BlueCross BlueShield of Alabama

Name of Policy:
Intraoperative Neurophysiologic Monitoring

Policy #: 306
Category: Medical

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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 evidence review does not address established neurophysiologic monitoring (i.e., somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, electromyography of cranial nerves, electroencephalography, electrocorticography), during spinal, intracranial, or vascular procedures.

Intraoperative Neurophysiologic Monitoring

The principal goal of intra-operative monitoring is the identification of the nervous system impairment in the hope that prompt intervention will prevent permanent deficits. Correctable factors at surgery include circulatory disturbance, excess compression from retraction, bony structures, or hematomas, or mechanical stretching. The technology is continuously evolving with refinements in equipment and analytic techniques including multimodal intraoperative monitoring in which more than one technique is used and recording in which several patients are monitored under the supervision of a physician who is outside the operating room.

The different methodologies of monitoring are described below:

Sensory-Evoked Potentials

Sensory-evoked potential describes the responses of the sensory pathways to sensory or electrical stimuli. Intra-operative monitoring of sensory-evoked potentials is used to assess the functional integrity of central nervous system (CNS) pathways during operations 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 neurological region at risk, selection and stimulation of a nerve that carries a signal through the at-risk region, and recording and interpretation of the signal at certain standardized points along the pathway. Monitoring of sensory-evoked potentials is commonly used during 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 broken down into the following categories according to the type of stimulation used:

- **Somatosensory-evoked potentials (SSEPs)** are cortical responses elicited by peripheral nerve stimulations. Peripheral nerves, such as the median, ulnar, or tibial nerve are typically stimulated, but in some situations the spinal cord may be stimulated directly. Recording is done either cortically or at the level of the spinal cord above the surgical procedure. Intra-operative monitoring of SSEPs 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 SSEP monitoring is in patients undergoing corrective surgery for scoliosis. In this setting, SSEP 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 (BAEPs)** 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 BAEPs have been extensively used to monitor auditory function during these procedures.
- **Visual-evoked potentials (VEPs)** are used to track visual signals from the retina to the occipital cortex light flashes. 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 Potential Monitoring

Motor-evoked potentials 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. Stimulation induces an electrical current in the brain or spinal cord which in turn can stimulate the motor neurons. Muscle activity is recorded by electrodes placed on the skin at prescribed points along the motor pathways. Motor evoked potentials, especially when induced by magnetic stimulation, can be affected by anesthesia. The Digitimer electrical cortical stimulator received U.S. Food and Drug Administration (FDA) premarket approval in 2002. Devices for transcranial magnetic stimulation have not been approved by FDA for this use.

Multimodal IONM, in which more than 1 technique is used, most commonly with SSEPs and MEPs, has also been described.

Electromyogram (EMG) 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 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 (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. In addition, these techniques may be used during procedures around the nerve roots and around 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.

EEG (Electroencephalogram) Monitoring

Spontaneous electroencephalogram (EEG) monitoring can also be recorded 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 in whom the EEG is normal. Carotid endarterectomy may be done with the patient under local anesthesia so that monitoring of cortical function can be directly assessed.

- Electrocorticography (Cog) is the recording of the EEG directly from a surgically exposed cerebral cortex. Cog is typically used to define the sensory cortex and to map the critical limits of a surgical resection. ECoG 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 SSEPs and MEPs using transcranial electrical stimulation, BAEPs, EMG of cranial nerves, EEG, and ECoG, has broad acceptance, particularly for spine surgery and open abdominal aorta aneurysm repairs. These indications have long been considered 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. Therefore, this evidence review focuses on monitoring of the recurrent laryngeal nerve during neck and esophageal surgeries and monitoring of peripheral nerves.

Policy:

Effective for dates of service on or after November 1, 2012:

Intraoperative monitoring, which includes **somatosensory-evoked potentials, motor-evoked potentials using transcranial electrical stimulation, brainstem auditory-evoked potentials, EMG of cranial nerves, EEG, and electrocorticography (ECoG), meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage **during spinal, intracranial, or vascular procedures** when **all** the following criteria are met:

1. There is clinical data in the medical record to support the medical necessity of ordering the test. The data could include radiological, neurological, consultative notes, or physical exam documentation; **and**
2. A licensed physician other than the operating surgeon or performing anesthesiologist must monitor the procedure and the monitoring physician must be on the premises and available to be in the operating room; **and**
3. The monitoring physician interprets no more than three cases concurrently.

