Medical Policy

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(See policy history boxes for previous effective dates)

Title: Intraoperative Neurophysiologic Monitoring

Description/Background

INTRAOPERATIVE NEUROPHYSIOLOGIC MONITORING
The principal goal of intraoperative neurophysiologic monitoring (IONM) 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. There are different methodologies of monitoring are described below.

Sensory-Evoked Potentials
Sensory-evoked potential describes 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 simulation 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 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 the U.S. Food and Drug Administration (FDA) premarket approval in 2002. Devices for transcranial magnetic stimulation have not been approved by FDA for this use.

Multimodal intraoperative neurophysiologic monitoring, in which more than 1 technique is used, most commonly with somatosensory-evoked potentials and MEPs, 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 (eg, to identify the extent of nerve damage prior to nerve grafting or during resection of tumors). For procedures with a risk of vocal cord paralysis due to damage to the recurrent laryngeal nerve (ie, 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 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 (ECoG) is the recording of EEG activity directly from a surgically exposed cerebral cortex. Electrocorticopgraphy 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.[1-6] Therefore, this evidence review focuses on monitoring of the recurrent laryngeal nerve during neck and esophageal surgeries and monitoring of peripheral nerves.

Neuromuscular Stimulation: Train of Four (TOF) Stimulation
Train of Four (TOF) is used by anesthesiologists to measure the effect of nondepolarizing Neuromuscular Blocking Agents during a surgical procedure. It consists of four successive supramaximal stimuli delivered at 2 Hz, no less than 10 seconds apart to a peripheral nerve, usually on the upper extremity.

Train-of-four testing is a form of anesthetic monitoring, not neurophysiologic monitoring as addressed in this policy and as such, it is not separately reimbursed.

Regulatory Status:

A number of EEG and EMG monitors have been cleared for marketing by the Food and Drug Administration (FDA) through the 510(k) process. FDA product code: GWQ.

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

Medical Policy Statement

Intraoperative neurophysiologic monitoring, which includes somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, EMG of cranial nerves, EEG, and electrocorticography, is established during spinal, intracranial, or vascular procedures.
Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve is established for individuals meeting inclusionary guidelines.

Intraoperative monitoring of visual-evoked potentials is considered **experimental/ investigational**.

Intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered **experimental/investigational**.

Inclusionary and Exclusionary Guidelines

<u>Inclusions</u>:
The following types of intraoperative monitoring are appropriate when performed during spinal, intracranial, or vascular surgeries or procedures:

- Somatosensory-evoked potentials
- Motor-evoked potentials using transcranial electrical stimulation
- Brainstem auditory-evoked potentials
- Electromyogram (EMG) of cranial nerves
- Electroencephalogram EEG
- Electrocorticography (ECoG)

Notes:

- Only qualified persons can perform this type of monitoring.
- Train-of-four monitoring is considered integral (not separately payable) to intraoperative procedures to measure the strength of anesthetic neuromuscular blockade.

Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve is established in individuals undergoing:

- high risk thyroid or parathyroid surgery, including:
    - total thyroidectomy

    - repeat thyroid or parathyroid surgery
    - surgery for cancer
    - thyrotoxicosis
    - retrosternal or giant goiter
    - thyroiditis
- anterior cervical spine surgery associated with any of the following increased risk situations:
    - prior anterior cervical surgery, particularly revision anterior cervical discectomy and fusion, revision surgery through a scarred surgical field, reoperation for pseudarthrosis or revision for failed fusion
    - multilevel anterior cervical discectomy and fusion
    - preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve.

