02.01.15 Surface Electromyography (sEMG)

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Related Policies:

02.01.21 Temporomandibular Joint (TMJ) Dysfunction: Diagnosis and Treatments

Summary

Description

Note: This medical policy covers surface electromyography (sEMG) for neuromuscular disorders, seizure disorders, and to evaluate abnormal patterns of electrical activity in the paraspinal muscles.

A noninvasive procedure that records the summation of muscle electrical activity, paraspinal surface electromyography (sEMG) has been investigated as a technique to evaluate the physiologic functioning of the back. sEMG technologies have been studied as a complement or potential alternative to needle electromyography (nEMG) and nerve condition studies (NCS) for the investigation of many conditions including but not limited to, neuromuscular disorders, seizure disorders and evaluate abnormal patterns of electrical activity in the paraspinal muscles in patients with back pain symptoms such as spasm,

tenderness, limited range of motion, or postural disorders. The sEMG recording techniques vary significantly, but all involve analysis of myoelectrical signals using sensors positioned on the skin surface.

Paraspinal surface electromyography (sEMG) is also referred to as paraspinal EMG scanning. Surface electromyography (sEMG)is also referred to as surface scanning EMG (dynamic sEMG/static sEMG)

Summary of Evidence

Neuromuscular Disorders

For individuals who receive paraspinal surface electromyography (sEMG) for evaluation and/or monitoring of neuromuscular disorders and abnormal patterns of electrical activity in the paraspinal muscles for any indication the evidence includes several nonrandomized studies on using findings to classify back pain. Relevant outcomes are test accuracy and validity, symptoms, functional outcomes, quality of life, and resource utilization. There have been no studies directly comparing sEMG with other noninvasive techniques for evaluating back pain, and standard criteria for normal and abnormal sEMG measurements have not been determined. Surface electromyography has been proposed as a noninvasive technique providing objective measurements that would inform treatment decisions in patients with back pain. While studies have shown that sEMG results have detected different pathologies in patients with back pain, none of the studies reported health outcomes. There are also no data on the impact of sEMG for managing back pain. Therefore, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

All Other Disorders

For individual using any type of surface electromyography (sEMG), including but not limited to high density surface electromyography (HD-sEMG), for all other disorders the evidence includes 1 systematic review, randomized controlled trial (RCTs). Relevant outcomes are test accuracy and validity, symptoms, functional outcomes, quality of life, and resource utilization. It is unclear as to how using sEMG monitoring for generalized tonic-clonic seizures (GTCS) would impact the management and treatment outcome. It is also unclear if the test performance of surface electromyography (sEMG) monitoring of conditions in an ambulatory or home setting would be similar to the results obtained the inpatient settings. Studies also identified a high false alarm rate for users of sEMG for seizures. Additional randomized, well powered trials demonstrating the clinical utility of the device are needed. The diagnostic utility is unknown and the role in an individual's management has not been established. Further well-designed clinical trials are needed to standardize sEMG approaches and diagnostic algorithms, increase diagnostic performance and to assess the role of sEMG in clinical practice. The evidence is insufficient to determine the effects of this technology on net health outcomes.

OBJECTIVE

The objective of this evidence review is to determine in individuals who have a condition, pain (i.e., muscle, joint, or disc disease), and/or symptom(s) whether the use of surface electromyography improves the net health outcome.

PRIOR APPROVAL

Not applicable.

POLICY

Surface electromyography is considered **investigational** for all indications because the evidence is insufficient to determine the effects of the technology on net health outcomes.

POLICY GUIDELINES

Coding

See the Codes table for details.

BACKGROUND

Surface Electromyography (sEMG)

Surface electromyography (sEMG) is also referred to as surface scanning EMG, is a non-invasive, computer-based technique that records the electrical impulses using electrodes placed on the surface of the skin overlying the nerve at rest (i.e., static) and during activity (i.e., dynamic). The procedure studies the topography of the motor unit action potential (MUAP) and is assessed by computer analysis of the frequency spectrum, amplitude, or root mean square of the electrical action potential. The sEMG differs from needle electromyography (nEMG) with respect to technical requirements and electrical properties. sEMG electrodes measure from a wide area of muscle, have a relatively narrow frequency band (range 20 to 500 Hz), have a low-signal resolution, and are highly susceptible to movement artifact. The proposed use for this type of EMG is to aid in the diagnosis of neuromuscular disorders and low back pain, and to aid in assessing the prognosis of disorders involving muscle lesions. The technology has also been used to monitor bruxism (i.e., grinding and clenching of teeth). The electrical activity of muscle may be recorded with surface EMG, although spontaneous electrical activity and voluntary motor units cannot be.

