**Intraoperative Neurophysiologic Monitoring**

**Policy Number:** 7.01.58  
**Origination:** 10/1988  
**Last Review:** 5/2019  
**Next Review:** 5/2020

**Policy**

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for intraoperative neurophysiologic monitoring when it is determined to be medically necessary because the criteria shown below are met.

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.

**When Policy Topic is covered**

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), may be considered *medically necessary* during spinal, intracranial, or vascular procedures.

Intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve may be considered *medically necessary* 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 disectomy and fusion, revision surgery through a scarred surgical field, reoperation for pseudarthrosis or revision for failed fusion
  - multilevel anterior cervical disectomy and fusion
  - time consuming anterior cervical disectomy and fusion (eg, tumor)
o preexisting recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve.

**When Policy Topic is not covered**

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

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

Due to the lack of FDA approval, intraoperative monitoring of motor-evoked potentials using transcranial magnetic stimulation is considered *investigational*.

The billing of 95999 (unlisted code) for train-of-four neurophysiologic testing is considered investigational.

Intraoperative EMG and nerve conduction velocity monitoring during surgery on the peripheral nerves is considered *not medically necessary*. (See Considerations section for further discussion)

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.

**Considerations**

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

Intraoperative monitoring typically is done in the operating room by a technician, with a physician as a remote backup. In some operating rooms there is a central physician monitoring room, where a physician may simultaneously monitor several cases.

Intraoperative monitoring is considered reimbursable as a separate service only when a licensed physician, other than the operating surgeon, performs the monitoring while in attendance in the operating room throughout the procedure.

Constant communication between surgeon, neurophysiologist, and anesthetist are required for safe and effective intraoperative neurophysiologic monitoring.
Implementation of a local policy on this technology may also involve discussions about credentialing of those providing the intraoperative monitoring services, as well as on-site versus remote real-time review and interpretation. Coding for intraoperative monitoring uses time-based codes; they are not based on the number (single vs. multiple) of modalities used.

### Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Individually:</strong> Who are undergoing thyroid or parathyroid surgery who are at high risk of injury to the recurrent laryngeal nerve</td>
<td>Interventions of interest are: - Intraoperative neurophysiologic monitoring</td>
<td>Comparators of interest are: - Surgery without neurophysiologic monitoring</td>
<td>Relevant outcomes include: - Morbid events - Functional outcomes - Quality of life</td>
</tr>
<tr>
<td><strong>Individually:</strong> Who are undergoing anterior cervical spine surgery who are at high risk of injury to the recurrent laryngeal nerve</td>
<td>Interventions of interest are: - Intraoperative neurophysiologic monitoring</td>
<td>Comparators of interest are: - Surgery without neurophysiologic monitoring</td>
<td>Relevant outcomes include: - Morbid events - Functional outcomes - Quality of life</td>
</tr>
<tr>
<td><strong>Individually:</strong> Who are undergoing esophageal surgery</td>
<td>Interventions of interest are: - Intraoperative neurophysiologic monitoring</td>
<td>Comparators of interest are: - Surgery without neurophysiologic monitoring</td>
<td>Relevant outcomes include: - Morbid events - Functional outcomes - Quality of life</td>
</tr>
<tr>
<td><strong>Individually:</strong> Who are undergoing surgery in proximity to a peripheral nerve</td>
<td>Interventions of interest are: - Intraoperative neurophysiologic monitoring</td>
<td>Comparators of interest are: - Surgery without neurophysiologic monitoring</td>
<td>Relevant outcomes include: - Morbid events - Functional outcomes - Quality of life</td>
</tr>
</tbody>
</table>

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 (ie, 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.

For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the recurrent laryngeal nerve (RLN) who receive IONM, the evidence includes a large randomized controlled trial and systematic reviews. Relevant outcomes are morbid events, functional outcomes, and quality of life. The
The strongest evidence on neurophysiologic monitoring derives from a randomized controlled trial of 1000 patients undergoing thyroid surgery. This randomized controlled trial 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. Current evidence is not sufficiently robust to determine 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.

Clinical input obtained in 2014 and professional society guidelines have supported the use of IONM 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. It should be noted that there is controversy about the utility of IONM in some surgical procedures. Most of the published literature is from Europe, and, while many articles have reported the sensitivity and specificity of motor-evoked potentials for
predicting postsurgical neurologic deficits, few have reported intraoperative interventions undertaken in response to information from monitoring.

Clinical input obtained in 2017 supports that the following indication provides a clinically meaningful improvement in net health outcome and is consistent with generally accepted medical practice:

- Use of intraoperative neurophysiologic monitoring 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.