Intraoperative neurophysiologic monitoring of the **recurrent laryngeal nerve meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage in patients 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
  - pre-existing 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 **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Intraoperative monitoring of visual-evoked potentials does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Intraoperative EMG and nerve conduction velocity monitoring during surgery on the peripheral nerves does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage**.**

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

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update was performed through February 23, 2018. Following is a summary of the key literature to date.

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

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 one 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.

Intraoperative Neurophysiologic Monitoring of the RLN during Thyroid or Parathyroid surgery

In 2016, Pardal-Refoyo and Ochoa-Sangrador reported on a systematic review of RLN injury during total thyroidectomy with or without intraoperative neurophysiologic monitoring (IONM). Included were 1 large (n=1000) and 1 small (n=23) RCT and 52 case series (total N=30,922 patients) that estimated the risk to the RLN. Twenty-nine studies used RLN monitoring and 25 did not. The prevalence of bilateral laryngeal paralysis in patients who had RLN monitoring was lower (2.43%; 95% confidence interval [CI], 1.55% to 3.5%) compared to series that did not (5.18%; 95% CI 2.53 to 8.7%). The absolute risk reduction was 2.75%, with a number needed to treat of 364.13.

The largest RCT of RLN neuromonitoring for thyroid surgery was reported by Barczynski et al in 2009. RLN 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 500 patients who had thyroidectomy with only visual RLN identification, there were 38 cases of transient RLN injuries and 12 cases of permanent RLN injuries. In the 500 patients who had visualization plus RLN monitoring, there were 19 transient injuries and 8 permanent RLN injuries. The absolute risk reduction with the addition of RLN monitoring was 2.3% for RLN

injury (p=0.007) and 1.9% for RLN paresis (p=0.011), with no significant difference in the prevalence of permanent RLN palsy (0.4%, p=NS). However, 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 in patients who had RLN monitoring (p=0.011) compared to those with 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.

Henry et al (2017) reported on a systematic review of meta-analyses published up to February 2017 that compared intraoperative neurophysiologic monitoring (IONM) with direct RLN visualization by assessing rates of vocal fold palsy. 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. Using the Jadad algorithm, reviewers determined the meta-analysis by Pisanu et al (2014)9 to have the highest quality; it found that concluded no statistically significant reductions in RLN injury between procedures using IONM vs direct RLN visualization. However, reviewers also noted that recent developments in IONM technology such as continuous vagal IONM and staged thyroidectomy might provide additional benefits, which were out of the scope of their systematic review and need to be assessed in further assessment in prospective multicenter trials.

Sun et al (2017) reported on a meta-analysis of RLN injury during thyroid surgery with or without IONM. Included were 2 prospective cohort studies and 7 retrospective cohort studies. Results are summarized in Tables 1 and 2. The absolute risk reduction was 2.75%, with a number needed to treat of 364.13. Observed differences in the subgroup analysis were very imprecise because the number of observed paralyses was very low. IONM was associated with a reduction in overall and permanent RLN palsy in thyroid reoperations. Limitations included small sample sizes and study heterogeneity.

Table 1. Characteristics of Systematic Reviews

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Pardal-Refoyo and Ochoa-Sangrador (2016)	1987-2013	• 2 RCTs • 52 case series	Studies reporting incidence of RLN paralysis after single-stage	30,922	• RCT • Case series	NR
Sun et al (2017)	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)	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 (range, 6-23 patients)	Meta-analysis	NR

Table 2. Results of Systematic Reviews

Study	Risk of Bilateral RLN Paralysis	Transient RLN Palsy	Permanent RLN Palsy
Pardal-Refoyo and Ochoa-Sangrador (2016)			
ARR (95% CI)	2.75% (NR)[a]		
NNT (95% CI)	364 (NR)[a]		
I^2 (p)	8%[a]		
	Overall RLN Palsy		
Sun et al (2017)			
With IONM	4.69%	3.98%[b]	1.26%[b]
Without IONM	9.27%	6.63%[b]	2.78%[b]
RR (95% CI) (p)	0.434 (0.206 to 0.916) (0.029)	0.607 (0.270 to 1.366) (0.227)[b]	0.426 (0.196 to 0.925) (0.031)[b]
NNT (95% CI)	NR	NR[b]	NR[b]
I^2 (p)	70.2%	67.4%[b]	13.7%[b]

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.

