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Intraoperative Neurophysiologic Monitoring (IONM)

Table of Contents

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
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Coverage

The following types of intraoperative neurophysiologic monitoring (IONM) **may be considered medically necessary** during spinal, intracranial, or vascular procedures:

- Somatosensory-evoked potentials (SSEPs),
- Motor-evoked potentials (MEPs) using transcranial electrical stimulation,
- Brainstem auditory-evoked potentials (BAEPs),
- Electromyography (EMG) of cranial nerves,
- Electroencephalography (EEG), and
- Electrocorticography (ECoG);

Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve **may be considered medically necessary** 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 pseudoarthrosis, or revision for failed fusion),
    - Multilevel anterior cervical discectomy and fusion, or
    - Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve.

Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during anterior cervical spine surgery not meeting the criteria above or during esophageal surgeries **is considered experimental, investigational and/or unproven.**

Intraoperative monitoring of visual-evoked potentials (VEPs) **is considered experimental, investigational and/or unproven.**

Due to the lack of monitors approved by the U.S. Food and Drug Administration, intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation **is considered experimental, investigational and/or unproven.**

Intraoperative EMG and nerve conduction velocity monitoring on the peripheral nerves during surgery **is considered experimental, investigational and/or unproven**.

NOTE 1: These policy statements refer only to use of these techniques as part of intraoperative neurophysiologic monitoring. Other clinical applications of these monitoring techniques, (e.g., VEPs and EMG) are not considered in this policy.

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 policy focuses on monitoring of the recurrent laryngeal nerve during neck surgeries and monitoring of peripheral nerves.

Description

Intraoperative neurophysiologic monitoring (IONM) 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 medical policy 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.

Intraoperative Neurophysiologic Monitoring

The principal goal of 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.

The different methodologies of monitoring are described next.

<u>Sensory-Evoked Potentials</u>

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.

<u>Somatosensory-Evoked Potentials</u>

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

Motor-Evoked Potentials

Motor-evoked potentials (MEPs) are recorded from muscles following direct or transcranial electrical stimulation of motor cortex or by pulsed magnetic stimulation provided by 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. MEPs, 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 IONM, in which more than 1 technique is used, most commonly with somatosensory-evoked potentials (SSEPs) 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 (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 electroencephalography (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 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 the EEG activity directly from a surgically exposed cerebral cortex. ECoG is typically used to define the sensory cortex and map the critical limits of a surgical resection. ECoG recordings have been most frequently used to identify epileptogenic regions for resection. In these applications, ECoG 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.

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.

IONM of MEPs using transcranial magnetic stimulation does not have FDA approval.

Rationale

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

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

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

Recurrent Laryngeal Nerve (RLN) Monitoring During Thyroid or Parathyroid Surgery

<u>Clinical Context and Therapy Purpose</u>

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

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

Populations

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

Interventions

The therapy being considered is IONM.

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 (QOL).

The existing literature evaluating IONM as a treatment for individuals who are undergoing thyroid or parathyroid surgery and are at high-risk of injury to the RLN has varying lengths of follow-up. While studies described below all reported at least one 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 long-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.

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 RLN injury during thyroid surgery with or without IONM. (10) Included were 2 prospective cohort studies and 7 retrospective cohort studies. Results are summarized in Tables 1 and 2. IONM was associated with a reduction in overall and permanent RLN palsy in thyroid reoperations. Limitations included small sample sizes and study heterogeneity.

Pardal-Refoyo and Ochoa-Sangrador (2016) reported on a systematic review of RLN injury during total thyroidectomy with or without IONM. (11) Included were 1 large (N=1000) and 1 small (N=23) RCT and 52 case series that estimated the risk to the RLN. Twenty-nine studies used RLN monitoring and 25 did not. Results are summarized in Table 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 (23-2546 patients)	• RCT • Case series	NR
Sun et al. (2017) (10)	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/ 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 (6-23 patients)	Meta-analysis	NR
Cozzi et al. (2023) (7)	Up to Jan 2023	• 12 RCTs • 80 prospective cohort studies	Studies reporting incidence of RLN complications	42,015 procedures with 73,325 nerves at risk	• RCTs • Prospective cohort • Case series	1 year or more