Exclusions:
- Intraoperative monitoring of visual-evoked potentials
- Intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation
- Intraoperative EMG and nerve conduction velocity monitoring during surgery on the peripheral nerves
- Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during anterior cervical spine surgery not meeting the criteria above or during esophageal surgeries
- Intraoperative monitoring performed during any surgical procedure not specified in the inclusions

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CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

92652	92653	95829	95867	95868	95925
95926	95927	95928**	95929**	95938	95939**
95940*	95955	G0453*			

Other codes (investigational, not medically necessary, etc.):

95907	95908	95909	95910	95911	95912
95913	95928	95929	95930	95939	95941
95999***					

***CPT codes 95940 or G0453 should be used to report intraoperative neurophysiological monitoring regardless of the specific test that is performed**

****CPT codes 95928, 95929 and 95939 are only established when used to report motor-evoked potentials using transcranial electrical stimulation**

*****95999 Train-of-four monitoring is considered integral (not separately payable) to intraoperative procedures to measure the strength of anesthetic neuromuscular blockade.**

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

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

RECURRENT LARYNGEAL NERVE MONITORING DURING THYROID OR PARATHYROID SURGERY

Clinical Context and Therapy Purpose

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

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

Populations
The relevant population of interest are 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:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- 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.[7] 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.[8] 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[9]; 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.[10] 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.[11] 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)[11]	1987-2013	2 RCTs 52 case series	Studies reporting incidence of RLN paralysis after single-stage total thyroidectomy through open cervicotomy	30,922 (23 to 2,546 patients)	RCTs Case series	NR
Sun et al (2017)[10]	Up to Aug 2016	9	Studies reporting incidence of RLN complications after thyroid surgery	2,436 nerves at risk (1,109 with IONM, 1,327 without IONM)	Prospective and retrospective cohort studies	NR
Henry et al (2017)[8]	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
Cozzi et al (2023)[7]	Up to Jan 2023	• 12 RCTs • 80 prospective cohort studies	Studies reporting incidence of RLN complications after thyroid surgery	42,015 procedures with 73,325 nerves at risk	• RCTs • Prospective cohort • Case series	1 year or more

		• 72 were prospective case series				

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)[11]			
ARR (95% CI)	2.75% (NR)[a]	NR	NR
NNT (95% CI)	364 (NR)[a]	NR	NR
I2 (p)	8%a (NR)[a]	NR	NR
	Overall RLN Palsy		
Sun et al (2017)[10]			
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)
Cozzi et al (2023)[7]			
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.
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.[12] 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.[13]

Table 3. Summary of Key Randomized Controlled Trial Characteristics

Study	Countries	Sites	Dates	Participants	Active	Comparator

Barczynski et al (2009)[12,]	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)[12,]			
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) (0.007)	1.9% (NR) (0.011)	0.4% (NR) (*NS*)
NNT (95% CI)	NR	NR	NR

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 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 are 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 are 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 principles described in the first indication.

Review of Evidence

Systematic Reviews

Ajiboye et al (2017) reported on the results of a systematic review that included 10 studies (N= 26,357).[14] 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.[15] 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.[16] 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 confidence intervals being included.

Table 5. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Ajiboye et al (2017)[14]	NR	10	Studies reporting IONM use for ACSS	26,357 (16-22,768)	· 9 retrospective · 1 prospective	NR
Erwood et al (2016)[15]	1998-2015	8	Studies reporting reoperative ACSS for RLN	238 (13-63)	· 5 prospective · 3 retrospective	2 wk to 24 mo
Daniel et al (2018)[16]	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)[14,]	
OR[a,b] (95% CI)	0.726 (0.287 to 1.833)
I2 (p)	0% (0.44)
Erwood et al (2016)[15,]	
Estimate[c] (95% CI)	0.14 (0.10 to 0.19)
I2 (p)	10.7% (NR)
Daniel et al (2018)[16,]	
OR[a] (95% CI)	0.72 (0.71 to 1.79)
I2 (p)	NR (.4584)

CI: confidence interval; NR: not reported; OR: odds ratio.
[a]Risk of neurologic injury after anterior cervical discectomy and fusion with or without intraoperative neurophysiologic monitoring.
[b]Included 2 studies.