High Density Surface Electromyography (HD-sEMG)

High-density surface electromyography (HD-sEMG) is a non-invasive technique to measure electrical muscle activity with multiple (more than 2) closely spaced electrodes overlying a restricted area of the skin. Besides temporal activity, HD-sEMG also allows spatial EMG activity to be recorded, thus expanding the possibilities to detect new muscle characteristics. Muscle fiber conduction velocity (MFCV) measurements and the evaluation of single motor unit (MU) characteristics come into view. In principle, HD-sEMG allows pathological changes at the MU level to be detected, especially changes in neurogenic disorders and channelopathies.

Paraspinal Surface Electromyography (sEMG)

Back pain is a common condition that affects most individuals at some point in their lives. Identifying the pathogenesis of back pain is challenging, in part due to the complex anatomy of the back, which includes vertebrae, intervertebral discs, facet joints, spinal nerve roots, and numerous muscles. Back pain may be related to osteoarthritis, disc disease, subluxation, or muscular pathologies, such as muscle strain or spasm. Moreover, due to referred pain patterns, the location of the pain may not be anatomically related to the pathogenesis of the pain. For example, buttock or leg pain may be related to pathology in the spine. In addition to the diagnostic challenges of back pain is the natural history of acute back pain.

Diagnosis

Aside from physical examination, diagnostic testing includes imaging technologies, such as magnetic resonance imaging, designed to identify pathology (e.g., bulging discs), or tests such as discography to localize the abnormality by reproducing the pain syndrome. However, these tests lack specificity and must be carefully interpreted in the context of the clinical picture. For example, magnetic resonance imaging

identifies 5% of asymptomatic patients as having bulging discs. However, the presence of a bulging disc may only be clinically significant if correlated with other symptoms. Assessment of the musculature may focus on a range of motion or strength exercises.

In contrast to anatomic imaging, surface electromyography (SEMG), which records the summation of muscle activity from groups of muscles, has been investigated as a technique to evaluate the physiologic functioning of the back. A noninvasive procedure, SEMG differs from needle electromyography, an invasive procedure in which the electrical activity of individual muscles is recorded. Paraspinal SEMG has been explored to evaluate abnormal patterns of electrical activity in the paraspinal muscles in patients with back pain symptoms such as spasm, tenderness, limited range of motion, or postural disorders. The technique is performed using a single or an array of electrodes placed on the skin surface, with recordings made at rest, in various positions, or after a series of exercises. Recordings can also be made by using a handheld device, which is applied to the skin at different sites. Electrical activity is assessed by computer analysis of the frequency spectrum (i.e., spectral analysis), amplitude, or root mean square of the electrical action potentials. In particular, a spectral analysis that focuses on the median frequency has been used to assess paraspinal muscle fatigue during isometric endurance exercises. Paraspinal SEMG has been researched as a technique to establish the etiology of back pain and has been used to monitor the response to therapy and establish physical activity limits, such as assessing capacity to lift heavy objects or ability to return to work.

Paraspinal surface EMG (SEMG) is an office-based procedure. The following clinical applications of the paraspinal sEMG have been proposed:

- Clarification of a diagnosis (i.e., muscle, joint or disc disease)
- Selection of a course of medical therapy
- Selection of a type of physical therapy
- Preoperative evaluation
- Postoperative rehabilitation
- Follow up of acute low back pain (LBP)
- Evaluation of exacerbation of chronicLBP
- Evaluation of pain management treatment techniques

Treatment

Most cases of acute LBP resolve with conservative therapy (e.g., physical therapy) while continuing normal activities within limits permitted by the pain. Therefore, initial imaging or other diagnostic testing is generally not recommended unless "red flag" warning signs are present, or the pain persists for more than 4 to 6 weeks. Red flag findings include significant trauma, history of cancer, unrelenting night pain, fevers or chills, and progressive motor or sensory deficits.