		• 72 were prospective case series	after thyroid surgery			

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
I^2 (p)	8% (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% (0.029)	67.4%[b] (0.227)	13.7%[b] (0.031)
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 11,947 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 RLN paresis was 2.9% lower in patients who had RLN monitoring (p=0.011) compared with those who received visual identification only. In low-risk patients, there was no significant difference in RLN 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 RLN monitoring was also shown in patients undergoing high-risk total thyroidectomy. (13)

Table 3. Summary of Key RCT 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 RCT 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)

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

Section Summary: RLN Monitoring During Thyroid or Parathyroid Surgery

The evidence on the use of IONM in reducing RLN 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 IONM overall, but a significant reduction in RLN 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 IONM is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as surgery without neurophysiologic monitoring, in individuals who are undergoing anterior cervical spine surgery and are at high-risk of injury to the RLN.

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

Populations

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

Interventions

The therapy being considered is IONM.

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 QOL.

The existing literature evaluating IONM as a treatment for individuals who are undergoing anterior cervical spine surgery and are at high-risk of injury to the RLN has varying lengths of follow-up. While studies described below all reported at least one 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 long-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.

Systematic Reviews
Ajiboye et al. (2017) reported on the results of a systematic review that included 10 studies (total N=26,357 patients). (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 IONM with no IONM were included. Based on data from these 2 studies, there was no statistically significant difference in the risk of neurologic injury with or without IONM (odds ratio [OR], 0.726; 95% confidence interval [CI], 0.287 to 1.833; p=0.498) (Tables 5 and 6).

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

Daniel et al. (2018) published a literature review and meta-analysis evaluating IONM during spinal operative surgical procedures. (16) Six retrospective studies, published between 2006 and 2016, with a total of 335,458 patients (range, 74–231,067) were included. Pooled OR for neurological events with and without IONM was 0.72 (95% CI: 0.71–1.79; p=0.4584), and sensitivity analysis, which included only 2 studies, had a pooled OR of 0.199 (95% CI, 0.038–

1.035; p=0.055). The review was limited by the lack of prospective studies, by only three 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) (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 (74-231,067)	• 2 cohort • 4 retrospective	NR

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

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)
I^2 (p)	0% (0.44)
Erwood et al. (2016) (15)	
Estimate [c] (95% CI)	0.14 (0.10 to 0.19)
I^2 (p)	10.7% (NR)
Daniel et al. (2018) (16)	
OR [a] (95% CI)	0.72 (0.71 to 1.79)
I^2 (p)	NR (0.4584)

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.

<u>Section Summary: RLN Monitoring During Cervical Spine Surgery</u>

The evidence on the use of IONM in reducing RLN 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.

RLN Monitoring During Esophageal Surgery

Clinical Context and Therapy Purpose

The purpose of IONM 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 policy.

Populations

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

Interventions

The therapy being considered is IONM.

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 QOL.

The existing literature evaluating IONM as a treatment for individuals who are undergoing esophageal surgery has varying lengths of follow-up. While studies described below all reported at least one 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 long-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.

Systematic Review

Chen et al. (2023) conducted a systematic review on the efficacy of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve during esophagectomy (Table 7). (17) Ten studies that compared intraoperative neurophysiologic monitoring to no monitoring during esophagectomy with mediastinal lymph node dissection were included. Table 8 summarizes the results of the analysis. Intraoperative neurophysiologic monitoring significantly reduced the incidence of recurrent laryngeal nerve palsy (OR, 0.32; 95% Cl, 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% Cl, 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. 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 to 142)	1 RCT, 9 nonrandomized studies	NR

NR: not reported; RCT: randomized controlled trial.

Table 8. 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] (-33.94-9.28)	-2.07[a] (-6.61 to 2.46)
I^2 (p)	42% (<0.0001)	49% (0.002)	59% (0.26)	56% (0.37)

CI: confidence interval.
[a] Weighted mean difference.

Section Summary: RLN 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 IONM 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 policy.

Populations

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

Interventions

The therapy being considered is IONM.

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 QOL.

The existing literature evaluating IONM as a treatment for individuals who are undergoing surgery proximal to a peripheral nerve has varying lengths of follow-up. While studies described below all reported at least one 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 long-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.