Section Summary: Recurrent Laryngeal Nerve Monitoring During Cervical Spine Surgery

The evidence on the use of intraoperative neurophysiologic monitoring in reducing recurrent laryngeal nerve injury during cervical spinal surgery includes 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 patients who are undergoing esophageal surgery.

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

Populations
The relevant population of interest are 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 principles described in the first indication.

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).[17] 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) [18]	•
Huang et al (2022) [19]	•
Zhao et al (2022) [20]	•
Yuda et al (2022) [21]	•

Takeda et al (2020) [22]	•
Fujimoto et al (2021) [23]	•
Kobayashi et al (2018) [24]	•
Zhu et al (2018) [25]	•
Hikage et al (2017) [26]	•
Zhong et al (2014) [27]	•

Table 8. Systematic Review Characteristics

Study	Dates	Trials	Participants	N(Range)	Design	Duration
Chen et al (2023) [17]	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) [17]				
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 cancer 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 patients 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 are 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 principles described in the first indication.

Review of Evidence

Case-Control Study
Kneist et al (2013) assessed monitoring peripheral nerves during surgery in a case-control study of 30 patients.[28] 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.[30] 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 with 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.[31]

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.[32,33,34]

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 patients 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.[35] 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.[36] 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) [37]	•	
Bindal et al (2007) [38]	•	
Bose et al (2002) [39]	•	
Clements et al (1996) [40]	•	
Darden et al (1996) [41]	•	

Luo et al (2012) [42]	•	
Maguire et al (1995) [43]	•	
Papadopoulos et al (2005) [44]	•	
Papadopoulos et al (2005)	•	
Sutter et al (2007) [45]	•	
Welch et al (1997) [46]	•	
Wood et al (2010) [47]	•	
Wood et al (2014) [48]	•	
Melachuri et al (2021) [49]	•	
Accadbled et al (2006) [50]		•
Eggspuehler et al (2007) [51]		•
El-Hawary et al (2006) [52]		•
Feng et al (2012) [53]		•
Kundnani et al (2010)[54]		•
Lo et al (2008)[55]		•
Luk et al (2001) [56]		•
MacDonald et al (2007) [57]		•
Noonan et al (2002)[58]		•
Pastorelli et al (2011) [59]		•
Pereon et al (1998) [60]		•
Schwartz et al (2007) [61]		•

Table 11. Systematic Review Characteristics

Study	Dates	Trials	Participants	N(Range)	Design	Duration
Reddy et al (2022) [35]	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) [36]	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 radio of stimulation predicting postoperative neurologic deficit
Reddy et al (2022) [36]				
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) [37]				
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 (N>1000) studies 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.[63] 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.[46] 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.

SUMMARY OF EVIDENCE
For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve who receive intraoperative neurophysiologic monitoring, the evidence includes a large RCT and systematic reviews. Relevant outcomes are morbid events,

functional outcomes, and quality of life. The strongest evidence on neurophysiologic monitoring derives from a randomized controlled trial of 1,000 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 nonrandomized comparative study. Relevant outcomes are morbid events, functional outcomes, and quality of life. One nonrandomized comparative study on surgery for esophageal cancer was identified. Interpretation of this study is confounded because only those patients who had visual identification of the nerve underwent neurophysiologic monitoring. Current evidence is not sufficiently robust to determine whether neurophysiologic monitoring reduces recurrent laryngeal nerve injury in patients undergoing surgery for esophageal cancer. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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.

