Surface Electromyography (SEMG) Including Paraspinal SEMG

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Surface electromyography (SEMG) is a non-invasive, computer-based procedure, most commonly used in an office setting to assess muscle function by recording muscle activity from above the muscle on the skin surface.

MEDICAL POLICY CRITERIA

Note: This policy addresses only the use of surface electromyography alone or in combination with other services. See the Cross References below for additional gait analysis criteria not specifically addressed in this policy.

Dynamic surface electromyography (SEMG), including paraspinal SEMG, is considered **investigational** for all indications, including but not limited to diagnosing and monitoring of back pain, evaluation of myoclonus, and as a component of gait analysis.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Gait Analysis, Medicine, Policy No. 107

BACKGROUND

SEMG includes a scanner with surface electrodes that record electrical impulses of nerves at rest (i.e. static) and during activity (i.e. dynamic) in order to characterize the electrical potential of a specific muscle or group of muscles. Electrical activity can be assessed by computer analysis of the frequency spectrum (i.e., spectral analysis), amplitude, or root mean square of the electrical action potentials.

Unlike needle electromyography (NEMG), SEMG utilizes electrodes that record from a wide muscle area, have a relatively low frequency band, low signal resolution, and are highly susceptible to movement.[1] SEMG has been proposed as a diagnostic tool in patients with various degenerative, neuromuscular or motor control disorders such as: back pain, intervertebral disc disease, soft tissue injury, temporomandibular joint dysfunction (TMJ), bruxism (teeth grinding), nerve root irritation, and scoliosis.

PARASPINAL SEMG

Like SEMG, paraspinal SEMG is performed using a single or multiple 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. Spectral analysis focusing on the median frequency has been used to assess paraspinal muscle fatigue during isometric endurance exercises.

Paraspinal SEMG is typically performed by physiatrists or chiropractors as a technique to evaluate the physiological functioning of the back, specifically the function of the paraspinal muscles. This technique has been intended for use in patients with back pain symptoms such as spasm, tenderness, limited range of motion, or postural disorders, particularly as it relates to assessing the patient's capacity to lift heavy objects, or the ability to return to work.

The following clinical applications of paraspinal SEMG have been proposed:

- Clarification of a diagnosis (i.e., muscle, joint, or disc disease)
- Selection of a medical therapy course
- Selection of a physical therapy plan
- Pre-operative evaluation
- Post-operative rehabilitation
- Follow-up evaluation of acute low back pain
- Evaluation of exacerbation of chronic low back pain
- Evaluation of pain management treatment techniques

REGULATORY STATUS

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. Several FDA-approved devices combine SEMG with other types of monitors.

EVIDENCE SUMMARY

Surface and paraspinal surface electromyography (SEMG) have been proposed as a research tool to evaluate the performance of nerves and muscles in patients with neuromuscular

disorders, as a component of gait analysis, and to further understand the etiology of the resulting symptomatology, such as pain. However, validation of its use as a clinical diagnostic technique involves a sequential three-step procedure as follows:

1. Analytical Validity- of a device is typically assessed by studies that compare test measurements with a gold standard, and those that compare results taken with the same device on different occasions ("test-retest").
2. Clinical Validity- is evaluated by the ability of a test to accurately diagnose a clinical condition in comparison with the gold standard. The sensitivity of a test is the ability to detect a disease when the condition is present (true positive), while specificity indicates the ability to detect patients who are suspected of disease but who do not have the condition (true negative). Therefore, evaluation of diagnostic performance requires independent assessment by the two methods in a population of patients who are suspected of disease but who do not all have the disease.
3. Clinical Utility- is established when the evidence demonstrates that the diagnostic information obtained from a test can be used to benefit patient management and improve health outcomes. Typically, randomized trials are needed to demonstrate the impact of the test on net health outcomes.

The following discussion focuses on these three steps as they apply to surface EMG, including paraspinal SEMG.

ANALYTICAL VALIDITY

Several studies using different SEMG devices have suggested that paraspinal SEMG, in general, is a reliable technique, based on coefficients of variation or test-retest studies,[2-7] or ability to differentiate healthy test subjects from those with back pain.[8-10] These studies use a range of different methodologies and SEMG parameters, and do not address the accuracy or validity of the test. No studies were identified that compared the performance of SEMG to a gold standard reference test.