Case-Control Study

Kneist et al. (2013) assessed monitoring peripheral nerves during surgery in a case-control study of 30 patients. (18) In patients undergoing total mesorectal excision, impaired anorectal function was observed in 1 (7%) of 15 patients who had intraoperative neurophysiologic monitoring compared with 6 (40%) of 15 without. Kneist et al. (2013) also reported on erectile function following low anterior rectal resection in a pilot study with 17 patients. (19) 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. (20) 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 these 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. (21)

Use of IONM of peripheral nerves has also been reported in patients undergoing orthopedic procedures including tibial/fibular osteotomies, hip arthroscopy for femoroacetabular impingement, and shoulder arthroplasty. (22-24)

Section Summary: Monitoring Peripheral Nerves

Surgical guidance with peripheral IONM 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 IONM 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 for this policy.

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.

IONM 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 IONM.

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 individuals 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:

- 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 long-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.

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. (25) 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. (26) 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 9. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Reddy et al. (2022) (25)	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) (26)	1998-2012	12	Patients undergoing idiopathic scoliosis correction surgery	2915 (25 to 1121)	Prospective and retrospective cohorts	Ranged from immediately postoperative to 3 months

Table 10. Systematic Review Results

Study	Postoperative Neurologic Deficits	Sensitivity	Specificity	Odds Ratio of Stimulation Predicting Postoperative Neurologic Deficit
Reddy et al. (2022) (25)				
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) (26)				
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.

<u>Observational Studies</u>

Numerous large cohort studies (N>1000) have evaluated the effect of IONM 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. (27) 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 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. (28) 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 (.079%) patients, true positive cases occurred in 66 (6.5%), patients, and false positive cases occurred in 8 (0.79%) patients. The specificity and sensitivity of multimodal intraoperative monitoring were 99% and 89%, respectively.

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

For individuals who are undergoing anterior cervical spine surgery and are at high-risk of injury to the recurrent laryngeal nerve who receive intraoperative neurophysiologic monitoring, the evidence includes 3 systematic reviews of case series and cohort studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. Two of the 3 analyses compared the risk of nerve injury using intraoperative neurophysiologic monitoring with no intraoperative neurophysiologic monitoring and found no statistically significant difference. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

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

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

- Use of IONM of the recurrent laryngeal nerve for individuals undergoing cervical spine surgery with:
    - Prior anterior cervical surgery, particularly revision anterior cervical discectomy and fusion, revision surgery through a scarred surgical field, reoperation for pseudarthrosis, or revision for failed fusion;
    - Multilevel anterior cervical discectomy and fusion; and
    - Preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve.

Additionally, clinical input also agreed that IONM 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 IONM of visual-evoked potentials and motor-evoked potentials using transcranial magnetic stimulation is investigational. Input was mixed on whether IONM of peripheral nerves would be considered medically necessary. Some reviewers recommended monitoring some peripheral nerves during spinal surgery (e.g., nerve roots, percutaneous pedicle screw placement, lateral transpsoas approach to the lumbar spine). Other reviewers suggested using IONM during resection of peripheral nerve tumors or surgery around the brachial plexus or facial/cranial nerves.

Practice Guidelines and Position Statements

American Academy of Neurology

In 1990, the American Academy of Neurology (AAN) published an assessment of IONM, 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. 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 a surgical resection or identify regions of greatest impairment, while sensory cortex SSEPs 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 SSEPs 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 (EMG) 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 the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM), concluded that the available evidence supported IONM using SSEPs 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 (last amended July 31, 2018). (29) 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. 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 (CNS) updated their position statement on IONM during routine spinal surgery. (30) 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 IONM 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. (31) 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.

<u>American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM)</u>

In 2023, the AANEM updated their position statement on electrodiagnostic medicine. (5) The recommendation 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.

<u>American Clinical Neurophysiology Society</u>

In 2009, the American Clinical Neurophysiology Society (ACNS) recommended standards for intraoperative neurophysiologic monitoring. (4) Guideline 11A included the following statement (32):

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

<u>American Head and Neck Society</u>

In 2022, the American Head and Neck Endocrine Surgery Section and the International Neural Monitoring Study Group published a clinical review of intraoperative nerve monitoring during pediatric thyroid surgery. (33) 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
The American Society of Neurophysiological Monitoring (ASNM) (2018) published practice guidelines on the supervising professional on IONM. (16) The ASNM 2013 position statement on intraoperative MEP monitoring indicated that MEPs are an established practice option for cortical and subcortical mapping and for monitoring during surgeries risking motor injury in the brain, brainstem, spinal cord, or facial nerve. (34)

Scoliosis Research Society
In 2020, the Scoliosis Research Society published an information statement on neurophysiologic monitoring during spinal deformity surgery. (35) 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
A 2008 Guidance from the National Institute for Health and Care Excellence (NICE) on IONM during thyroid surgery finds no major safety concerns. (36) Regarding efficacy, IONM was indicated as helpful "in performing more complex operations such as reoperative surgery and operations on large thyroid glands."