Table 3. Summary of Key Trial Characteristics

Study	Countries	Sites	Dates	Participants	Active	Comparator
Barczynski et al (2009)	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)			
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

Section Summary: Intraoperative Neurophysiologic Monitoring of the RLN during Thyroid or Parathyroid Surgery

The evidence on the use of IONM in reducing RLN injury includes a large RCT and systematic reviews on thyroid and parathyroid surgery. The strongest evidence derives from an RCT of 1000 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.

IONM of the RLN during Cervical Spine Surgery

Ajiboye et al (2017) reported on the results of a systematic review that included 10 studies (total N= 26,357 patients). All studies were of low methodologic quality but had a low risk of bias. Only studies compared the risk of nerve injury using IONM with no IONM. 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, 0.726; 95% confidence interval [CI], 0.287 to 1.833; p=0.498) (see 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. 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 (total 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).

Table 5. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Ajiboye et al (2017)	NR	10	Studies reporting IONM use for ACSS	26,357 (16-22,768)	• 9 retrospective • 1 prospective	NR
Erwood et al (2016)	1998-2015	8	Studies reporting reoperative ACSS for RLN	238 (13-63)	• 5 prospective • 3 retrospective	2 wk to 24 mo

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

Table 6. Systematic Review Results

Study	Risk of Neurologic Injury
Ajiboye et al (2017)	
OR (95% CI) (p)[a]	0.726 (0.287 to 1.833) (0.44)[b]
NNT (95% CI)	NR
I^2 (p)	0% (NR)
Erwood et al (2016)	
Estimate (95% CI) (p)[a]	0.14 (0.10 to 0.19)
NNT (95% CI)	NR
I^2 (p)	10.7% (NR)

CI: confidence interval; NNT: number needed to treat; 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: IONM of the RLN during Cervical Spine Surgery
The evidence on the use of IONM in reducing RLN injury during cervical spinal surgery includes a 2017 systematic review and a meta-analysis. Of the 10 studies included in the systematic review, two compared the risk of nerve injury using IONM with no IONM and found no difference.

IONM of the RLN during Esophageal Surgery
One 2014 comparative study from Asia was identified on RLN monitoring during surgery for esophageal cancer. One hundred fifteen patients with esophageal cancer were enrolled in this prospective study. In 54 patients, the left RLN was found and underwent monitoring. In the remainder (n=61), the RLN was not located. No RLN injury was reported during surgery in either group, but 6 of 61 patients who did not receive monitoring had notable RLN injury identified postoperatively. It is unclear whether the difference in outcomes was due to monitoring or to the inability to identify the RLN during surgery.

Section Summary: IONM of the RLN during Esophageal Surgery
One nonrandomized comparative study on surgery for esophageal cancer was identified. Interpretation of this study is confounded because only the patients who had visual identification of the nerve underwent IONM. Current evidence does not support conclusions on whether IONM reduces RLN injury in patients undergoing surgery for esophageal cancer.

IONM of Peripheral Nerves
Monitoring peripheral nerves during surgery was assessed by Kneist et al (2013) in a case-control study of 30 patients. In patients undergoing total mesorectal excision, impaired anorectal function was observed in 1 (7%) of 15 patients who had IONM 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. In this study, the combined intraoperative measurement of 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.

A 2011 report by Clarkson et al described the use of intraoperative nerve recording for suspected brachial plexus root avulsion. Included in this retrospective review were 25 consecutive patients who underwent intraoperative nerve recording during surgery for unilateral brachial plexus injury. Of 55 roots thought to be avulsed preoperatively, 14 (25%) were found to be intact using intraoperative nerve recording. Eleven of 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. Use of IONM of peripheral nerves has been reported in patients undergoing orthopedic procedures, including tibial/fibular osteotomies, hip arthroscopy for femoroacetabular impingement, and shoulder arthroplasty.

Section Summary: IONM of 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.