CLINICAL VALIDITY

It is recognized that the pathology of individual muscles (i.e., radiculopathy, neuropathy, etc.) may represent a different process than the pathology of muscle groups (i.e., muscle strain, spasm, etc.); thus, SEMG may be considered by its advocates as a unique test for which there is currently no gold standard. Even if one accepts this premise, there are inadequate data to evaluate the diagnostic performance of SEMG. No articles were identified in the published peer-reviewed literature that established definitions of normal or abnormal SEMG. In some instances, asymmetrical electrical activity may have been used to define abnormality; results may be compared to a "normative data base." However, there is a lack of published literature defining what degree of asymmetry would constitute abnormality, or how a normative database was established.[11]

In the absence of a gold standard diagnostic test, correlation with the clinical symptoms and physical examination is critical.

Systematic Reviews

Ribeiro (2018) published a systematic review (SR) of SEMG biofeedback compared to other direct vocal therapy interventions for the treatment of behavioral dysphonia in adults.[12] Two studies met inclusion criteria. There was high clinical heterogeneity and risk of bias. A

descriptive analysis showed reduced muscle electrical activity and improved vocal self-assessment, but was not able to determine the effect size.

Audag (2017) published a SR comparing tools for screening for dysphagia and evaluation in neuromuscular diseases.[13] Four studies including four evaluation tools for Duchenne muscular dystrophy met inclusion criteria. Evaluation tools included were the Sydney Swallow Questionnaire, surface electromyography, Neuromuscular Disease Swallowing Status Scale, and videofluoroscopic swallow study. Three studies were assessed as fair quality and one as good quality. Two studies compared between different evaluation tools and two compared between groups of subjects. The only study that assessed SEMG compared results from patients and healthy controls. Greater intrasubject variability was observed for Duchenne muscular dystrophy patients than healthy controls, but there were no differences within patients between those with and without dysphagia. The SR concluded that more research was needed to identify the best assessment method.

In 2016, Villafane conducted a SR of studies testing the validity and clinical applicability of SEMG among patients with chronic non-specific low back pain (CNSLBP).[14] The literature review, conducted through September 2014, identified 24 studies for inclusion. Quality of the studies was assessed using a modification of the checklist for cohort, case-control, and cross-sectional studies from Strengthening the Reporting of Observational Studies in Epidemiology. The checklist has 22 items, and the authors used the 15 items that related to methods and results. Out of a possible total 15 points, the studies' scores ranged from 6 to 12. The review focused on the 10 studies with scores from 10 to 12. One study was large (N=349), the second largest had 67 patients, while the remaining studies had less than 40 patients. While SEMG recordings were taken, patient position (upright, seated) and type of test (for example, isometric trunk extension, semi-crouched lifting, Roman Chair endurance, etc.) varied among the studies. Villafane report inconsistent findings of validity and reliability for SEMG in discriminating between patients with CNSLBP and healthy controls. Conclusions were limited due to the heterogeneity in methods across the studies.

Wang (2016) published a SR including eleven case-control, cohort, and cross-sectional studies that evaluated the benefit of trunk muscle activity for patients with spinal cord injury (SCI), using SEMG.[15] The studies methodology varied; thus, could not be evaluated together. For example, two studies compared trunk muscles in SCI patients versus those in a normal healthy control group and three studies compared truck muscle activity in SCI patients with different levels of trunk muscle impairment. The authors concluded that because trunk muscle activity can increase independence and quality of life, SEMG is a useful objective tool for measuring muscle activity for patients with SCI, but more larger studies are needed with attention to comparison of trunk muscle activity in different SCI populations and to further define SEMG protocols.

Randomized Controlled Trials

Azola (2017) published a small RCT comparing submental SEMG (sSEMG) with videofluoroscopy (VF) biofeedback on hyo-laryngeal accuracy when training on a swallowing maneuver.[16] The first stage of the study involved accurate demonstration of the volitional laryngeal vestibule closure maneuver (vLVC) and the second stage involved 20 vLVC training swallows. Thirty healthy adults were randomized into three groups. One group received sSEMG biofeedback only, one group received VF feedback only, and one group received VF

for the first stage and sSEMG for the second stage of the study (mixed feedback). The participants and clinicians viewed the biofeedback in real time during the procedure and the clinician provided guidance based on the biofeedback. The accuracy of the vLVC performance and the clinician cues was greater (p<0.001) when biofeedback was provided with VF as compared to sSEMG or mixed biofeedback.