Thus, the above indication may be considered medically necessary considering the suggestive evidence and clinical input support.

**Background**

**Intraoperative Neurophysiologic Monitoring**

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

The different methodologies of monitoring are described next.

**Sensory-Evoked Potentials**

Sensory-evoked potential (SEP) describes the responses of the sensory pathways to sensory or electrical stimuli. Intraoperative monitoring of SEPs 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 SEP 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 SEPs 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. SEPs can be further categorized by type of simulation used, as follow.
**Somatosensory-Evoked Potentials**

Somatosensory-evoked potentials (SSEPs) 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 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**

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**

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

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

**Electromyogram Monitoring and Nerve Conduction Velocity Measurements**

Electromyography (EMG) monitoring and nerve conduction velocity measurements can be performed in the operating room and may be used to assess the status of the cranial or peripheral nerves (eg, to identify the extent of nerve damage 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 (ie, during carotid
artery, thyroid, parathyroid, goiter, or anterior cervical spine procedures), monitoring of the vocal cords or vocal cord muscles has been performed. These techniques may also be used during procedures proximal to the nerve roots and peripheral nerves to assess the presence of excessive traction or other impairment. Surgery in the region of cranial nerves can be monitored by electrically stimulating the proximal (brain) end of the nerve and recording via EMG activity in the facial or neck muscles. Thus, monitoring is done in the direction opposite that of SEPs, 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 a normal EEG activity. Carotid endarterectomy may be done with the patient under local anesthesia so that monitoring of cortical function can be directly assessed.

- Electrocorticography (ECoG) is the recording of EEG activity directly from a surgically exposed cerebral cortex. 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.

IONM, 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 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. 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 FDA through the 510(k) process. FDA product code: GWQ.

IONM of MEPs using transcranial magnetic stimulation does not have FDA approval.
Rationale
This evidence review was created in November 1997 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through February 23, 2018.

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.

RLN Monitoring During Thyroid or Parathyroid Surgery
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) 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.

Pardal-Refoyo and Ochoa-Sangrador (2016) reported on a systematic review of RLN injury during total thyroidectomy with or without IONM. 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 absolute risk reduction was 2.75%, with a number needed to treat of 364.13. The observed differences in the subgroup analysis were very imprecise because the number of observed instances of paralysis was very low.

**Table 1. Characteristics of Systematic Reviews**

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pardal-Refoyo and Ochoa-Sangrador (2016)</td>
<td>1987-2013</td>
<td>2 RCTs, 52 case series</td>
<td>Studies reporting incidence of RLN paralysis after single-stage</td>
<td>30,922</td>
<td>RCT, Case series</td>
<td>NR</td>
</tr>
<tr>
<td>Sun et al (2017)</td>
<td>Up to Aug 2016</td>
<td>9</td>
<td>Studies reporting incidence of RLN complications after thyroid surgery</td>
<td>2436 nerves at risk (1109 with IONM, 1327 without IONM)</td>
<td>Prospective/retrospective cohort studies</td>
<td>NR</td>
</tr>
<tr>
<td>Henry et al (2017)</td>
<td>Up to Feb 2017</td>
<td>8 meta-analyses</td>
<td>Meta-analyses of RCTs and non-RCTs comparing IONM with direct visualization for RLNs during thyroidectomy</td>
<td>8 meta-analyses (range, 6-23 patients)</td>
<td>Meta-analysis</td>
<td>NR</td>
</tr>
</tbody>
</table>

IONM: intraoperative neurophysiologic monitoring; NR: not reported; RCT: randomized controlled trial; RLN: recurrent laryngeal nerve.

**Table 2. Results of Systematic Reviews**

<table>
<thead>
<tr>
<th>Study</th>
<th>Risk of Bilateral RLN Paralysis</th>
<th>Transient RLN Palsy</th>
<th>Permanent RLN Palsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pardal-Refoyo and Ochoa-Sangrador (2016)</td>
<td>2.75% (95% CI)</td>
<td>3.98%&lt;sup&gt;b&lt;/sup&gt;</td>
<td>1.26%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Sun et al (2017)</td>
<td>With IONM</td>
<td>4.69%</td>
<td>3.98%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td></td>
<td>Without IONM</td>
<td>9.27%</td>
<td>6.63%&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
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.