North American Spine Society
In 2024, the North American Spine Society (NASS) published coverage recommendations on intraoperative neurophysiologic monitoring. (37) Relevant recommendation statements regarding cervical spine surgery and spinal instrumentation or distraction are below. The recommendations state that whenever the clinical scenario requires IONM, the standard multimodality IONM plan for spine should typically involve "use of all three primary IONM modalities of MEPs, SSEPs, and EMG", although there may be clinical reasons to exclude the use of certain modalities.

Surgical procedures with associated typical diagnoses	**Coverage recommendation**
Instrumented deformity corrections for scoliosis or other deforming dorsopathies in the cervical, thoracic, or lumbar spine.	Coverage of multimodality IONM is recommended.
Spinal realignment procedures that involve significant distraction that may occur during vertebral corpectomies or interbody fusion	Coverage of multimodality IONM is recommended.

procedures involving very significant disc space distraction in the cervical, thoracic, or lumbar spine.	
Pediatric spinal procedures including tethered cord release, selective dorsal rhizotomies for cerebral palsy, or placement of growing instrumentation elements (rods, expandable ribs).	Coverage of multimodality IONM is recommended.
Cervical/thoracic discectomy, fusion, or arthroplasty procedures involving decompression of the spinal cord in patients with spondylotic myelopathy, spinal cord compression, or vertebral artery compression syndrome.	Coverage of multimodality IONM is recommended.
Cervical discectomy, fusion, or arthroplasty procedures involving decompression of spinal nerve roots in patients with cervical radiculopathy, but without myelopathy or spinal cord compression if any of the following are present/ performed: laminectomy, weakness/ absent reflexes/ preoperative diagnostic electromyographic evidence of denervation, patient history of previous surgical treatment for cervical or thoracic myelopathy or spinal cord compression. Note: Anterior cervical decompression (fusion or arthroplasty) as a treatment for isolated cervical radiculopathy without myelopathy or spinal cord compression not meeting previously recommended criteria (see NASS policy) is insufficient to meet this level of indication for multimodality IONM.	Coverage of multimodality IONM is conditionally recommended (evidentiary support, but lack of full consensus).
Placement of a cervical or thoracic spinal cord paddle lead for spinal cord stimulation via laminotomy if: the procedure is performed under general anesthesia and neuromonitoring is being utilized to guide both the safe and effective placement of the electrodes.	Coverage of multimodality IONM is conditionally recommended (evidentiary support, but lack of full consensus).
Instrumented spinal fusion procedures in the cervical, thoracic, or lumbar spine not meeting the more stringent criteria listed in	Coverage of multimodality IONM is recommended on an exceptional basis if there is a demonstrable, elevated potential

sections 1 or 2 of the NASS coverage recommendations document.	risk of neurologic injury, due to patient or procedural factors not listed in previous sections, that may be mitigated by multimodal IONM.
Cervical and thoracic laminectomy procedures involving decompression of the spinal cord not meeting the more stringent criteria listed in sections 1 or 2 of the NASS coverage recommendations document.	Coverage of multimodality IONM is recommended on an exceptional basis if there is a demonstrable, elevated potential risk of neurologic injury, due to patient or procedural factors not listed in previous sections, that may be mitigated by multimodal IONM.
During anterior cervical discectomy, arthroplasty, or fusion procedures, the following maybe employed: cranial nerve EMG of the recurrent laryngeal nerve, laryngeal adductor reflex monitoring. During lumbosacral laminectomy, detethering or fusion procedures the following may be employed: EMG of anal/urethral sphincter and/or sacral reflex monitoring.	These modalities are at the surgeon's discretion as additional to standard multimodal IONM.

EMG: electromyography; IONM: intraoperative neuromonitoring; NASS: North American Spine Society.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 11.