Seizure Monitoring Surface Electromyography (sEMG)

Surface electromyography (sEMG) devices have been proposed as an adjunct in recording and storing data for characterization of seizure events in the home during periods of rest. The sEMG device is placed on the belly of the biceps muscle of an individual. An alarm alerts the caregivers when the device detects signal patterns associated with unilateral, appendicular, tonic extension that is potentially related to a generalized tonic-clonic seizures (GTCS).

Regulatory Status

Neuromuscular Disorders

Surface electromyography devices approved by the U.S. Food and Drug Administration (FDA) include those that use a single electrode or a fixed array of multiple surface electrodes. Examples include the CMAP Pro (Medical Technologies) and Model 9200 EMG System (Myotronics-Noromed).

Several FDA approved devices combine sEMG along the spine with other types of monitors. For example, in 2007, the Insight Discovery (Fasstech) was cleared for marketing through the 510(k) process. The device contains 6 sensor types, 1 of which is for sEMG. The indications include measuring bilateral differences insEMG along the spine and measuring sEMG along the spine during functional tasks. (Earlier Insight models had fewer sensors.) FDA product code: IKN.

Please note, the regulatory status section is not intended to be all inclusive.

Seizure

sEMG devices have been proposed as an adjunct in recording and storing data for characterization of seizure events in the home or healthcare facilities during periods of rest. The sEMG device is placed on the belly of the biceps muscle of an individual. An alarm alerts caregivers when the device detects signal patterns associated with unilateral, appendicular, tonic extension that is potentially related to a GTCS. While continuing to record sEMG data for future review, the alarms can be turned off by a physician order (U.S. Food and Drug Administration, 2019).

The U.S. Food and Drug Administration (FDA) cleared the SPEAC System (Brain Sentinel, Inc., San Antonio, TX), formerly known as the Brain Sentinel Monitoring and Alerting System (Predicate), through the 510(k) premarket approval process on May 11, 2019, as an adjunct to seizure monitoring in adults in the home or healthcare facilities during periods of rest. The SPEAC System Traditional 510(k) Summary lists several warnings and limitations, including (FDA, 2019):

- The System should not be used as a standalone monitor for monitoring seizures and is not intended to be used during physical activity.
- The System alarms are not for standalone use and should not be used to guide medical therapy decisions.
- The System has not been demonstrated to affect any clinical outcome such as status epilepticus, brain damage, or death following a GTC seizure.
- The System does not predict sEMG signals that may be associated with GTC seizures.
- The device provides an alert following the onset of sEMG activity that may be associated with a GTC seizure.
- The System does not predict seizure onset.
- The safety and effectiveness of the System has not been established in pediatric populations.
- The safety and effectiveness of the SPEAC System has not been established in monitoring sEMG signals that may be associated with seizures other than the GTC seizure.

New features in the SPEAC System compared to the Brain Sentinel Monitoring and Alerting System include an increase in the surface area of the electrode patch and a feature for the physician to turn off alarms while still recording data. Currently, there are no other FDA cleared sEMG devices for seizure monitoring.

Please note, the regulatory status section is not intended to be all inclusive.

RATIONALE

This evidence review was created in September 2010 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 2025.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Paraspinal Surface Electromyography (sEMG)

Paraspinal surface electromyography (sEMG) has been used as a research tool to evaluate the performance of paraspinal muscles in individuals with back pain and to further understand the etiology of low back pain (LBP). Preliminary research has also been performed to determine which sEMG parameters best differentiate individuals with and without back pain..

Clinical Context and Test Purpose

The purpose of paraspinal SEMG in individuals who have back pain is to identify the pathogenesis of the pain (i.e., muscle, joint, or disc disease) to inform a decision on a treatment plan.

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

Populations

The relevant population of interest is individuals with back pain.

Interventions

Paraspinal sEMG is a noninvasive technique that aggregates data on muscle activity from groups of muscles. One or more electrodes are placed on the skin surface, and recordings are taken at rest, in various positions, or during a series of exercises.

Comparators

Other noninvasive techniques to assess back pain include clinical examination and imaging technologies.

Outcomes

The general outcomes of interest are a reduction in back pain and improvement in activities of daily living.

Both false-positive test results and false-negative results can lead to an incorrect recommendation for the type of treatment or no treatment at all. Some treatments are long-term programs, and if individuals are incorrectly referred to the program, more appropriate therapy will be delayed.