The largest RCT evaluating RLN neuromonitoring for thyroid surgery was reported by Barczynski et al (2009) and is summarized in Tables 3 and 4.\(^1\) 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 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.\(^1\)

**Table 3. Summary of Key Trial Characteristics**

<table>
<thead>
<tr>
<th>Study</th>
<th>Countries</th>
<th>Sites</th>
<th>Dates</th>
<th>Participants</th>
<th>Active</th>
<th>Comparator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barczynski et al</td>
<td>Poland</td>
<td>1</td>
<td>2006-2007</td>
<td>Patients undergoing bilateral neck surgery</td>
<td>500</td>
<td>500</td>
</tr>
</tbody>
</table>

**Table 4. Summary of Key RCT Results**

<table>
<thead>
<tr>
<th>Study</th>
<th>RLN Injury</th>
<th>RLN Paresis</th>
<th>Permanent RLN Palsy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barczynski et al (2009)(^1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RLN visualization alone, n/N</td>
<td>8/500</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>RLN visualization plus monitoring, n/N</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>ARR (95% CI) (p)</td>
<td>2.3% (NR) (0.007)</td>
<td>1.9% (NR) (0.011)</td>
<td>0.4% (NR) (NS)</td>
</tr>
<tr>
<td>NNT (95% CI)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
</tbody>
</table>

ARR: absolute risk reduction; CI: confidence interval; NNT: number needed to treat; NR: not reported; 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 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.
**RLN Monitoring 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).\(^{14}\) 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 2studies, 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.\(^{15}\) 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 (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

<table>
<thead>
<tr>
<th>Study</th>
<th>Dates</th>
<th>Trials</th>
<th>Participants</th>
<th>N (Range)</th>
<th>Design</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ajiboye et al (2017)(^{14})</td>
<td>NR</td>
<td>10</td>
<td>Studies reporting IONM use for ACSS</td>
<td>26,357 (16-22,768)</td>
<td>9 retrospective</td>
<td>NR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 prospective</td>
<td></td>
</tr>
<tr>
<td>Erwood et al (2016)(^{15})</td>
<td>1998-2015</td>
<td>8</td>
<td>Studies reporting reoperative ACSS for RLN</td>
<td>238 (13-63)</td>
<td>5 prospective</td>
<td>2 wk to 24 mo</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 retrospective</td>
<td></td>
</tr>
</tbody>
</table>

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

### Table 6. Systematic Review Results

<table>
<thead>
<tr>
<th>Study</th>
<th>Risk of Neurologic Injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ajiboye et al (2017)(^{14})</td>
<td>OR (95% CI) (p)(^{a}) 0.726 (0.287 to 1.833) (0.44)(^{b})</td>
</tr>
<tr>
<td></td>
<td>NNT (95% CI)</td>
</tr>
<tr>
<td></td>
<td>(I^2) (p)</td>
</tr>
<tr>
<td>Erwood et al (2016)(^{15})</td>
<td>Estimate (95% CI) (p)(^{a}) 0.14 (0.10 to 0.19)</td>
</tr>
<tr>
<td></td>
<td>NNT (95% CI)</td>
</tr>
<tr>
<td></td>
<td>(I^2) (p)</td>
</tr>
</tbody>
</table>

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: RLN Monitoring 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.

**RLN Monitoring During Esophageal Surgery**

A comparative study from Asia by Zhong et al (2014) evaluated RLN monitoring during surgery for esophageal cancer.\(^{16}\) 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 (10%) 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: RLN Monitoring 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.

Monitoring 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 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.

A report by Clarkson et al (2011) 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 them were then used for reconstruction, of which 9 (82%) had a positive functional outcome. Electrophysiologic monitoring has also been reported to guide selective rhizotomy for glossopharyngeal neuralgia in a series of 8 patients.

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.

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.
Summary of Evidence
For individuals who are undergoing thyroid or parathyroid surgery and are at high risk of injury to the RLN who receive IONM, the evidence includes a large RCT and systematic reviews. Relevant outcomes are morbid events, functional outcomes, and quality of life. The strongest evidence on neurophysiologic monitoring derives from a randomized controlled trial of 1000 patients undergoing thyroid surgery. This randomized controlled trial 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. Current evidence is not sufficiently robust to determine 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.

Clinical Input
Objective
In 2017, clinical input was sought for intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve (RLN) to determine whether monitoring improves health outcomes when used during cervical spine surgery.