Table 11. Summary of Key Trials

NCT Number	Trial Name	Enrollment Planned	Completion Date
Ongoing			
NCT01630785	Retrospective Data Analysis of Neurophysiological Data for Intraoperative or Epilepsy Monitoring	5000	Dec 2025

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	95829, 95865, 95867, 95868, 95907, 95908, 95909, 95910, 95911, 95912, 95913, 95925, 95926, 95927, 95928, 95929, 95930, 95938, 95939, 95940, 95941, 95955
HCPCS Codes	G0453

References

1. Assessment: Intraoperative Neurophysiology. Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. Nov 1990; 40(11):1644-1646. PMID 2234418
2. Nuwer MR, Emerson RG, Galloway G, et al. Evidence-based guideline update: Intraoperative Spinal Monitoring with Somatosensory and Transcranial Electrical Motor Evoked Potentials: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology and the American Clinical Neurophysiology Society. Neurology. Feb 21 2012; 78(8):585-589. PMID 22351796
3. Skinner SA, Cohen BA, Morledge DE, et al. Practice guidelines for the supervising professional: intraoperative neurophysiological monitoring. J Clin Monit Comput. Apr 2014; 28(2):103-111. PMID 24022172
4. American Clinical Neurophysiology Society. ACNS Guidelines and Consensus Statements. Available at: <https://www.acns.org> (accessed February 21, 2025).
5. American Association of Neuromuscular & Electrodiagnostic Medicine. Position Statement: Recommended Policy for Electrodiagnostic Medicine. Updated 2023. Available at: <https://www.aanem.org> (accessed March 1, 2025).
6. Resnick DK, Choudhri TF, Dailey AT, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 15: electrophysiological monitoring and lumbar fusion. J Neurosurg Spine. Jun 2005; 2(6):725-732. PMID 16028743
7. Cozzi AT, Ottavi A, Lozza P, et al. Intraoperative neuromonitoring does not reduce the risk of temporary and definitive recurrent laryngeal nerve damage during thyroid surgery: a systematic review and meta-analysis of endoscopic findings from 73,325 nerves at risk. J Pers Med. Sep 23 2023; 13(10):1429. PMID 37888040
8. Henry BM, Graves MJ, Vikse J, et al. The current state of intermittent intraoperative neural monitoring for prevention of recurrent laryngeal nerve injury during thyroidectomy: a PRISMA-compliant systematic review of overlapping meta-analyses. Langenbecks Arch Surg. Jun 2017; 402(4):663-673. PMID 28378238
9. Pisanu A, Porceddu G, Podda M, et al. Systematic review with meta-analysis of studies comparing intraoperative neuromonitoring of recurrent laryngeal nerves versus visualization alone during thyroidectomy. J Surg Res. May 1 2014; 188(1):152-161. PMID 24433869