Study Selection Criteria

For the evaluation of clinical validity of the paraspinal sEMG test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;

- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.
- Studies with duplicative or overlapping populations were excluded.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
In December of 2005 Hayes a symplr company, completed a Health Technology Assessment which was last reviewed in March 2010 on surface electromyography for evaluation of low back pain. For the investigation of chronic or intermittent/recurrent low back pain without underlying pathology the assessment rated the testing a D. A D rating indicates, “no proven benefit. Published evidence shows that the technology does not improve health outcomes or patient management for the reviewed application(s) or is unsafe. There is insufficient published evidence to assess the safety and/or impact on health outcomes or patient management."

No articles that directly compare the results of sEMG (which tests groups of muscles) with needle electromyography (which tests individual muscles) for diagnosing any specific muscle pathology were identified in literature searches. However, the pathology of individual muscles (i.e., radiculopathy, neuropathy) may represent a different process than the pathology of muscle groups (i.e., muscle strain, spasm), and thus sEMG may be considered by its advocates as a unique test for which there is currently no criterion standard. Nevertheless, even if one accepts this premise, there are inadequate data to evaluate the diagnostic performance of sEMG. In some instances, the asymmetrical electrical activity may have been used to define abnormality; results may be compared with normative data. However, no published literature was identified defining what degree of asymmetry would constitute abnormality.

A study by du Rose and Breen (2016) looked into the relationship between lumbar intervertebral range of motion and paraspinal muscle activity in healthy adults, as measured by sEMG and quantitative fluoroscopy, to establish "normal" measurements. Fluoroscopic images and sEMG measurements were taken for 20 men with no history of LBP. What would be considered normal intervertebral ranges of motion were related to a diverse set of muscle activation patterns as measured by sEMG. The authors concluded that larger sample sizes and measurements from patients with LBP would be needed to established standard criterion.

Absent a criterion standard diagnostic test, correlation with the clinical symptoms and physical exam is critical. De Luca (1993) published a series of studies investigating a type of sEMG called the Back Analysis System, consisting of surface electrodes and other components to measure the electrical activity of muscles during isometric exercises designed to produce muscle fatigue. Using physical exam and clinical history as a criterion standard, De Luca (1993) found that the Back Analysis System accurately identified control and back pain patients 84% and 91% of the time, respectively, with the values increasing to 100% in some populations. Accuracy was defined as the sum of true-positive and true-negative results. However, these studies were not designed as a clinical diagnostic tool per se but were intended to investigate the etiology of back pain and to investigate muscular fatigue patterns in patients with and without back pain.

Hu et al (2014, 2010) published two articles on dynamic topography, an approach to analyzing sEMG findings. Both studies included patients with LBP and healthy controls. All participants underwent SEMG at study enrollment and then back pain patients participated in a rehabilitation program. The first study found different dynamic topography at baseline between the healthy people and back pain samples (a

more symmetric pattern in healthy controls). After physical therapy, the dynamic topography images of back pain patients were more similar to the healthy controls on some of the parameters assessed. In the second study, following rehabilitation, back pain patients were classified as responders or nonresponders based on changes in back pain severity. Some associations were found between baseline sEMG parameters and response to rehabilitation. sEMG was not repeated after the rehabilitation program, and thus it is unclear whether there are any significant associations between continued symptoms and sEMG abnormalities. Moreover, it is unclear how sEMG analysis would affect treatment decisions for individuals with low back pain.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

A number of studies have described sEMG as an aid in classifying low back pain (LBP) Most of this research has focused on the use of sEMG to assess muscle fatigability rather than on how information from test findings could enhance an individual's management. While sEMG may be used to document muscle spasm or other muscular abnormalities objectively, it is unclear how such objective documentation would supplant or enhance clinical evaluation, or how this information would be used to alter the treatment plan. In part, the difficulty in clinical interpretation is understanding the extent to which the sEMG abnormalities are primary or secondary. Additionally, as noted in the Background section, no specific workup is recommended for acute LBP without warning signs.

The following studies have proposed using sEMG results to inform treatment decisions; however, none provided data to validate whether treatment based on sEMG results in improved outcomes.