Respondents
Clinical input was provided by the following medical specialty societies (listed alphabetically):

- American Academy of Neurological Surgeons and Congress of Neurological Surgeons (AANS/CNS)
- American Academy of Orthopaedic Surgeons and North American Spine Society (AAOS/NASS combined response)
- American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS)

Clinical input provided by the specialty society at an aggregate level is attributed to the specialty society. Clinical input provided by a physician member designated by the specialty society or health system is attributed to the individual physician and is not a statement from the specialty society or health system. Specialty society and physician respondents participating in the Evidence Street® clinical input process provide a review, input, and feedback on topics being evaluated by Evidence Street. However, participation in the clinical input process by a special society and/or physician member designated by the specialty society or health system does not imply an endorsement or explicit agreement with the Evidence Opinion published by BCBSA or any Blue Plan.

Clinical Input Responses
Figure 1:
Additional Comments

- “While there is little evidence to support the use of intraoperative monitoring of the recurrent laryngeal nerve during primary anterior cervical spine surgery, it has been well-studied in soft-tissue surgery of the neck, including thyroidectomy. Given the increased difficulty, scarring and aberrant anatomy sometimes associated with revision anterior cervical surgery, we extrapolate from the available literature that monitoring of the recurrent laryngeal nerve may increase patient safety in these revision situations. Thus, each case and use of monitoring would be up to the surgeons’ discretion.” (AAOS/NASS)

- “We feel that it is generally at the surgeon’s discretion whether neurophysiologic monitoring of the recurrent laryngeal nerve is indicated in patients undergoing cervical spine surgery. As referenced above, for monitoring of the recurrent laryngeal nerve, there are certain circumstances where this nerve is at much higher risk of injury, and perhaps monitoring of this nerve may play a role in preventing injuries to it.” (AANS/CNS)

- “If there is a pre-existing injury to the RLN and there is no nerve function it would seem that monitoring that side has no value. If the included definition of RLN pathology was partial and not complete there would be value in monitoring the affected nerve. However, if they are talking about the contralateral RLN that was currently working well, the answer should be high confidence and

<table>
<thead>
<tr>
<th>Clinical Indication</th>
<th>Respondent</th>
</tr>
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<tbody>
<tr>
<td>Revision anterior cervical discectomy and fusion</td>
<td>AANS/CNS</td>
</tr>
<tr>
<td>Revision surgery through a scarred surgical field</td>
<td>AAO-HNS</td>
</tr>
<tr>
<td>Reoperation for pseudarthrosis or revision for failed fusion</td>
<td>AAOS/NASS</td>
</tr>
<tr>
<td>Prior anterior cervical surgery</td>
<td>AAOS/NASS</td>
</tr>
<tr>
<td>Multilevel anterior cervical discectomy and fusion</td>
<td>AANS/CNS</td>
</tr>
<tr>
<td>Time consuming anterior cervical discectomy and fusion (eg, tumor, etc)</td>
<td>AANS/CNS</td>
</tr>
<tr>
<td>Pre-existing recurrent laryngeal nerve pathology, when there is residual function of the recurrent laryngeal nerve.</td>
<td>AAO-HNS</td>
</tr>
<tr>
<td>Lower level cervical spine surgery</td>
<td>AAO-HNS</td>
</tr>
<tr>
<td>Right-sided approach</td>
<td>AAO-HNS</td>
</tr>
</tbody>
</table>

Would use of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve be expected to improve health outcomes by reducing nerve injury and post-operative morbidity?

<table>
<thead>
<tr>
<th>Clinical Indication</th>
<th>Respondent</th>
<th>Low</th>
<th>Intermediate</th>
<th>High</th>
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<td>AAO-HNS</td>
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<td>Yes</td>
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</table>

Is the use of intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve be in accordance with generally accepted medical practice?

<table>
<thead>
<tr>
<th>Clinical Indication</th>
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</table>
monitored in every situation. Monitoring the contralateral RLN in the presence of ipsilateral pathology would be yes with high confidence. However, monitoring the already damaged RLN would not be valuable as described above.” (AAO-HNS)

See Appendices 1 and 2 for details of the clinical input.

SUPPLEMENTAL INFORMATION

Clinical Input From Physician Specialty Societies and Academic Medical Centers

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

2017 Input

In response to requests, clinical input on intraoperative neurophysiologic monitoring (IONM) of the recurrent laryngeal nerve for individuals undergoing cervical spine surgery was received from 5 specialty society-level response while this policy was under review in 2017.