Summary of Evidence
For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve (RLN) who receive intraoperative neurophysiologic monitoring (IONM), 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 an RCT of 1000 patients undergoing thyroid surgery. This RCT found 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. A low volume of surgeries might also contribute to a higher risk for RLN injury. The evidence is

sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing anterior cervical spine surgery and are at high risk of injury to the RLN who receive IONM, the evidence includes systematic reviews of case series and cohort studies. Relevant outcomes are morbid events, functional outcomes, and quality of life. The evidence on the use of IONM to reduce RLN injury during cervical spinal surgery includes a 2017 systematic review and a meta-analysis. Of the 10 studies assessed in the systematic review, two compared the risk of nerve injury with use of IONM vs no IONM and found no difference. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are undergoing esophageal surgery who receive IONM, 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. There is insufficient evidence to evaluate whether neurophysiologic monitoring reduces RLN injury in patients undergoing surgery for esophageal cancer. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are undergoing surgery proximal to a peripheral nerve who receive IONM, 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 IONM 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)

A 2012 position statement on electrophysiologic monitoring during routine spinal surgery by the American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS) states that intraoperative electrophysiological monitoring during spinal surgery may assist in diagnosing neurologic injury. However, the AANS/CNS finds no evidence that such monitoring either 1) reduces the incidence of neurologic injury or 2) mitigates the severity of it. The position of the AANS/CNS is that routine use of intraoperative electrophysiologic monitoring is neither warranted nor recommended, although intraoperative electrophysiologic monitoring should be performed if the diagnostic information gained is of value, particularly in high-risk cases such as deformity, gross instability, navigation through or around peripheral nerves, or intramedullary procedures.

A 2014 guideline update from AANS/CNS found no conflicting evidence with their previous recommendations for intraoperative monitoring for lumbar fusion. They found no evidence that intraoperative monitoring can prevent injury to the nerve roots. They found limited evidence that

intraoperative monitoring can indicate a medial pedicle breach by a pedicle screw, but once a nerve root injury has taken place, changing the direction of the screw does not alter the outcome.

American Association of Neuromuscular & Electrodiagnostic Medicine
A 2013 position statement on SSEPs from the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) states that intraoperative SEPs have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts. AANEM states that intraoperative SEP monitoring is indicated for selected spine surgeries in which there is a risk of additional nerve root or spinal cord injury. Indications for SEP monitoring may include, but are not limited to, complex, extensive, or lengthy procedures, and when mandated by hospital policy.

American Clinical Neurophysiology Society
In 2009 the American Clinical Neurophysiology Society (ACNS) published recommended standards for intraoperative neurophysiologic monitoring. Guideline 11A includes the following statement:

> "The monitoring team should be under the direct supervision of a physician with training and experience in NIOM. 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 Academy of Neurology
AAN published an assessment of IONM in 1990 with an evidence-based guideline update in 2012 by the AAN and ACNS. The 1990 assessment indicates that monitoring requires a team approach with a well-trained physician-neurophysiologist to provide or supervise monitoring. 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. EMG monitoring during procedures around 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, MEPs were considered investigational by many neurophysiologists. The 2012 update, which was endorsed by the AANEM, concluded that the available evidence supports IONM using SSEPs or MEPs when conducted under the supervision of a clinical neurophysiologist experienced with IONM. Evidence was insufficient to evaluate IOMN when conducted by technicians alone or by an automated device.

AAN published a model policy on principles of coding for intraoperative neurophysiologic monitoring (IOM) and testing in 2012. The background section of this document provides the following information on the value of IOM 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 IOM using SEP 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 IOM is capable of substantially reducing injury in surgeries that pose a risk to spinal cord integrity. It recommended combined SEP/MEP 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 two 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. IOM 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 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 SSEP and MEPs. According to a recent review of spinal monitoring using SSEP and MEPs by the Therapeutics and Technology Assessment Subcommittee of AAN and ACNS, IOM 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 SSEP.

American Society of Neurophysiological Monitoring
In 2013, the American Society of Neurophysiological Monitoring (ASNM) published practice guidelines on the supervising professional on IONM. 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.

National Institute for Health and Care Excellence
A 2008 guidance from the U.K.'s National Institute for Health and Care Excellence on intraoperative nerve monitoring during thyroid surgery found no major safety concerns. In terms of efficacy, IONM 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.

Key Words:
Intra-operative neurophysiologic monitoring, sensory-evoked potentials, somatosensory-evoked potentials (SSEPs), Brainstem auditory-evoked potentials (BAEPs), Visual-evoked potentials (VEPs), Electromyogram (EMG), Motor-evoked potential, electroencephalogram (EEG), electrocorticography (ECoG), nerve conduction velocity, transcranial magnetic stimulation, Digitimer electrical cortical stimulator

Approved by Governing Bodies:
A number of electroencephalography and electromyography monitors have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process.