Qiao et al (2019) completed a study on the paraspinal muscle surface electromyography in acute nonspecific lower back pain. Aim of this study was to determine if surface electromyography (sEMG) could provide objective data in monitoring the alteration of signal amplitude of myoelectric activity of the paraspinal muscles in the patients with acute nonspecific lower back pain (ANLBP), and to explore the correlation between sEMG data and symptom relief in the ANLBP patients before and after massage therapy. Forty-five ANLBP patients and 20 healthy subjects were enrolled into this study. Patients were given massage therapy for 1 week. The average electromyography (AEMG), visual analogue scale (VAS), and distance of finger to floor (DFTF) were measured before and after treatment. AEMG at flexion and maintained flexion positions were significantly higher in the ANLBP group compared to that in the control group. At extension position, in contrast, AEMG was significantly lower in the ANLBP patients than that of control group, and there was no significant difference between the 2 groups at upright position. After massage therapy for the ANLBP patients, AEMG was significantly reduced at flexion and maintained flexion positions, but significantly increased at extension position than that before treatment. VAS and DFTF were also significantly reduced after treatment. In addition, AEMG alteration at maintained flexion position was significantly correlated with improvement of VAS or DFTF.

Myoelectric activity of the paraspinal muscles in the ANLBP patients was different from that of healthy subjects. Massage therapy not only relived patients' symptoms, but also normalized myoelectric activity of

the paraspinal muscles in the ANLBP patients. In contrast, the paraspinal muscle activity and myoelectric signal was smaller at extension, and thus, AEMG amplitude was decreased during extension. After 1-week massage therapy, symptoms were remarkably relieved and lower back function was recovered, which was reflected by the normalized AEMG signal of the paraspinal muscles and positive correlation between the symptom relief and AEMG signal change. Taken together, the present study demonstrated that sEMG could objectively reflect lower back muscle activity, massage was effective for the treatment of ANLBP, and sEMG could be used for diagnosis of lower back tissue injury as well as for monitoring the recovery of the injury.

Schabrun et al (2017) completed a study of individuals with LBP (n=27) and pain-free controls (n=23) by sEMG detected a loss of discrete motor cortical organization of the paraspinal muscles among those with LBP. The invasive technique of needle electromyography is usually performed to detect this pathology. Patients with cortical reorganization may benefit from motor skill training.

Kienbacher et al (2016) noted in a study of patients with chronic LBP (N=216) by sEMG showed potential to discriminate between impaired and unimpaired neuromuscular regulation of back extensors, which would provide useful information for designing individualized exercise programs.

In 2 older studies (1988, 1992), SEMG was shown to differentiate muscle spasm from muscle contracture. Muscle spasm would be treated with relaxation therapy, and contracture would be treated with stretching exercises.

Chain of Evidence: Paraspinal Surface Electromyography (sEMG)

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Current evidence on clinical validity does not permit construction of a chain of evidence to support the use of sEMG as a diagnostic tool for evaluating and monitoring back pain.

Section Summary: Paraspinal Surface Electromyography (sEMG)

No studies were identified that were adequately powered that have directly evaluated whether using sEMG to determine evaluation and/or monitoring the paraspinal muscles improves the health outcomes such as change in symptoms and improvement in activities of daily living. The diagnostic utility is unknown and the role in an individual's management has not been established. Further well-designed clinical trials are needed to standardize sEMG approaches and diagnostic algorithms, increase diagnostic performance and to assess the role of sEMG in clinical practice.

High Density-Surface Electromyography (HD-sEMG)

Clinical Context and Test Purpose

The purpose of a high-density surface electromyography (HD-sEMG) is a non-invasive technique to measure electrical muscle activity with multiple (more than 2) closely spaced electrodes overlying a restricted area of the skin. Besides temporal activity, HD-sEMG also allows spatial EMG activity to be recorded, thus expanding the possibilities to detect new muscle characteristics thus providing further information to aid in a decision on a treatment plan.

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

Populations
The relevant population of interest is individuals where the identification of movement intention and its strength is needed.

Interventions
sEMG is a noninvasive technique that aggregates data on muscle activity from groups of muscles. Multiple closely spaced electrodes are placed on the skin surface, especially muscle fiber conduction velocity (MFCV) measurements and the evaluation of single motor unit (MU) characteristics come into view.

Comparators
Other noninvasive techniques to assess an individual include but are not limited to clinical examination and imaging technologies.

Outcomes
The general outcomes of interest are a reduction in symptoms and improvement in activities of daily living and change in morbid events.

Both false-positive test results and false-negative results can lead to an incorrect recommendation for the type of treatment or no treatment at all. Some treatments are long-term programs, and if individuals are incorrectly referred to the program, more appropriate therapy will be delayed.