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

2014 Input

In response to requests, input was received from 5 physician specialty societies (7 responses) and 2 academic medical centers while this policy was under review in 2014. Input agreed that 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 (eg, 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 Association of Neurological Surgeons and Congress of Neurological Surgeons
The 2012 position statement on electrophysiologic neurophysiologic monitoring (IONM) during routine spinal surgery by the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), updated in 2014, has stated that IONM may assist in diagnosing the neurologic injury. However, AANS and CNS found no evidence that such monitoring either (1) reduces the incidence of neurologic injury or (2) mitigates the severity of it. The position taken by AANS and CNS indicated that routine use of IONM is neither warranted nor recommended, although IONM 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. In the 2014 update, AANS and CNS found no evidence that would conflict with their previous recommendations for IONM for lumbar fusion. The societies found no evidence that IONM can prevent injury to the nerve roots. They found limited evidence that IONM 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 2014 position statement on somatosensory-evoked potentials (SSEPs) from the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) has indicated that intraoperative sensory-evoked potentials (SEPs) have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts. AANEM stated that intraoperative SEP monitoring is indicated for select 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. However, intraoperative SEP monitoring may not be indicated for routine lumbar or cervical root decompression.

American Clinical Neurophysiology Society
In 2009, the American Clinical Neurophysiology Society (ACNS) recommended standards for IONM. Guideline 11A included the following statement:

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

**American Academy of Neurology**

The 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.\(^1\)\(^2\). The 1990 assessment indicated that monitoring requires a team
approach with a well-trained physician-neurophysiologist to provide or supervise
monitoring. Electroencephalography (EEG) monitoring is used during carotid
endarterectomy or for other similar situations in which cerebral blood flow is at
high risk. Electrocorticography from surgically exposed cortex can help to define
the optimal limits of surgical resection or identify regions of greatest impairment,
while sensory cortex 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 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 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.

AAN published a model policy on principles of coding for IONM and testing in
2012.\(^2\)\(^6\). The background section of this document provides the following
information on the value of IONM in averting neural injuries during surgery:

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 [intraoperative neurophysiologic monitoring]
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 quadriplegia 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 [electromyography] 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 published practice guidelines on the supervising professional on IONM. The Society’s 2013 position statement on intraoperative MEP monitoring indicated that MEPs are an established practice option for cortical and subcortical mapping and monitoring during surgeries risking motor injury in the brain, brainstem, spinal cord or facial nerve.
National Institute for Health and Care Excellence
A 2008 guidance from the National Institute for Health and Care Excellence on IONM during thyroid surgery found no major safety concerns.\textsuperscript{28} Regarding 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.

Medicare National Coverage
The Centers for Medicare & Medicaid Services has indicated that EEG monitoring “may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted.”\textsuperscript{29} Coverage determinations for other modalities were not identified.

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

In the Final Rule, the Centers established a HCPCS G code (see Policy Guidelines section) for reporting physician monitoring performed from outside of the operating room (nearby or remotely). HCPCS code G0453 “may be billed only for undivided attention by the monitoring physician to a single beneficiary [1:1 technologist to oversight physician billing], and not for simultaneous attention by the monitoring physician to more than one patient.”\textsuperscript{30}

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 7.

Table 7. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<tr>
<td>NCT02395146</td>
<td>Intra-operative Monitoring of the External Branch of the Superior Laryngeal Nerve (EBSLN) During Thyroid Surgery: Does it Improve Voice Preservation?</td>
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<td>NCT01585727</td>
<td>Continuous Intraoperative Monitoring of the Pelvic Autonomic Nerves During Total Mesorectal Excision (TME) for the Prevention of Urogenital and Anorectal Dysfunction in Patients With Rectal Cancer (NEUROS)</td>
<td>188</td>
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<tr>
<td>NCT01630785</td>
<td>Observation of Neurosurgical Interventions With Intraoperative Neurophysiological Monitoring IONM</td>
<td>5000</td>
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<tr>
<td><strong>Unpublished</strong></td>
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NCT02187653  Spine Registry Exposure for Lumbar and Cervical Surgery Utilizing IOM  10,000  Dec 2016 (unknown)

