spinal cord, or facial nerve.⁶⁸

Scoliosis Research Society

In 2020, the Scoliosis Research Society published an information statement on neurophysiologic monitoring during spinal deformity surgery.⁶⁹ The Society concluded that neurophysiologic monitoring can allow for early detection of complications and possibly prevent postoperative neurologic injury, and is considered optimal care when the spinal cord is at risk, which warrants a strong recommendation unless there are contraindications. The standard method of intraoperative monitoring should include transcranial motor evoked potentials and somatosensory evoked potentials with or without electromyographic monitoring.

National Institute for Health and Care Excellence

In 2008, a guidance from NICE on intraoperative neurophysiologic monitoring during thyroid surgery found no major safety concerns.⁷⁰ Regarding efficacy, intraoperative neurophysiologic monitoring was indicated as helpful "in performing more complex operations such as reoperative surgery and operations on large thyroid glands."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

The Centers for Medicare & Medicaid Services has indicated that EEG monitoring "may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted."⁷¹ Coverage determinations for other modalities were not identified.

The Centers for Medicare & Medicaid Services Physician Fee Schedule Final Rule (2013) discussed payment of neurophysiologic monitoring. The rule states that CPT code 95940, which is reported when a physician monitors a patient directly, is payable by Medicare. CPT code 95941, which is used for remote monitoring, was made invalid for submission to Medicare.

In the Final Rule, the Centers established a HCPCS G code (see Policy Guidelines section) for reporting physician monitoring performed from outside of the operating room (nearby or remotely). HCPCS code G0453 “may be billed only for undivided attention by the monitoring physician to a single beneficiary [1:1 technologist to oversight physician billing], and not for simultaneous attention by the monitoring physician to more than one patient.”⁷²

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 13.

Table 13. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT05710016	Evaluation Of Intra-Operative Neuro-Monitoring Alarm During Complex Spine Surgery	20	Dec 2023
NCT01630785	Retrospective Data Analysis of Neurophysiological Data for Intraoperative or Epilepsy Monitoring	5000	Dec 2025

NCT: national clinical trial.

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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

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

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

Type	Code	Description
CPT®	95829	Electrocorticogram at surgery (separate procedure)
	95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days
	95865	Needle electromyography; larynx
	95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
	95868	Needle electromyography; cranial nerve supplied muscles, bilateral
	95907	Nerve conduction studies; 1-2 studies
	95908	Nerve conduction studies; 3-4 studies
	95909	Nerve conduction studies; 5-6 studies
	95910	Nerve conduction studies; 7-8 studies
	95911	Nerve conduction studies; 9-10 studies
	95912	Nerve conduction studies; 11-12 studies
	95913	Nerve conduction studies; 13 or more studies
	95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
	95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
	95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
	95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs
	95929	Central motor evoked potential study (transcranial motor stimulation); lower limbs
	95930	Visual evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
	95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
	95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs
	95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)

Type	Code	Description
	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.
06/01/2023	Annual review. Policy statement and literature review updated.

Definitions of Decision Determinations

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

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with

generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

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

Prior Authorization Requirements and Feedback (as applicable to your plan)

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

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

We are 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.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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

Appendix A

POLICY STATEMENT

BEFORE <u>Red font: Verbiage removed</u>	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>Intraoperative Neurophysiologic Monitoring 7.01.58</p> <p>Policy Statement: Intraoperative neurophysiologic monitoring, which includes somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography (EMG) of cranial nerves, electroencephalography (EEG), and electrocorticography (ECoG), may be considered medically necessary during any of the following procedures:</p> <ul style="list-style-type: none"> A. Spinal B. Intracranial C. Vascular procedures D. Epilepsy ablation <p>Intraoperative neurophysiologic monitoring may be considered medically necessary for protection of the spinal cord where work is performed in close proximity to the cord, as in the placement or removal of old hardware or where there have been numerous interventions.</p> <p>Intraoperative neurophysiologic monitoring may be considered medically necessary during any of the following procedures:</p> <ul style="list-style-type: none"> A. Surgery for acoustic neuroma congenital auricular lesions or cranial based lesions B. Surgery for middle ear and mastoid regions (i.e., cholesteatoma surgery, chronic otitis media surgery, and mastoid surgery) C. Surgical excision of neuromas of the facial nerve D. Microvascular decompression of the facial nerve for hemifacial spasm 	<p>Intraoperative Neurophysiologic Monitoring 7.01.58</p> <p>Policy Statement:</p> <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> A. Spinal B. Intracranial C. Vascular procedures D. Epilepsy ablation II. Intraoperative neurophysiologic monitoring may be considered medically necessary for protection of the spinal cord where work is performed in close proximity to the cord, as in the placement or removal of old hardware or where there have been numerous interventions. III. Intraoperative neurophysiologic monitoring may be considered medically necessary during any of the following procedures: <ul style="list-style-type: none"> A. Surgery for acoustic neuroma congenital auricular lesions or cranial based lesions B. Surgery for middle ear and mastoid regions (i.e., cholesteatoma surgery, chronic otitis media surgery, and mastoid surgery) C. Surgical excision of neuromas of the facial nerve D. Microvascular decompression of the facial nerve for hemifacial spasm

POLICY STATEMENT

<p>BEFORE</p> <p><u>Red font: Verbiage removed</u></p>	<p>AFTER</p> <p><u>Blue font: Verbiage Changes/Additions</u></p>
<p>Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered medically necessary in patients undergoing either of the following:</p> <ul style="list-style-type: none"> I. High-risk thyroid or parathyroid surgery, including: <ul style="list-style-type: none"> A. Total thyroidectomy B. Repeat thyroid or parathyroid surgery C. Surgery for cancer D. Thyrotoxicosis E. Retrosternal or giant goiter F. Thyroiditis II. Anterior cervical spine surgery associated with any of the following increased risk situations: <ul style="list-style-type: none"> A. Prior anterior cervical surgery, particularly revision anterior cervical discectomy and fusion, revision surgery through a scarred surgical field, reoperation for pseudarthrosis, or revision for failed fusion B. Multilevel anterior cervical discectomy and fusion C. Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve <p>Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during anterior cervical spine surgery not meeting the criteria above or during esophageal surgeries is considered investigational.</p> <p>Intraoperative monitoring of visual-evoked potentials is considered investigational.</p> <p>Due to the lack of monitors approved by the U.S. Food and Drug Administration (FDA), intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered investigational.</p>	<ul style="list-style-type: none"> IV. Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered medically necessary in individuals undergoing either of the following: <ul style="list-style-type: none"> A. High-risk thyroid or parathyroid surgery, including: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 V. 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. VI. Intraoperative monitoring of visual-evoked potentials is considered investigational. VII. 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. VIII. Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered investigational.

POLICY STATEMENT	
BEFORE <u>Red font: Verbiage removed</u>	AFTER <u>Blue font: Verbiage Changes/Additions</u>
<p>Intraoperative electromyography (EMG) and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered investigational.</p> <p>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.</p>	<p>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.</p>