Study Selection Criteria
For the evaluation of clinical validity of the paraspinal SEMG test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described;
- Studies with duplicative or overlapping populations were excluded.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Review of Evidence
No studies examining clinical utility or clinical validity of HD-SEMG were identified.

Section Summary: High Density-Surface Electromyography (HD-sEMG)
No studies were identified that were adequately powered that have directly evaluated whether using HD-sEMG to determine evaluation and/or monitoring improves the health outcomes such as change in symptoms and improvement in activities of daily living, or a decrease in morbid events. Additionally, it is

not possible to construct a chain of evidence for clinical utility due to the lack of evidence on clinical validity.

Miscellaneous Conditions

Neuromuscular Surface Electromyography (sEMG)

Clinical Context and Test Purpose

The purpose of paraspinal sEMG in individuals who have neuromuscular conditions is to detect and characterize the condition to inform a decision on a treatment plan.

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

Populations

The relevant population of interest is individuals with neuromuscular conditions.

Interventions

Neuromuscular sEMG is a noninvasive technique that aggregates data on muscle activity from groups of muscles. One or more electrodes are placed on the skin surface, and recordings are taken.

Comparators

Other techniques to assess seizures include clinical examination and imaging technologies.

Outcomes

The general outcomes of interest are improvement in activities of daily living and change in morbid events.

Both false-positive test results and false-negative results can lead to an incorrect recommendation for the type of treatment or no treatment at all. Some treatments are long-term programs, and if individuals are incorrectly diagnosed/managed, more appropriate therapy will be delayed.

Study Selection Criteria

For the evaluation of clinical validity of the paraspinal SEMG test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.
- Studies with duplicative or overlapping populations were excluded.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Review of Evidence

Meekins et al (2008) published a systematic review on the use of surface electromyography in the diagnosis and study of neuromuscular disorders on behalf of the AANEM. From a search of Medline and PubMed from January 1994 to February 2006 that identified 5682 abstracts, 21 articles were evaluated. The AAN classification for diagnostic articles was used to rate the strength of evidence for each article. Based on their systematic review, author conclusions are as follows:

- On the basis of two class III studies, sEMG may be useful to detect the presence of neuromuscular disease (Level C: possibly effective, ineffective or harmful for the given condition in the specified population)
- The data are insufficient to determine the clinical utility of sEMG for distinguishing between neuropathic and myopathic conditions or for detecting the more specific neuromuscular conditions of post-poliomyelitis syndrome, pathologic fasciculations, acquired demyelinating peripheral neuropathy, amyotrophic lateral sclerosis, myotonic dystrophy, and hypokalemic periodic paralysis (Level U: data inadequate or conflicting given current knowledge, treatment is unproven)
- The data are insufficient to address the question of disease severity detectable by sEMG (Level U: data inadequate or conflicting given current knowledge, treatment is unproven)
- The data are insufficient to compare diagnostic utility of sEMG with the conventional technologies of nEMG, NCS and muscle ultrasonography (Level U: data inadequate or conflicting given current knowledge, treatment is unproven)

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse). Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

There have been a limited number of clinical validity studies in the peer-reviewed medical literature addressing the use of surface electromyography (sEMG) devices for neuromuscular monitoring. Due to insufficient evidence of clinical validity, no inferences can be drawn about the clinical utility of seizure monitoring using sEMG.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No evidence is available from randomized or nonrandomized controlled studies in which outcomes from groups of well-matched individuals managed using neuromuscular monitoring with sEMG were compared with those managed without.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Current evidence on clinical validity does not permit construction of a chain of evidence to support the use of sEMG as a diagnostic tool for evaluating and monitoring neuromuscular conditions.

Section Summary: Neuromuscular Surface Electromyography (sEMG)

No studies were identified that were adequately powered that have directly evaluated whether using sEMG to determine evaluation and/or monitoring neuromuscular conditions improves the health outcomes such as change in symptoms and improvement in activities of daily living. The diagnostic utility is unknown and the role in an individual's management has not been established. Further well-designed clinical trials are needed to standardize sEMG approaches and diagnostic algorithms, increase diagnostic performance and to assess the role of sEMG in clinical practice.