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

REFERENCES


**Billing Coding/Physician Documentation Information**

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>92585</td>
<td>Auditory evoked potentials for evoked response audiometry and/or testing of the central nervous system; comprehensive</td>
</tr>
<tr>
<td>95822</td>
<td>Electroencephalogram (EEG); recording in coma or sleep only</td>
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</table>
95829  Electroencephalogram at surgery (separate procedure)
95860  Needle electromyography; 1 extremity with or without related paraspinal areas
95861  Needle electromyography; 2 extremities with or without related paraspinal areas
95863  Needle electromyography; 3 extremities with or without related paraspinal areas
95864  Needle electromyography; 4 extremities with or without related paraspinal areas
95865  Needle electromyography; larynx
95866  Needle electromyography; hemidiaphragm
95867  Needle electromyography; cranial nerve supplied muscle(s), unilateral
95868  Needle electromyography; cranial nerve supplied muscles, bilateral
95869  Needle electromyography; thoracic paraspinal muscles (excluding T1 or T12)
95870  Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters
95907  Nerve conduction studies; 1-2 studies
95908  Nerve conduction studies; 3-4 studies
95909  Nerve conduction studies; 5-6 studies
95910  Nerve conduction studies; 7-8 studies
95911  Nerve conduction studies; 9-10 studies
95912  Nerve conduction studies; 11-12 studies
95913  Nerve conduction studies; 13 or more studies
95925  Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper limbs
95926  Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95927  Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in the trunk or head
95928  Central motor evoked potential study (transcranial motor stimulation); upper limbs
95929  Central motor evoked potential study (transcranial motor stimulation); lower limbs
95930  Visual evoked potential (VEP) testing central nervous system, checkerboard or flash
95933  Orbicularis oculi (blink) reflex, by electrodiagnostic testing
95937  Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method
95938  Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
95939  Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs
95940  Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)

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

95955  Electroencephalograph during non-cranial surgery (eg. carotid surgery)

95999  Unlisted neurologic or neuromuscular diagnostic procedure

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)

**ICD10 Codes**

C41.2  Malignant neoplasm of vertebral column
C71.0-  Malignant neoplasm of brain; code range
C71.9
C72.0  Malignant neoplasm of spinal cord
C73   Malignant neoplasm of thyroid gland
C75.0  Malignant neoplasm of parathyroid gland
C79.31- Secondary malignant neoplasm of brain and cerebral meninges; code range
C79.32
D33.0-  Benign neoplasm of brain and other parts of central nervous system; code range
D33.9
D34   Benign neoplasm of thyroid gland
D35.1  Benign neoplasm of parathyroid gland
D43.0-  Neoplasm of uncertain behavior of brain and central nervous system; code range
D43.9
D44.0  Neoplasm of uncertain behavior of thyroid gland
D44.2  Neoplasm of uncertain behavior of parathyroid gland
D49.6  Neoplasm of unspecified behavior of brain
E04.0-  Other nontoxic goiter code range
E04.9
E05.00- Thyrotoxicosis code range
E05.91
E06.0-  Thyroiditis code range
E06.9
E21.0- Hyperparathyroidism code range (E21.0 is primary
E2.15  hyperparathyroidism)
I71.00- Aortic aneurysm and dissection; code range
I71.9
M50.00- Cervical disc disorders; code range
M50.93
M48.00- Spinal stenosis; code range
M48.08
M40.00- Kyphosis and lordosis; code range
M40.57
M41.00- M41.9  Scoliosis; code range
I65.01- I65.9  Occlusion and stenosis of precerebral arteries, not resulting in cerebral infarction; code range

Codes 95940 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.

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/1/88</td>
<td>New policy.</td>
</tr>
<tr>
<td>5/1/00</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/01</td>
<td>Policy statement revised to include monitoring of motor evoked potentials within the brain and visual-evoked potentials as investigational. Monitoring of peripheral nerves during surgery is considered part of the total procedure.</td>
</tr>
<tr>
<td>5/1/02</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/03</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/04</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/05</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/06</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/07</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/08</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/10</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/11</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>9/1/11</td>
<td>Policy statements changed to indicate motor-evoked potentials using transcranial electrical stimulation may be considered medically necessary and motor-evoked potential using transcranial magnetic stimulation is investigational, other policy statements unchanged.</td>
</tr>
<tr>
<td>5/1/12</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/13</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/14</td>
<td>Added a statement in the Policy Guidelines about the associated nerve testing codes that would be reported with codes 95940 and 95941.</td>
</tr>
<tr>
<td>5/1/15</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>7/1/15</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/16</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/17</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>7/1/17</td>
<td>New clinical input obtained in 2017 is added regarding cervical spine surgery. Intraoperative monitoring is considered medically necessary for high risk thyroid and anterior cervical spine surgeries. Title changed to “Intraoperative Neurophysiologic Monitoring.”</td>
</tr>
<tr>
<td>5/1/18</td>
<td>No policy statement changes.</td>
</tr>
</tbody>
</table>
| 8/1/18     | Added Investigational Statement regarding train of four}
neurophysiologic testing.

No policy statement changes.

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.