Nonrandomized Studies

Pietropaoli (2019) published an observational study of muscle activity quantified using SEMG and subjective pain of the masseter and temporalis muscles in 50 patients with painful temporomandibular disorder (TMD) and concurrent tension-type headache (TTH). An overall moderate correlation between muscle tenderness and SEMG values ($y = 1 + 1.2 \cdot x$; $r^2 = 0.62$; $p < 0.0001$) was observed. Although these data suggest a relationship between subjective pain perception and objective measurement of muscle activity, additional data are needed to identify the added value of these findings to informing clinical care decisions.

A 2016 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, in order to establish "normal" measurements.[17] Fluoroscopic images and SEMG measurements were taken on 20 males with no history of low back pain. 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 low back pain are needed to establish standard criterion.

Earp (2016) published a study that compared vastus lateralis muscle activity during heavy squat (HS) and unloaded jump squat (JS) activities for 10 patients using SEMG.[18] Testing occurred over two days to determine if regional hypertrophy occurred during heavy squat and unloaded squat activities. The authors concluded that SEMG showed more hypertrophy in HS versus JS, which was opposite of previous research outcomes. They concluded SEMG is not a good tool for this type of assessment.

Chmielewska (2016) published a six-week biofeedback training for 21 continent women who had never been pregnant beyond 20 weeks, using SEMG as a measurement tool.[19] The goal was to determine if SEMG-biofeedback training could assist in pelvic floor muscle relaxation; thus, decreasing involuntary urine leakage. Training occurred three times a week for six weeks. SEMG evaluation occurred at baseline, three weeks, six weeks and one month following training. The results showed an increase in pelvic floor relation. The authors concluded that additional research is needed.

De Luca (2016) published a series of studies investigating a type of SEMG called the Back Analysis System (BAS), consisting of surface electrodes and other components to measure the electrical activity of muscles during isometric exercises designed to produce muscle fatigue.[20] Using physical examination and clinical history as a gold standard, the author found that BAS was able to accurately identify "control" and "back pain" patients 84% and 91% of the time, respectively, with the values increasing to 100% in some populations of patients. (Accuracy is the sum of true positive and true negative results.) However, these studies were not designed as a clinical diagnostic tool, but were intended to investigate the etiology of back pain and to investigate muscular fatigue patterns in patients with and without back pain.

Hu (2010, 2014) published two articles on dynamic topography, an approach to analyzing SEMG findings.[21, 22] The studies had similar protocols. Both included low back pain patients and healthy controls; all participants underwent SEMG at study enrollment and then back pain patients participated in a rehabilitation program. The first study[22] found different dynamic topography at baseline between healthy people and people with back pain, e.g., 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 that were assessed. In the second study, following rehabilitation, back pain patients were classified as responders or nonresponders based on changes in back pain severity.[21] Some associations were found between baseline SEMG parameters and response to rehabilitation. SEMG was not repeated following the rehabilitation program, and thus it is not clear whether there are any significant associations between continued symptoms and SEMG abnormalities. Moreover, it is not clear how SEMG analysis would affect treatment decisions for low back pain patients.

CLINICAL UTILITY

Systematic Reviews

A 2000 SR by Pullman, indicated that SEMG was not found to be better or equivalent to needle electromyography (NEMG) in diagnosing neuromuscular disease due to electrical cross-talk of muscles, intervening soft tissues, and poor fidelity recordings as a result of limited spatial resolution.[1]

In 2008, Meekins conducted a SR of studies published from 1994-2006 which evaluated SEMG in the diagnosis and treatment of nerve and muscle disorders.[23] Authors concluded that:

1. SEMG may be useful in adding information in the study of fatigue in post-poliomyelitis syndrome and electromechanical coupling dysfunction in myotonic dystrophy." However, this recommendation was based upon Class III, Level C data indicating studies were retrospective in nature, focused on SEMG for a specific condition and that data indicated SEMG may be possibly effective, ineffective, or harmful for the given condition in the specific population.