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 by the Blue Cross Blue Shield Association 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 the 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 by Blue Cross Blue Shield Association from 5 physician specialty societies (7 responses) and 2 academic medical centers while their policy was under review in 2014. Input agreed that intraoperative monitoring with somatosensory-evoked potentials, moto-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, EMG of cranial nerves, EEG, or ECoG, may be medically necessary during spinal, intracranial, or vascular procedures. There was general agreement that intraoperative 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 of some peripheral nerves during spinal surgery (eg, nerve roots, percutaneous pedicle screw placement, lateral transpsoas approach to the lumbar spine). Other reviewers suggested neurophysiologic monitoring for resection of peripheral nerve tumors or during 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 21,2023).[1,2] The 1990 assessment indicated that monitoring requires a team approach with a well-trained physician-neurophysiologist to provide or supervise monitoring. Electroencephalography (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 (MEPs) were considered investigational by many neurophysiologists. The 2012 update, which was endorsed by American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), concluded that the available evidence supported IONM using somatosensory-evoked potentials or MEPs when conducted under the supervision of a clinical neurophysiologist experienced with IONM. Evidence was insufficient to evaluate IONM when conducted by technicians alone or by an automated device.

In 2012, the AAN published a model policy on principles of coding for IONM and testing in 2012.[64] The background section of this document provides the following information on the value of IONM 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. EEG monitoring is capable of detecting cerebral ischemia, a serious prelude to injury. Studies of continuous monitoring established the ability of 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 SEP and MEP 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 (SEP and MEP) 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 IOM 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. 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 SSEP and MEPs 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 IOM changes (Level A)."

The AAN model policy also offered guidance on personnel and monitoring standards for IONM 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.[5] 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 pedicle screw insertion.

In 2014, the same organizations published guidance on electrophysiological monitoring for lumbar fusion procedures.[66] 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) published recommended standards for intraoperative neurophysiologic monitoring.(4) Guideline 11A included the following statement.[28]

“The monitoring team should be under the direct supervision of a physician with training and experience in NIOM [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 NIOM data. The monitoring physician should be present in the operating room or have access to NIOM 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 monitoring physician must be available to be in the operating room, and the specifics of this availability (i.e., types of surgeries) should be decided by the hospital credentialing committee. In order to devote the needed attention, it is recommended that the monitoring physician interpret no more than three cases concurrently.“

American Society of Neurophysiological Monitoring
In 2018, the American Society of Neurophysiological Monitoring published practice guidelines for the supervising professional on intraoperative neurophysiologic monitoring.[18] 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.[29]

National Institute for Health and Care Excellence
In 2008, a guidance from the National Institute for Health and Care Excellence on intraoperative neurophysiologic monitoring during thyroid surgery found no major safety concerns.[30] 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.

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 Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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
Unpublished			
Terminated			

NCT: national clinical trial

Government Regulations
National:

National Coverage Determination (NCD): Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature (160.8)
Effective date of this version: 6/19/2006

Indications and Limitations of Coverage

Electroencephalographic (EEG) monitoring is a safe and reliable technique for the assessment of gross cerebral blood flow during general anesthesia and is covered under Medicare. Very characteristic changes in the EEG occur when cerebral perfusion is inadequate for cerebral function. EEG monitoring as an indirect measure of cerebral perfusion requires the expertise of an electroencephalographer, a neurologist trained in EEG, or an advanced EEG technician for its proper interpretation.

The 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.

Billing Medicare for Remote Intraoperative Neurophysiology Monitoring (HCPCS Code G0453) in CY 2013, Updated September 2020

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 the 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 for reporting physician monitoring performed from outside of the operating room (nearby or remotely). HCPCS code G0453 "can be billed only for undivided attention by the monitoring physician to a single beneficiary, and not for simultaneous attention by the monitoring physician to more than one patient.

Local:

Wisconsin Physicians Service Insurance Corporation (WPS), Local Coverage Determination (LCD): Intraoperative Neurophysiological Testing (L34623)
Original Determination Effective Date: For services performed on or after 10/01/2015
Revision Effective Date: For services performed on or after 02/01/2024

Coverage Indications, Limitations, and/or Medical Necessity
Intraoperative neurophysiological testing may be used to identify/prevent complications during surgery on the nervous system, its blood supply, or adjacent tissue.

Monitoring can identify new neurologic impairment, identify, or separate nervous system structures (e.g., around or in a tumor), and can demonstrate which tracts or nerves are still functional. Intraoperative neurophysiological testing may provide relative reassurance to the surgeon that no identifiable complication has been detected up to a certain point, allowing the surgeon to proceed further and provide a more thorough or careful surgical intervention than would have been provided in the absence of monitoring.