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

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT codes:

92585	Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive
95829	Electrocorticogram at surgery (separate procedure)
95865	Needle electromyography; larynx
95867	Needle electromyography; cranial nerve supplied muscle(s), unilateral
95868	Needle electromyography; cranial nerve supplied muscles, bilateral
95885	Needle electromyography, each extremity, with related paraspinal areas, when performed, done with nerve conduction, amplitude and latency/velocity study; limited (list separately in addition to code for primary procedure)
95886	;complete, five or more muscles studied, innervated by three or more nerves or four or more spinal levels (list separately in addition to code for primary procedure)
95887	Needle electromyography, non-extremity (cranial nerve supplied or axial) muscle(s) done with nerve conduction, amplitude and latency/velocity study (list separately in addition to code for primary procedure)
95907	Nerve conduction studies; 1-2 studies
95908	Nerve conduction studies; 3-4 studies
95909	Nerve conduction studies; 5-6 studies
95910	Nerve conduction studies; 7-8 studies
95911	Nerve conduction studies; 9-10 studies
95912	Nerve conduction studies; 11-12 studies
95913	Nerve conduction studies; 13 or more studies
95925	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95927	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
95928	Central motor evoked potential study (transcranial motor stimulation); **;** upper limbs

95929 **;** lower limbs

95930 Visual evoked potential (VEP) checkerboard or flash testing, central nervous system glaucoma, with interpretation and report.

95940 Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)

95941 Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure)

95955 Electroencephalogram (EEG) during non-intracranial surgery (e.g., carotid surgery)

HCPCS codes:

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

Codes 95040 and 95941 would be reported in conjunction with the code(s) for the testing performed, i.e., 92585, 95822, 95860-95870, 95907-95913, and 95925-95939.

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Policy History:

Medical Policy Group, March 2007 **(3)**
Medical Policy Administration Committee, April 2007
Available for comment April 12-May 26, 2007
Medical Policy Group, March 2009 **(1)**
Medical Policy Group, June 2009 **(2)**
Medical Policy Administration Committee, July 2009
Available for comment July 1-August 14, 2009
Medical Policy Panel, July 2011
Medical Policy Group, August 2011 **(2):** Update Description, Key Points, Key Words, Government Approval, References
Medical Policy Administration Committee, August 2011
Available for comment August 11 – September 26, 2011
Medical Policy Group, December 2011 **(3)**: Added new 2012 Codes – 95885, 95886, 95887
Medical Policy Panel, March 2012
Medical Policy Group, September 2012 **(2);** Policy statements changed to indicate motor-evoked potentials using transcranial electrical stimulation meets coverage criteria and motor-evoked potential using transcranial magnetic stimulation is investigational. Key Points and References updated to support Policy changes.
Medical Policy Administration Committee, September 2012
Available for comment September 18 through October 31, 2012

Medical Policy Group, November 2012: Added new 2013 Codes G0453, 95940, 95941, 95907, 95908, 95909, 95910, 95911, 95912, & 95913 effective January 1, 2013; Deleted Codes 95920, 95900, 95903, & 95904 effective January 1, 2013.
Medical Policy Panel, December 2012
Medical Policy Group, August 2013 **(2):** Updated Key Points and References from literature search through October 2012. No change in policy statement.
Medical Policy Panel, May 2014
Medical Policy Group, July 2014 (**4**): Updated Key Points and References. No changes to the policy at this time.
Medical Policy Panel, May 2015
Medical Policy Group, May 2015 **(6):** Updates to Key Points, Approved by Governing Bodies, and References; no change to policy statement.
Medical Policy Group, March 2016 **(6):** Clarification to policy statement; no change in policy intent.
Medical Policy Group, July 2016: Removed Policy section prior to November 1, 2012 in policy cleanup.
Medical Policy Panel, May 2017
Medical Policy Group, June 2017 **(6)**: Updates to Description, Policy statement edited to allow coverage for monitoring of the Recurrent Laryngeal Nerve, Key points, Key Words, Practice Guidelines, Governing Bodies, Coding, and References.
Medical Policy Group, December 2017. Annual Coding Update 2018. Updated verbiage for revised cpt code 95930.
Medical Policy Panel April 2018
Medical Policy Group, May 2018 **(6)**: Updates to Key Points and References.
