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Medical Policy Transcutaneous Electrical Nerve Stimulation

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Policy History

Policy Number: 003

BCBSA Reference Number: 1.01.09 (For Plan internal use only)

Related Policies

- Interferential Stimulation for Treatment of Pain, #509
- Temporomandibular Joint Dysfunction, #035
- Percutaneous Electrical Nerve Stimulation or Percutaneous Neuromodulation Therapy, #172

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

A trial of transcutaneous electrical nerve stimulation (TENS) of at least 30 days may be considered <u>MEDICALLY NECESSARY</u> to establish efficacy for the management of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when the following conditions have been met:

- The pain is unresponsive to at least 3 months of conservative medical therapy, AND
- The trial is monitored by a physician.

Refractory chronic pain is defined in this policy as pain that causes significant disruption of function and has not responded to at least 3 months of conservative therapy, including nonsteroidal anti-inflammatory medications, ice, rest, and/or physical therapy.

Documentation for the trial should include:

- Initial assessment/evaluation of the nature, duration, and perceived intensity of pain;
- The types and duration of prior treatments;
- Treatment plan including ongoing medications and proposed use of TENS unit, including the frequency and duration of treatment.

Clinical summary of the trial to determine efficacy should include:

- Perceived intensity of pain with and without TENS (e.g., 2 point or 30% improvement in visual analog scale [VAS]),
- Ongoing medication requirements for pain relief (if any),
- Other modalities (if any) in use for pain control, and
- Actual use of TENS on a daily basis (frequency and duration of application).

Continued use of TENS may be considered <u>MEDICALLY NECESSARY</u> for treatment of refractory chronic pain (e.g., chronic musculoskeletal or neuropathic pain) that causes significant disruption of function when the following conditions have been met:

- Efficacy has been demonstrated in an initial therapeutic trial; AND
- Compliance has been demonstrated in the therapeutic trial with the device used on a regular basis (eg, daily or near daily use) throughout the trial period.

Note: A TENS billed as a purchased unit (modifier NU) must meet above criteria for continued use.

TENS is **INVESTIGATIONAL** for the management of acute pain (e.g., postoperative or during labor and delivery).

TENS is considered **INVESTIGATIONAL** for the prevention or treatment of migraine headache.

TENS is considered **INVESTIGATIONAL** for the management of essential tremor.

TENS is considered **INVESTIGATIONAL** for the management of attention deficit hyperactivity disorder.

The use of TENS for any other condition, including but not limited to the treatment of dementia is **INVESTIGATIONAL**.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

HCPCS	Codes
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HCPCS	
codes:	Code Description
A4595	Electrical stimulator supplies, 2 lead, per month, (e.g., TENS, NMES)
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
E0720	Transcutaneous electrical nerve stimulator (TENS) device, two lead, localized stimulation
E0730	Transcutaneous electrical nerve stimulation (TENS) device, four or more leads, for multiple nerve stimulation

E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive
	fibers separated from the patient's skin by layers of fabric

The following CPT code is considered investigational for <u>Commercial Members: Managed Care</u> (HMO and POS), PPO, and Indemnity.

CPT Codes

CPT codes:	Code Description
	Transcutaneous electrical modulation pain reprocessing (eg, scrambler therapy),
0278T	each treatment session (includes placement of electrodes)

Description

Transcutaneous electrical nerve stimulation (TENS) has been used to treat chronic intractable pain, migraine headache pain, postsurgical pain, and pain associated with active or post trauma injury unresponsive to other standard pain therapies. It has been proposed that TENS may provide pain relief through the release of endorphins in addition to potential blockade of local pain pathways. TENS has also been used to treat dementia by altering neurotransmitter activity and increasing brain activity that is thought to reduce neural degeneration and stimulate regenerative processes.

Percutaneous electrical nerve stimulation (see policy $\frac{172}{172}$) is similar to TENS but uses microneedles that penetrate the skin instead of surface electrodes. Interferential stimulation (see policy $\frac{509}{100}$) uses a modulated waveform for deeper tissue stimulation, and the stimulation is believed to improve blood flow to the affected area.

Summary

Description

Transcutaneous electrical nerve stimulation (TENS) describes the application of electrical stimulation to the surface of the skin. In addition to more traditional settings such as a physician's office or an outpatient clinic, TENS can be self-administered in a patient's home.