Seizure Monitoring Surface Electromyography (sEMG)

Clinical Context and Test Purpose

The purpose of paraspinal sEMG in individuals who have seizures is to detect and characterize the seizure to inform a decision on a treatment plan.

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

Populations

The relevant population of interest is individuals with seizures.

Interventions

Seizure sEMG is a noninvasive technique that aggregates data on muscle activity from groups of muscles. One or more electrodes are placed on the skin surface, and recordings are taken.

Comparators

Other techniques to assess seizures include clinical examination, imaging technologies such as electroencephalograph (EEG), magnetoencephalography (MEG), and functional magnetic resonance imaging (fMRI)

Outcomes

The general outcomes of interest are improvement in activities of daily living and change in morbid events.

Both false-positive test results and false-negative results can lead to an incorrect recommendation for the type of treatment or no treatment at all. Some treatments are long-term programs, and if individuals are incorrectly diagnosed/managed, more appropriate therapy will be delayed.

Study Selection Criteria

For the evaluation of clinical validity of the paraspinal SEMG test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard;
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Clinical Validity Studies

Beniczky et al (2018) reported on the results of a prospective, multicenter study that evaluated the accuracy of surface electromyography (sEMG) device in the detection of generalized tonic-clonic seizures (GTCS) in 71 individuals at 3 centers between October 2014 and January 2017. Individuals underwent video EEG (vEEG) monitoring as a comparison for the sEMG device and results were reviewed by three clinical neurophysiologists and epileptologists who were blinded to all sEMG device data until the analysis of the vEEG recordings was completed. The data showed that 20 (28%) individuals had at least 1 GTCS with a total of 32 GTCS. The sensitivity of the sEMG device, defined as the percentage of GTCS detected, was 93.8% (30 out of 32 GTCS) (95% CI, 86%-100%). The specificity of the sEMG device, defined as the false alarm rate (FAR), was 0.67 per day. There was a total of 161 seizures other than GTCS that were identified in the vEEG recordings. Large field studies, with long-term, ambulatory use of the device, are necessary to evaluate its potential in reducing the number of seizure-related injuries and ultimately the number of sudden unexpected death in epilepsy (SUDEP).

Halford et al (2017) published a prospective, multicenter, phase III trial that investigated a surface electromyography (sEMG) monitoring system for the detection of generalized tonic-clonic seizures (GTCS). In 11 epilepsy centers, 199 individuals were monitored for GTCS by the sEMG seizure monitoring system between August 2013 and December 2015; however, 50 (25%) individuals did not have proper placement of the sEMG device or had technical issues, such as sEMG data not being archived for reprocessing, but were still included in the trial. There were 29 (15%) individuals who withdrew from the trial early; however, the sEMG data recorded prior to withdrawal was included in the final data analysis. Three video EEG (vEGG) reviewers, who were not study site investigators, evaluated system detections and GTCS identified by clinical care providers. Using a majority rules approach, the data was independently adjudicated by the vEEG reviewers, who were blinded to system detections and sEMG recordings. Results showed that 37 (19%) of the individuals had at least one GTCS with a total of 46 GTCS identified with vEEG. The sEMG device detected 35 of the 46 GTCS (76%; 95% CI, 0.65-1.0) with a mean false alarm rate (FAR) of 2.5 per 24 hours. For data recorded while the device was appropriately positioned over the midline of the biceps muscle, the test system detected 29 of 29 GTCS (100%; 95% CI, 0.88-1.00) with a mean false alarm rate (FAR) of 1.44 per 24 hours. However, FAR for those properly wearing the device varied between 0 and 10 per 24 hours. The results of this small validation study are promising but challenged by a high false alarm rate for many of the users.

A prospective, single center, phase II study was published in 2015 by Szabó et al aimed to validate the sensitivity, specificity, and latency of a seizure-detection algorithm for the analysis of sEMG signals using inpatient vEEG monitoring as the comparator. Between November 2011 and December 2012, 36 individuals with medically refractory epilepsy and a history of GTCS were admitted to the epilepsy monitoring unit, enrolled in the study, and had concurrent sEMG recording and vEEG monitoring. vEEG recordings were independently reviewed and analyzed by at least two epileptologists. The sEMG signal recordings were analyzed offline using a frequency-based, automated algorithm. If a GTCS was identified, by the algorithm, within 60 seconds of the video-EEG onset, it was considered a true positive. If a GTCS was not identified, and EMG was actively being recorded during the GTCS, the event was considered a false negative. The time of onset of motor symptoms associated with GTCS observed by video-EEG analysis was correlated with the time of seizure detection by sEMG. ”In 1,399 h of continuous recording, there were 196 epileptic seizures (21 GTCS, 96 myoclonic, 28 tonic, 12 absence, and 42 focal seizures with or without loss of awareness) and 4 nonepileptic spells. During retrospective, offline evaluation of sEMG from the biceps alone, the algorithm detected 20 GTCS (95%) in 11 patients, averaging within 20 s of electroclinical onset of generalized tonic activity, as identified by video-EEG monitoring. Only one false-positive detection occurred during the postictal period following a GTCS, but

