Surface Electromyography (sEMG)

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DESCRIPTION

Note: This medical policy covers Surface Electromyography (sEMG) for Neuromuscular Disorders and to Evaluate Abnormal Patterns of Electrical Activity in the Paraspinal Muscles.

Surface electromyography (sEMG) technologies have been studied as a complement or potential alternative to needle electromyography (nEMG) and nerve condition studies (NCS) for the investigation of neuromuscular 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.

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. The clinical utility of surface EMG has not been proven in the peer-reviewed medical literature.

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. The clinical effectiveness of HD-sEMG has not been established; well- designed studies are needed to ascertain the clinical utility of HD-sEMG.

Clinical Context and Test Purpose
The purpose of paraspinal sEMG in individual who have a condition, pain, and/or symptom(s) is to identify the pathogenesis and to inform a decision on a treatment plan.

The question addressed in this evidence review is: Does the net health outcome in individuals improve who have a condition, pain and/or symptom(s) where sEMG could provide 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 improve who have a condition, pain and/or symptom(s) where sEMG could provide information to aid in a decision on a treatment plan.

Interventions
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 or a period of rest.

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.

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.

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, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Paraspinal Surface Electromyography (sEMG)
The difficulty in identifying the source of pathology for most low back pain disorders has led researchers to develop new technology to help in the diagnosis of low back pain. Assessment approaches based on paraspinal sEMG signal techniques have been proposed to overcome some of the problems identified in other technologies. The concept is to measure and identify the presence of abnormal muscle functioning in a manner that will suggest a form of treatment.

Paraspinal sEMG, also referred to as paraspinal EMG scanning, has been investigated as a method of assessing the paraspinal muscles of individuals with back pain which provide support to the spinal column and to further understand the etiology of low back pain (LBP). Impairment of the paraspinal muscles may lead to abnormal motion and pain. The paraspinal sEMG is performed using a single electrode or an array of electrodes placed on the skin surface with recordings that are typically made at rest, in various positions or after physical activity.

Paraspinal surface EMG (SEMG) is an office-based procedure that may be most commonly used by physiatrists or chiropractors. 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
- Evaluation of exacerbation of chronic low back pain
- Evaluation of pain management treatment techniques

Preliminary research has been performed to determine which sEMG parameters best differentiate individuals with and without back pain. The diagnostic utility of paraspinal sEMG is not known, and its role in patient management has not been established

Review of Evidence: Paraspinal Surface Electromyography (sEMG)
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.

(2016) A study by du Rose and Breen 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.

(2014, 2010) Hu et al. 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.

Direct Evidence: Paraspinal Surface Electromyography (sEMG)
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.

(2019) Qiao et al. 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.

(2017) Schabrun et al. 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.

(2016) Kienbacher et al. 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.

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.

Summary of Evidence: Paraspinal Surface Electromyography (sEMG)
For individuals who have back pain who receive paraspinal SEMG for evaluation and monitoring, 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. SEMG 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 is also no data on the impact of SEMG for managing individuals.

There is insufficient evidence in the medical literature to support the use of any type of surface electromyography (sEMG) as 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. Therefore, this testing is considered investigational for all indications.

Surface Electromyography (sEMG) for Seizure Monitoring
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).

There have been a limited number of studies in the peer-reviewed medical literature addressing the use of surface electromyography (sEMG) devices for seizure monitoring. Currently, there are no society guidelines that have published recommendations on the use of sEMG for this indication.

Review of Evidence: Surface Electromyography (sEMG) for Seizure Monitoring
(2018) Beniczky et al. 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).

(2017) Halford et al. 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.

Summary of Evidence: Surface Electromyography (sEMG) for Seizure Monitoring
Studies published to date are limited to studies performed in an inpatient setting. It is unclear if the test performance of surface electromyography (sEMG) monitoring of generalized tonic-clonic seizures (GTCS) in an ambulatory or home setting would be similar to the results obtained the inpatient settings. It is also unclear as to how using sEMG monitoring for GTCS would impact the management and treatment outcome (for example, seizure frequency, status epilepticus, aspiration, injury or death) of individuals with this disorder. Randomized, prospective comparative trials demonstrating the clinical utility of the device are needed. The evidence is insufficient to determine the effects of the technology on net health outcomes.

Practice Guidelines and Position Statements

American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) (2008) AANEM provided an Evidenced Based Review: Use of Surface Electromyography in the Diagnosis and Study of Neuromuscular Disorders which stated:

- 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)

Further research is necessary to determine the clinical utility of sEMG in the diagnosis of neuromuscular diseases and in the differentiation of primary myopathic and neuropathic conditions. (*Accessed May 2022*)

American College of Occupational and Environmental Medicine (ACOEM)
(2019) The American College of Occupational and Environmental Medicine (ACOEM) updated their practice guideline for diagnostic tests for low back disorders which states the following:

- Surface electromyography (sEMG) has been used to diagnose LBP and involves the recording of summated muscle electrical activity by skin electrodes (such as those used in an electrocardiogram or EKG). There are four moderate-quality studies incorporated into this analysis and no quality evidence of diagnostic efficacy, and thus, is not recommended to diagnose LBP (Not Recommended, Insufficient Evidence (I), High Confidence). (*Accessed May 2022*)

North American Spine Society (NASS) and American Academy of Pain Medicine (AAPM)
(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., the guideline lacks any statement on surface electromyography. (*Accessed May 2022*)

Regulatory Status

Neuromuscular Disorders
SEMG 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, one of which is for SEMG. The indications include measuring bilateral differences in SEMG along the spine and measuring SEMG along the spine during functional tasks.

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).
Please note, this section is not intended to be all inclusive.

Seizure
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, this section is not intended to be all inclusive.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies:
02.01.21 Temporomandibular Joint (TMJ) Dysfunction: Diagnosis and Treatments

Neuromuscular Disorders
Surface electromyography (sEMG), for the evaluation and monitoring of neuromuscular disorders and abnormal patterns of electrical activity in the paraspinal muscles for any indication is considered **investigational** to include but not limited to the following:

- High-density surface electromyography (HD-sEMG)
- Paraspinal surface electromyography (sEMG) also referred to as paraspinal EMG scanning
- Surface electromyography (sEMG) also referred to as surface scanning EMG (dynamic sEMG/static sEMG)

Seizure & All Other Indications
The use of surface electromyography (sEMG) devices for seizure monitoring and all other indications is considered **investigational** because the evidence is insufficient to determine the effects of the technology on net health outcomes.

There is insufficient evidence in the medical literature to support the use of any type of surface electromyography (sEMG) as the diagnostic utility is unknown and the role on how this testing affects patient 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.

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- S3900 Surface electromyography (EMG)
- 96002 Dynamic surface electromyography, during walking or other functional activities 1-12 muscles

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POLICY HISTORY

Date	Reason	Action
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		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
PO Box 9232
Des Moines, IA 50306-9232

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