Some high-risk patients may be candidates for a surgical procedure only if monitoring is available. To establish medical necessity the following guidelines must be followed:

Intraoperative testing may be indicated with the following types of surgery:
1. Surgery of the aortic arch, its branch vessels, or thoracic aorta, including internal carotid artery surgery, when there is risk of cerebral ischemia
2. Resection of epileptogenic brain tissue or tumor
3. Resection of brain tissue close to the primary motor cortex and requiring brain mapping
4. Protection of cranial nerves:
    a. tumors that are optic, trigeminal, facial, auditory nerves
    b. cavernous sinus tumors
    c. oval or round window graft
    d. endolymphatic shunt for Ménière's disease
    e. vestibular section for vertigo
    f. microvascular decompression of cranial nerves
5. Correction of scoliosis or deformity of spinal cord involving traction on the cord
6. Protection of spinal cord where work is performed in close proximity to cord as in the removal of old hardware or where there have been numerous interventions
7. Spinal instrumentation requiring pedicle screws or distraction
8. Decompressive procedures on the spinal cord or cauda equina carried out for myelopathy or claudication where function of spinal cord or spinal nerves is at risk
9. Resection of:
    a. Spinal cord tumors
    b. Neuromas of peripheral nerves or brachial plexus, when there is risk to major sensory or motor nerves
10. Surgery for:
    a. intracranial AV malformations
    b. arteriovenous malformation of spinal cord
    c. surgery for intractable movement disorders
    d. cerebral vascular aneurysms
    e. surgery for intractable movement disorders

11. Arteriography, during which there is a test occlusion of the carotid artery
12. Circulatory arrest with hypothermia
13. Distal aortic procedures, where there is risk of ischemia to spinal cord; and
14. Leg lengthening procedures, where there is traction on sciatic nerve or other nerve trunks
15. Basil ganglia movement disorders
16. Surgery as a result of traumatic injury to spinal cord/brain
17. Deep brain stimulation

Limitations
For reimbursement this test must be requested by the operating surgeon and the monitoring must be performed by a physician, other than:

- The operating surgeon
- The technical/surgical assistant; or
- The anesthesiologist rendering the anesthesia

The benefits of intraoperative neurophysiologic testing are attainable under optimal recording and interpreting conditions.

Due to the nature of these services and the potential for significant morbidity in some procedures requiring intraoperative monitoring, Medicare expects to see these services used in the hospital setting only. As the level of anesthesia may significantly impact the ability to interpret intraoperative studies, continuous communication between the anesthesiologist and the monitoring physician is expected when medically indicated.

It is also expected that a specifically trained technician, preferably registered with one of the credentialing organizations will be in continuous attendance in the operating room, recording and monitoring a single surgical case, with either the physical or electronic capacity for real-time communication with the supervising neurologist or other physician trained in neurophysiology.

Intraoperative monitoring is not medically necessary in situations where historical data and current practices reveal no potential for damage to neural integrity during surgery. Monitoring under these circumstances will exceed the patient's medical need.

Due to the potential risk for morbidity with many of the above noted surgeries and the need for explicit and focused attention to both the monitoring and the procedure, Medicare does not expect to see operating surgeons submitting claims for this code. Monitoring may be performed from a remote site, as long as a trained technician (see detail above) will be in continuous attendance in the operating room, with either the physical or electronic capacity for real-time communication with the supervising physician (MD/DO). Technical criteria (mandatory) include that at least eight recording channels be available (16 if EEG is monitored) for all intraoperative neurophysiological monitoring. The remotely supervising physician must have the ability to watch the tracings as they are obtained in real-time in the operating room, as well as the baseline electrophysiological test and the monitoring tracings from earlier in the case.