2. On the basis of two class III studies, SEMG may be useful to detect the presence of neuromuscular disease (Level C rating).

3. Data were deemed insufficient to determine the ability of SEMG in distinguishing between neuropathic and myopathic disorders, disease severity, to compare the utility of SEMG with NEMG, or as a 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.

Included studies were small in sample size and differed in the utilization of SEMG techniques, diagnostic reference standard and outcome measures. Authors indicated that additional studies were needed that compare SEMG to a carefully selected gold standard, in studies with adequate blinding which address a broad spectrum of subjects. The authors also noted that the lack of standardization of SEMG protocols and lack of methodological documentation prohibited pooled analysis. Well-designed, randomized controlled trials (RCTs) which evaluate

SEMG compared to standard assessment measures are required in order to assess the efficacy of SEMG as a diagnostic tool for any condition.

Nonrandomized Studies

Numerous studies were identified which incorporated the use of SEMG as an assessment tool to evaluate muscle strength and movement,[24-29] temporomandibular joint dysfunction and disorders,[30-32] and various causes of muscle pain.[33-36] Several studies have proposed using SEMG results to inform treatment decisions; however, none of these studies provided data to validate that treatment based on SEMG results improved outcomes.

- In a 2016 study of patients with chronic LBP (N=216), SEMG showed potential to discriminate between impaired and unimpaired neuromuscular regulation of back extensors, which would provide useful information for designing individualized exercise programs.[37]

- In a 2015 study of patients with LBP (n=27) and pain-free controls (n=23), SEMG detected a loss of discrete motor cortical organization of the paraspinal muscles among those with LBP.[38] The invasive technique of needle electromyography is usually performed to detect this pathology. Patients with cortical reorganization may benefit from motor skill training.

- In two 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.[39, 40]

Paraspinal SEMG to Diagnose Back Pain

Several articles described the use of SEMG as an aid in classifying low back pain.[41-50] The articles focused on the use of spectral analysis to assess muscle fatigability. However, it is unclear how this information may be used in the management of the patient. For example, while the innovators of the BAS system indicated that SEMG can suggest potential therapies by distinguishing deconditioning from muscle inhibition secondary to pain-related behavior, no clinical studies described the use of SEMG in suggesting therapy.[41]

In another application of SEMG, Arena (1991) assessed the amplitude of SEMG recordings as a measure of paraspinal muscle tension in 66 patients and reported that the degree of muscle tension did not correlate with pain levels.[51] These findings raised questions about the role of biofeedback, muscle relaxants, or other therapies designed to reduce muscle tension.

While SEMG may be used to objectively document muscle spasm or other muscular abnormalities, 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. For example, SEMG has been proposed as a technique to differentiate muscle spasm from muscle contracture, with muscle spasm treated with relaxation therapy, and contracture treated with stretching exercises. However, there are no data to validate that such treatment suggested by SEMG resulted in improved outcomes.[39, 52] Part of the difficulty in clinical interpretation is understanding, to what extent, the SEMG abnormalities are primary or secondary. In addition, no specific workup is recommended for acute low back pain without warning signs.

A review of spinal muscle evaluation in low-back pain patients indicated that the validity of SEMG remains controversial.[53] The authors noted that although many studies showed increased fatigability of the paraspinal muscles in patients with low back pain, it is not known

whether these changes are causes or consequences of the low back pain. Also, "the considerable inter-individual variability and the absence of normative data complicate the description of normal or abnormal profiles, thereby limiting the diagnostic usefulness of SEMG."

Gait Analysis

The ideal study design to demonstrate the clinical utility of gait analysis would be a RCT comparing treatment decisions and health outcomes in patients managed with and without SEMG as a component of gait analysis. Although numerous studies were identified in which SEMG was used as a component of gait analysis to evaluate a specific treatment, no RCTs were identified which evaluated the contribution of SEMG as a component of gait analysis to diagnose or treat any condition.