APPENDIX 1: CLINICAL INPUT

Appendix Table 1. Respondent Profile

<table>
<thead>
<tr>
<th>No.</th>
<th>Specialty Society</th>
<th>Name of Organization</th>
<th>Clinical Specialty</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>American Academy of Neurological Surgeons / Congress of Neurological Surgeons</td>
<td>Neurosurgery</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>American Academy of Otolaryngology-Head and Neck Surgery</td>
<td>Otolaryngology, Head and Neck Surgery</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>American Academy of Orthopaedic Surgeons / North American Spine Society</td>
<td>Orthopaedic Surgery, Spine Disorders</td>
<td></td>
</tr>
</tbody>
</table>

Appendix Table 2. Respondent Conflict of Interest Disclosure

<table>
<thead>
<tr>
<th>No.</th>
<th>1. Research support related to the topic where clinical input is being sought</th>
<th>2. Positions, paid or unpaid, related to the topic where clinical input is being sought</th>
<th>3. Reportable, more than $1000, health care–related assets or sources of income for myself, my spouse, or my dependent children related to the topic where clinical input is being sought</th>
<th>4. Reportable, more than $350, gifts or travel reimbursements for myself, my spouse, or my dependent children related to the topic where clinical input is being sought</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>No</td>
<td>Yes (Triological Society Career Development Award recipient. Topic of research is the study of laryngeal motor neuropathy through the evaluation of transcranial magnetic stimulation-evoked myogenic potentials.)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>3</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Conflict of Interest Policy Statement

The North American Spine Society (NASS) employs rigorous checks and balances to ensure that its comments and recommendations on payors’ coverage policies/evidence reports are scientifically sound and unbiased. These checks and balances include requiring all individuals involved in drafting, reviewing, revising and approving the comments to disclose any conflicts of interest he or she may have. Using an evidence-based approach when possible, the multi-disciplinary team works together to develop the comments which requires multiple levels of review. The individuals who provide the final reviews and approvals are further required to divest themselves of most financial interests in any medical industry-related concerns. For more information on NASS’ Level 1 disclosure policy, please visit NASS website.

Individual physician respondents answered at individual level. Specialty Society respondents provided aggregate information that may be relevant to the group of clinicians who provided input to the Society-level response.
NR: not reported.

APPENDIX 2: CLINICAL INPUT RESPONSES

Objective

Clinical input is sought for intraoperative neurophysiologic monitoring of the recurrent laryngeal nerve to determine whether monitoring improves health outcomes when used during cervical spine surgeries.
Responses
1. For patients undergoing cervical spine surgery, are there patient factors and/or surgical factors that would increase the risk of recurrent laryngeal nerve injury?

<table>
<thead>
<tr>
<th>No.</th>
<th>Yes/No</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Yes</td>
<td>A meta-analysis by Erwood from 2016 was performed to determine the rate of recurrent laryngeal nerve (RLN) injuries after recurrent ACDF’s. They report a rate of RLN injury after reoperative ACDF of 14.1% (95% confidence interval [CI] 9.8%-19.1%). This number is much greater than what is reported for routine ACDFs, and as such we must take into account that monitoring of the RLN may be indicated in patients undergoing revision ACDF procedures. Tan et al (2014 Spine J) also confirm that there is significant evidence that revision ACDF increase the risk of laryngeal palsy. An article from Dimopoulos (2009) reviewed the role of laryngeal intraoperative electromyography (IEMG) in predicting the development of postoperative recurrent laryngeal nerve (RLN) palsy in patients undergoing anterior cervical disectomy and fusion (ACDF). They found significantly increased IEMG activity in patients with previous surgical intervention, patients undergoing multilevel procedures, long-lasting procedures, and cases in which self-retained retractors were used. They therefore conclude that IEMG can provide real-time information and can potentially minimize the risk of operative RLN injury.</td>
</tr>
</tbody>
</table>

2. For each situation you described in Question 1:
   a. Please fill in the first column of the table below with each indication you reported.
   b. Please respond YES or NO whether the use of intraoperative neurophysiologic monitoring would be expected to improve health outcomes by reducing nerve injury and postoperative morbidity.
   c. Please use the 1 to 5 scale outlined below to indicate your level of confidence that there is adequate evidence that supports your conclusions.

<table>
<thead>
<tr>
<th>No.</th>
<th>Fill in the blanks below with each indication you reported in Question 1</th>
<th>Yes/No</th>
<th>Low Confidence</th>
<th>Intermediate Confidence</th>
<th>High Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Revision anterior cervical disectomy and fusion</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Multilevel anterior cervical disectomy and fusion</td>
<td>Yes</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Time consuming anterior cervical disectomy and fusion (eg, tumor)</td>
<td>Yes</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Revision surgery through a scarred surgical field</td>
<td>Yes</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Preexisting recurrent laryngeal nerve</td>
<td>Yes</td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

References:
3. For each situation you described in Question 1:

a. Please fill in the first column of the table below with each indication you reported.

b. Please respond YES or NO whether this clinical use is in accordance with generally accepted medical practice.

c. Please use the 1 to 5 scale outlined below to indicate your level of confidence that this clinical use is in accordance with generally accepted medical practice.