false alarms were not triggered by other seizure types or spells. Further studies are needed in larger patient groups, including children, especially in the outpatient setting."

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if individuals receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse). Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

There have been a limited number of clinical validity studies in the peer-reviewed medical literature addressing the use of surface electromyography (sEMG) devices for seizure monitoring. Due to insufficient evidence of clinical validity, no inferences can be drawn about the clinical utility of seizure monitoring using sEMG.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for individuals managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs.

No evidence is available from randomized or nonrandomized controlled studies in which outcomes from groups of well-matched individuals managed using seizure monitoring sEMG were compared with those managed without.

Chain of Evidence

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse). Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Due to insufficient evidence of clinical validity, no inferences can be drawn about the clinical utility of seizure monitoring with sEMG.

Section Summary: Surface Electromyography (sEMG) for Seizure Monitoring

Studies identified a high false alarm rate for users of sEMG for seizures. No studies were identified that determined utilizing sEMG for evaluation and/or monitoring of seizures improves the health outcomes such as change in symptoms and improvement in activities of daily living, or a decrease in morbid events.

SUPPLEMENTAL INFORMATION

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

Practice Guidelines and Position Statements

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

American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)

In 2008, the AANEM provided an Evidenced Based Review: Use of Surface Electromyography in in the Diagnosis and Study of Neuromuscular Disorders. Author conclusions regarding the added value of sEMG in the study of neuromuscular disease are as follow:

1. "sEMG may be useful in adding information in the study of fatigue in post-poliomyelitis syndrome and electromechanical coupling dysfunction in myotonic dystrophy on the basis of two class III studies each (level C rating).
2. The data are insufficient to determine the added value of sEMG myoelectric signal changes in the study of fatigue in myophosphorylase deficiency, muscle fiber and motor unit propagation in myotonia congenita and hypokalemic periodic paralysis, or in evaluation of disease progression in myotonic dystrophy and Charcot–Marie–Tooth disease (level U rating)."

American College of Occupational and Environmental Medicine (ACOEM)

In 2019, the guideline from the American College of Occupational and Environmental Medicine on diagnostic tests for low back disorders does not recommend surface electromyography as a technique for diagnosing low back disorders, based on insufficient evidence of efficacy.

North American Spine Society (NASS) and American Academy of Pain Medicine (AAPM)

In 2020, the North American Spine Society with input from the American Academy of Pain Medicine issued a guideline on the diagnosis and treatment of low back pain. When discussing the diagnostic accuracy of nonimaging tests, the guideline lacks any statement on surface electromyography.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review can be located at clinicaltrials.gov.

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CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	96002	Dynamic surface electromyography, during walking or other functional activities 1-12 muscles
HCPCS		
	S3900	Surface electromyography (EMG)
Type of Service	Medicine	
Place of Service	Outpatient/ Inpatient	

POLICY HISTORY

Date	Reason	Action
August 2025	Annual Review	Policy Renewed
August 2024	Annual Review	Policy Revised
August 2023	Annual Review	Policy Revised
June 2022	Annual Review	Policy Revised
June 2021	Annual Review	Policy Revised
June 2020	Annual Review	Policy Renewed
June 2019	Annual Review	Policy Renewed
June 2018	Annual Review	Policy Renewed
June 2017	Annual Review	Policy Renewed
November 2016	Interim Review	Policy Revised
June 2016	Annual Review	Policy Revised
July 2015	Annual Review	Policy Revised
July 2014	Annual Review	Policy Renewed
September 2013	Annual Review	Policy Renewed
October 2012	Annual Review	Policy Renewed
October 2011	Annual Review	Policy Renewed
September 2010	Annual Review	Policy Renewed

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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