Technical criteria (mandatory) for remote monitoring also include (a) routine real-time auditory or written communication between the supervising physician and the operating room and (b) the capability for telephone communications as needed between the supervising physician and the monitoring technologist, operating surgeon and the anesthesiologist.

The equipment must also provide for all of the monitoring modalities that may be applied - auditory-evoked response, electroencephalography/electrocorticography, electromyography and nerve conduction and somatosensory-evoked response.

Undivided attention to a unique patient may be required during some surgeries, such as during response to acute events or identification of the cerebral cortex to be resected or spared from resection. The monitoring physician must have a plan in place to transfer care to another physician of any other case during those times. When paying undivided attention to a unique patient, the physician must code and bill only for that one case during those times. For other medically necessary intraoperative neurophysiologic monitoring, a physician may monitor up to three cases simultaneously.

Medicare does not provide for reimbursement of "incident to" care in the hospital setting. More than one patient may be monitored at once; however, claims for physician services must be submitted only for the time devoted to monitoring when attention is directed exclusively to one patient.

Wisconsin Physicians Service Insurance Corporation (WPS), Local Coverage Article: Billing and Coding: Intraoperative Neurophysiological Testing (A57604)
Original Effective Date: 11/01/2019; Revision Effective Date: 02/01/24

Article Guidance
Article Text

The billing and coding information in this article is dependent on the coverage indications, limitations, and/or medical necessity described in the related LCD L34623 Intraoperative Neurophysiological Testing.
Documentation Requirements
All documentation must be maintained in the patient’s medical record and available to the contractor upon request.

Every page of the medical record must be legible and include appropriate patient identification information (e.g. complete name, dates of service). The record must include the physician or non-physician practitioner responsible for providing the care of the patient.

The patient’s medical record should document the time spent in monitoring in correlation to the surgery performed.

The submitted medical record should support the use of the selected diagnosis code(s).
The submitted CPT/HCPCS code should describe the service performed.

Utilization Guidelines

Intraoperative neurophysiology monitoring should not be reported by the physician performing the operative procedure since it is included in the global package for the surgery.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Automated Visual Evoked Potentials for Routine Vision Screening In Pediatrics
- Electrocorticography (retired)
- Electroencephalograms (EEG) (retired)
- Magnetoencephalography / Magnetic Source Imaging
- Topographic Brain Mapping (TBM) (retired)

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/8/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
12/1/12	9/27/12	9/27/12	Joint policy established
7/1/13	6/18/13	6/27/13	Routine maintenance Deleted procedure codes 95900-95904; 95920; added new CPT codes 95907-95913; 95940-95941; G0453 (effective 1/1/13).
11/1/15	8/24/15	9/14/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine maintenance Updated local Medicare policy
9/1/18	6/19/18	6/19/18	Routine maintenance Added Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve in patients undergoing high-risk thyroid or parathyroid surgery and anterior cervical spine surgery associated with increased risk situations (See policy inclusions)
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance. Deleted codes: 92585, 92586; added codes: 92652, 92653.
9/1/22	6/21/22		Routine maintenance
9/1/23	6/13/23		Routine maintenance (jf) Vendor Managed: NA In the inclusion and exclusions, the word “patients” was changed to “individuals” Added new PICO: Spinal Instrumentation Requiring Screws or Distraction Ref added: 6,17,18,19,20,21,22,23,24,25,26,36, 37,38,39,40,41,42,43,44,45,46,47,49

			,50,51,52,53,54,55,56,57,58,59,60,65
11/1/23	8/15/23		• Added under notes section: Train-of-four monitoring is considered integral (not separately payable) to intraoperative procedures to measure the strength of anesthetic neuromuscular blockade • Added Train of Four under Description section • Added code 95999 Train of Four code under not separately payable. Ref added 7
9/1/24	6/11/24		Routine Maintenance (jf) Vendor Managed: NA Ref added 7

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: INTRAOPERATIVE NEUROPHYSIOLOGIC MONITORING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.