Amyotrophic Lateral Sclerosis

Bashford (2020) published a SR of 42 studies evaluating SEMG in the diagnosis, prognosis, or monitoring of patients with amyotrophic lateral sclerosis (ALS).[54] The review focused primarily on the types of analyses that can be conducted with data obtained from SEMG recordings, the most prominent being motor unit action potentials (MUAPs), motor unit number estimation (MUNE), multiplet discharge (MD) detection, motor unit number index (MUNIX), and motor unit size index (MUSIX). The utility of SEMS-derived metrics, including MD, to differentiate ALS patients from control patients was found to be highly variable, ranging from no diagnostic utility[55] to 90% sensitivity and 100% specificity when high density arrays for acquisition and machine learning analysis methods were used.[56] Study limitations including anatomical restriction (testing site), infrequency of measured events, and small sample sizes in individual studies were thought to have contributed to the inconsistent findings. While some studies reported data pointing towards the potential utility of SEMG-based metrics as a prognostic marker in ALS, additional studies are needed to both validate these findings and to compare them to gold standard (NEMG) metrics. Studies evaluating the utility of SEMG as a disease-monitoring tool also had considerable variance in outcomes, and this was considered to be an area for future research. Large volume datasets, including those acquired with high density arrays or over long time periods were more commonly found to hold clinical value. The authors recommend that future research is needed to further develop this potential tool.

Mechanical Ventilation

A SR on SEMG for monitoring respiratory responses during mechanical ventilation (MV) was published by AbuNurah in 2020.[57] Studies on SEMG of extra-diaphragmatic muscles during invasive MV in patients at least 13 years old were included. Studies in patients with neuromuscular disorders, receiving neuromuscular blocking agents, or studies using needle EMG were not reviewed. Seven studies were included in the review. The planned meta-analysis was not possible due to heterogeneity of methods across studies. All included studies were prospective and study populations principally included subjects with respiratory failure due to various cardiopulmonary conditions and/or prolonged MV. The QUADAS-2 tool was used to assess the quality of the studies in terms of risk of bias and applicability concerns. Risk of bias was high across the studies due primarily lack of randomization. The authors reported that the response of extra-diaphragmatic muscle activity measured via SEMG matched at least one of the respiratory responses assessed (i.e., respiratory mechanical loading/unloading or respiratory sensation) in six of the seven studies, however, they also noted that studies lacked evidence of SEMG accuracy in assessing MV clinical outcomes such as respiratory failure, MV

liberation readiness, or success/failure. Future RCTs with larger sample sizes and robust research designs are needed, including random sampling of patients, blinding to index test and reference standards, and the use of gold standard reference tests for assessing MV outcomes.

Myoclonus

The evidence regarding the use of SEMG to diagnose or treat myoclonus associated with any condition is limited to small case series and case reports.

PRACTICE GUIDELINE SUMMARY

Guidelines from the American College of Occupational and Environmental Medicine (2019) do not recommend surface electromyography for diagnosing low back pain, based on low quality evidence of diagnostic efficacy.[58]

In 2020, the North American Spine Society with input from the American Academy of Pain Medicine issued guidelines on the diagnosis and treatment of low back pain.[59] When discussing the diagnostic accuracy of nonimaging tests, the guidelines lacks any statement on surface electromyography."

SUMMARY

There is not enough research to show that surface electromyography (SEMG), including paraspinal SEMG improves health outcomes for any indication, including but not limited to the diagnosis and monitoring of back pain, evaluation of myoclonus or as a component of gait analysis. No clinical guidelines based on research recommend SEMG for any indication. Therefore, the use of the use of SEMG, including paraspinal SEMG, is considered investigational for all indications.

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CODES

Codes	Number	Description
CPT	95999	Unlisted neurological or neuromuscular diagnostic procedure
	96002	Dynamic surface electromyography, during walking or other functional activities, 1 to 12 muscles
	96004	Review and interpretation by physician or other qualified health care professional of comprehensive computer-based motion analysis, dynamic plantar pressure measurements, dynamic surface electromyography during walking or other functional activities, and dynamic fine wire electromyography, with written report
	97799	Unlisted physical medicine/rehabilitation service or procedure
	99199	Unlisted special service, procedure or report
HCPCS	S3900	Surface electromyography (EMG)

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