<table>
<thead>
<tr>
<th>No.</th>
<th>Indication you reported in Question 1</th>
<th>Fill in the blanks below with each Yes/No</th>
<th>Low Confidence</th>
<th>Intermediate Confidence</th>
<th>High Confidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Revision anterior cervical disectomy and fusion</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Multilevel anterior cervical disectomy and fusion</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Time consuming anterior cervical disectomy and fusion</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Revision surgery through a scarred surgical field</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Preexisting recurrent laryngeal nerve pathology</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Lower level cervical spine surgery</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Right-sided approach</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Prior anterior cervical surgery</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Reoperation for pseudarthrosis or revision for failed fusion</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Additional comments and/or any citations supporting your clinical input on the clinical use of intraoperative neurophysiologic monitoring in patients undergoing cervical spine surgery.

1. **Revision surgery through a scarred surgical field**

2. **Preexisting recurrent laryngeal nerve pathology**
   - Preexisting recurrent laryngeal nerve pathology:
     - If there is a pre-existing injury to the RLN and there is no nerve function it would seem that monitoring that side has no value. If the included definition of RLN pathology was partial and not complete there would be value in monitoring the affected nerve. However, if they are talking about the contralateral RLN that was currently working well, the answer should be high confidence and monitored in every situation.
     - Monitoring the contralateral RLN in the presence of ipsilateral pathology would be yes with high confidence.

3. **Lower level cervical spine surgery**
   - Apfelbaum RI, Kriskovich MD, Haller JR. On the incidence, cause, and prevention of recurrent laryngeal nerve...
3. While there is little evidence to support the use of intraoperative monitoring of the recurrent laryngeal nerve during primary anterior cervical spine surgery, it has been well-studied in soft-tissue surgery of the neck, including thyroidectomy. Given the increased difficulty, scarring and aberrant anatomy sometimes associated with revision anterior cervical surgery, we extrapolate from the available literature that monitoring of the recurrent laryngeal nerve may increase patient safety in these revision situations. Thus, each case and use of monitoring would be up to the surgeons’ discretion.

5. Is there any evidence missing from the attached draft review of evidence?

<table>
<thead>
<tr>
<th>No.</th>
<th>Yes/No</th>
<th>Citations of Missing Evidence</th>
</tr>
</thead>
</table>
| 1   | Yes   | In 2010 Fehlings et al offered a systematic review of the literature on IOM recordings during spinal surgery. They screened 103 articles and reviewed 32 that met rigid inclusion criteria. The authors concluded that “high level” medical evidence supports the use of IOM as a sensitive and specific means to monitor spinal cord function and integrity and to detect intraoperative neurological injury during spinal surgery. (Fehlings MG, Brodke DS, Norvell DC, et al. The evidence for intraoperative neurophysiological monitoring in spine surgery: does it make a difference? Spine (Phil Pa 1976). 2010 Apr;35(9 Suppl):S37-46. PMID: 20405850.)
|     |       | Retrospective review of 427 cervical spine procedures for broad-spectrum pathology monitored with SSEP and TcMEP, comparing both modalities to neurological outcome. I TcMEP sensitivity and specificity were 100%. SSEP was 100% specific but only 25% sensitive. TcMEPs superior to SSEPs to detect motor tract deficits. Eggspuehler et al, Eur Spine J, 2007 (Eggspeuehler A, Sutter MA, Grob D, et al. Multimodal intraoperative monitoring (MIOM) during cervical spine surgical procedures in 246 patients. Eur Spine J. 2007 Nov;16 Suppl 2:S209-15. PMID: 17610090.)
|     |       | Retrospective series of 52 consecutive patients undergoing surgery for cervical myelopathy with SSEP and TcMEP monitoring. I/I TcMEP sensitivity and specificity were 100% and 90% vs. 0% and 100% for SSEP. TcMEP positive predictive value was 17% (ie, five of six alerts were false positive). Class I: TcMEPs superior to SSEP. Class II: Limited to small CSM population.

|     |       | Krisikovich MD, Apfelbaum RI, Haller JR. Vocal fold paralysis after anterior cervical spine surgery: incidence, mechanism, and prevention of injury. Laryngoscope. 2000 Sep; 110(9):1467-73. PMID: 10983944