10. Sun W, Liu J, Zhang H, et al. A meta-analysis of intraoperative neuromonitoring of recurrent laryngeal nerve palsy during thyroid reoperations. Clin Endocrinol (Oxf). Nov 2017; 87(5):572-580. PMID 28585717
11. Pardal-Refoyo JL, Ochoa-Sangrador C. Bilateral recurrent laryngeal nerve injury in total thyroidectomy with or without intraoperative neuromonitoring. Systematic review and meta-analysis. Acta Otorrinolaringol Esp. 2016; 67(2):66-74. PMID 26025358
12. Barczynski M, Konturek A, Cichon S. Randomized clinical trial of visualization versus neuromonitoring of recurrent laryngeal nerves during thyroidectomy. Br J Surg. Mar 2009; 96(3):240-246. PMID 19177420
13. Vasileiadis I, Karatzas T, Charitoudis G, et al. Association of intraoperative neuromonitoring with reduced recurrent laryngeal nerve injury in patients undergoing total thyroidectomy. JAMA Otolaryngol Head Neck Surg. Oct 1 2016; 142(10):994-1001. PMID 27490310
14. Ajiboye RM, Zoller SD, Sharma A, et al. Intraoperative neuromonitoring for anterior cervical spine surgery: What is the evidence? Spine (Phila Pa 1976). Mar 15 2017; 42(6):385-393. PMID 27390917
15. Erwood MS, Hadley MN, Gordon AS, et al. Recurrent laryngeal nerve injury following reoperative anterior cervical discectomy and fusion: a meta-analysis. J Neurosurg Spine. Aug 2016; 25(2):198-204. PMID 27015129
16. Daniel JW, Botelho RV, Milano JB, et al. Intraoperative neurophysiological monitoring in spine surgery: A systematic review and meta-Analysis. Spine (Phila Pa 1976). Aug 2018; 43(16):1154-1160. PMID 30063222.
17. Chen B, Yang T, Wang W, et al. Application of intraoperative neuromonitoring (IONM) of the recurrent laryngeal nerve during esophagectomy: a systematic review and meta-analysis. J Clin Med. Jan 10 2023; 12(2):565. PMID 36675495
18. Kneist W, Kauff DW, Juhre V, et al. Is intraoperative neuromonitoring associated with better functional outcome in patients undergoing open TME? Results of a case-control study. Eur J Surg Oncol. Sep 2013; 39(9):994-999. PMID 23810330
19. Kneist W, Kauff DW, Rubenwolf P, et al. Intraoperative monitoring of bladder and internal anal sphincter innervation: a predictor of erectile function following low anterior rectal resection for rectal cancer? Results of a prospective clinical study. Dig Surg. 2013; 30(4-6):459-465. PMID 24481247
20. Clarkson JHW, Ozyurekoglu T, Mujadzic M, et al. An evaluation of the information gained from the use of intraoperative nerve recording in the management of suspected brachial plexus root avulsion. Plast Reconstr Surg. Mar 2011; 127(3):1237-1243. PMID 21364425
21. Zhang W, Chen M, Zhang W, et al. Use of electrophysiological monitoring in selective rhizotomy treating glossopharyngeal neuralgia. J Craniomaxillofac Surg. Jul 2014; 42(5):e182-185. PMID 24095216
22. Ochs BC, Herzka A, Yaylali I. Intraoperative neurophysiological monitoring of somatosensory evoked potentials during hip arthroscopy surgery. Neurodiagn J. Dec 2012; 52(4):312-319. PMID 23301281
23. Jahangiri FR. Multimodality neurophysiological monitoring during tibial/fibular osteotomies for preventing peripheral nerve injuries. Neurodiagn J. Jun 2013; 53(2):153-168. PMID 23833842

24. Nagda SH, Rogers KJ, Sestokas AK, et al. Neer Award 2005: Peripheral nerve function during shoulder arthroplasty using intraoperative nerve monitoring. J Shoulder Elbow Surg. 2007; 16(3 Suppl):S2-8. PMID 17493556
25. Reddy RP, Chang R, Coutinho DV, et al. Triggered electromyography is a useful intraoperative adjunct to predict postoperative neurological deficit following lumbar pedicle screw instrumentation. Global Spine J. Jun 2022; 12(5):1003-1011. PMID 34013769
26. Thirmula PD, Crammond DJ, Loke YK, et al. Diagnostic accuracy of motor evoked potentials to detect neurological deficit during idiopathic scoliosis correction: a systematic review. J Neurosurg Spin. Mar 2017; 26(3):374-383. PMID 27935448
27. Tsirikos AI, Duckworth AD, Henderson LE, et al. Multimodal intraoperative spinal cord monitoring during spinal deformity surgery: efficacy, diagnostic characteristics, and algorithm development. Med Princ Pract. 2020; 229(1):6-17. PMID 31158841
28. Sutter MA, Eggspuehler A, Grob D, et al. Multimodal intraoperative monitoring (MIOM) during 409 lumbosacral surgical procedures in 409 patients. Eur Spine J. Nov 2007; 16 Suppl 2(Suppl 2):S221-S228. PMID 17912559
29. American Academy of Neurology. Model Coverage Policy: Principles of Coding for Intraoperative Neurophysiologic Monitoring (IOM) and Testing. 2012. Available at: <https://www.aan.com> (accessed February 27, 2025).
30. American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS). Joint Section on Disorders of the Spine and Peripheral Nerves. Updated Position Statement: Intraoperative Electrophysiological Monitoring. January 2018. Available at: <https://www.spinesection.org> (accessed February 26, 2025).
31. Sharan A, Groff MW, Dailey AT, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 15: electrophysiological monitoring and lumbar fusion. J Neurosurg Spine. Jul 2014; 21(1):102-105. PMID 24980592
32. American Clinical Neurophysiology Society. Guideline 11A: Recommended Standards for Neurophysiologic Intraoperative Monitoring Principles. 2009. Available at: <https://www.acns.org> (accessed February 27, 2025).
33. Diercks GR, Rastatter JC, Kazahaya K, et al. Pediatric intraoperative nerve monitoring during thyroid surgery: a review from the American Head and Neck Society Endocrine Surgery Section and the International Neural Monitoring Study Group. Head Neck. Jun 2022; 44(6):1468-1480. PMID 35261110
34. Macdonald DB, Skinner S, Shils J, et al. Intraoperative motor evoked potential monitoring - a position statement by the American Society of Neurophysiological Monitoring. Clin Neurophysiol. Dec 2013; 124(12):2291-2316. PMID 24055297
35. Halsey MF, Myung KS, Ghag A, et al. Neurophysiological monitoring of spinal cord function during spinal deformity surgery: 2020 SRS neuromonitoring information statement. Spine Deform. Aug 2020; 8(4):591-596. PMID 32451978
36. National Institute for Health and Care Excellence (NICE). Intraoperative nerve monitoring during thyroid surgery [IPG255]. 2008. Available at: <https://www.nice.org.uk> (accessed February 27, 2025).
37. North American Spine Society. NASS Coverage Recommendations: Intraoperative Neurophysiological Monitoring. North American Spine Society; 2024. Available at: <https://www.spine.org> (accessed September 26, 2025).

38. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Electroencephalographic Monitoring During Surgical Procedures Involving the Cerebral Vasculature (160.8) (2006). Available at: <https://www.cms.gov> (accessed March 2, 2025).
39. Centers for Medicare & Medicaid Services. Billing Medicare for Remote Intraoperative Neurophysiology Monitoring in CY 2013. Updated September 2020. Available at: <https://www.cms.gov> (accessed March 1, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

CMS 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." (38) 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 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." (39)

Policy History/Revision

Date	Description of Change
11/15/2025	Document updated. Coverage revised for clarity; intent unchanged. Reference 37 added; others updated.
10/15/2024	Document updated with literature review. Coverage unchanged. References 7, 17, 25-28, 31, 33, 35 added; others updated, and some removed.
01/01/2024	Reviewed. No changes.

01/01/2023	Document updated with literature review. The following change was made to Coverage: 1) Modified statement on intraoperative EMG and nerve conduction velocity monitoring on the peripheral nerves during surgery from "not medically necessary" to "experimental, investigational and/or unproven"; 2) Removed criteria addressing separate reimbursable services. No references added, some references were updated.
01/01/2022	Document updated with literature review. Coverage unchanged. Some references were updated.
10/15/2020	Reviewed. No changes.
09/15/2019	Document updated with literature review. Coverage unchanged. The following references were added/updated: 5, 7, 16, 27, 30-31.
11/15/2018	Document updated with literature review. The following changes were made to Coverage: 1) Clarified language to indicate that motor-evoked potentials using transcranial electrical stimulation may be considered medically necessary and motor-evoked potentials using transcranial magnetic stimulation is considered experimental, investigational and/or unproven; 2) Added language to consider intraoperative monitoring as medically necessary for high risk thyroid and anterior cervical spine surgeries. Added references 5-6 and 8-16. Title changed from "Intraoperative Neurophysiological Monitoring (IONM)".
04/15/2017	Document updated with literature review. Coverage unchanged.
09/15/2016	Reviewed. No changes.
08/15/2015	Document updated with literature review. The following language was added to the experimental, investigational and/or unproven coverage statement: "Intraoperative monitoring is considered experimental, investigational and/or unproven for all other IONM techniques including but not limited to": "transcranial magnetic stimulation".
08/15/2013	Document updated with literature review. Coverage unchanged. The following was added to the pricing section: Physician services for intraoperative neurophysiological monitoring (IONM) should be submitted for no more than 3 cases performed simultaneously. CPT/HCPCS code(s) updated.
02/15/2010	Removed reimbursement issues from medical document. Coverage position remains conditional. No changes in coverage.
02/01/2008	Revised/updated entire document
12/11/2003	Revised/updated entire document
11/01/2000	Revised/updated entire document
08/01/1999	Revised/updated entire document
03/01/1996	Revised/updated entire document
10/01/1992	Revised/updated entire document
05/01/1990	New medical document