Summary of Evidence

For individuals who have chronic pain (eg, musculoskeletal, neuropathic, and mixed pain conditions) who receive transcutaneous electrical nerve stimulation (TENS), the evidence includes numerous randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), and medication use. The overall strength of the evidence is weak. The best evidence exists for the treatment of chronic, intractable pain. Available evidence indicates that TENS can improve chronic intractable pain in some patients, and there is support for its use in clinical guidelines by specialty societies. To best direct TENS toward patients who will benefit, a short-term trial of TENS is appropriate, with continuation only in patients who show an initial improvement. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have acute pain (eg, surgical, musculoskeletal, labor, and mixed pain conditions) who receive TENS, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Overall, evidence for the use of TENS from high-quality trials remains inconclusive for most indications. A systematic review of TENS for acute and chronic pain found some evidence that TENS reduces pain intensity over and above that seen with placebo and other control groups in patients with acute pain, but small-sized trials contributed to imprecision in magnitude estimates. Systematic reviews have found that TENS may help reduce pain in patients with post-operative pain (post-caesarean and total knee arthroplasty), dysmenorrhea, and pain associated with labor and delivery. For low back pain, systematic reviews have found insufficient evidence to support or refute the use of TENS. Randomized controlled trials have reported mixed results in the efficacy of TENS across various acute pain conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have essential tremor who receive TENS, the evidence includes a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results from the nonrandomized study suggest that TENS therapy is effective and safe for patients with essential tremor. However, the trial was limited by its open-label, single-arm design, lack of defined standards for what constitutes a clinically meaningful improvement in stated endpoints, and exclusion of patients who exited the study early from the pre-specified primary and secondary endpoint analyses. Further studies comparing TENS to standard of care therapy for essential tremor are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have attention deficit hyperactivity disorder (ADHD) who receive TENS, the evidence includes an RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the RCT concluded that TENS is an effective and safe treatment option for pediatric patients with ADHD. However, the study included a small patient sample and was of short duration. Further studies comparing TENS to standard of care therapy for ADHD are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic or episodic migraine who receive TENS for treatment of acute migraine, the evidence includes 3 double-blind, sham-controlled RCTs. Two of the RCTs evaluated healthcareprovider administration of a TENS device during a single episode in emergency departments, and 1 evaluated self-administration of the device at home during acute episodes over a 3-month period. The studies conducted in emergency departments showed clinically and statistically significant reductions in pain intensity and medication use within 2 hours of use. The self-administration study had mixed results: The difference in median pain scores before and after treatment was significantly higher in the TENS group at months 1 and 2, but at month 3 the difference was not statistically significant. Function and analgesic medication use did not differ between groups at any time point. Strengths of the RCTs included the use of a sham device and blinded outcome assessment using validated outcome measures. Although short-term pain relief was demonstrated at some time points, the quality of the overall body of evidence was downgraded due to inconsistency of results and heterogeneity in study settings. It is not clear whether the pain intensity reductions demonstrated in emergency department settings would generalize to other settings over longer time periods. Supporting evidence from RCTs is needed. Additionally, based on the existing evidence, it is unclear how TENS would fit into the current migraine treatment pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or secondline therapies, or who may have a contraindication to pharmacologic therapies. The specific intended use must be specified in order to adequately evaluate net health benefit. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic or episodic migraine who receive TENS for migraine prevention, the evidence includes 1 RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. The RCT (N=67) reported a greater proportion of participants achieving at least a 50% reduction in migraines with TENS than with sham placebo and modest reductions in the number of total headache and migraine days. In the intention-to-treat analysis, the reduction in the number of migraine days (run-in vs. 3-months) was not statistically significant. The proportion of responders (≥50% reduction in the number of migraine days/month) significantly higher in the TENS group. The number of migraine attacks from the run-in period to the 3-month evaluation, number of headache days, and antimigraine medication use were significantly lower for the active TENS group. The severity of migraine days did not differ significantly between groups. This manufacturer-sponsored trial needs corroboration before conclusions can be made with certainty about the efficacy of TENS for preventing migraine headaches. Additionally, based on the existing evidence, it is unclear how TENS would fit into the current migraine prevention pathway, although it could provide benefit for those who do not receive adequate benefit from pharmacologic first- or second-line therapies, or who may have a contraindication to pharmacologic therapies. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy History

Date	Action
2/2024	Annual policy review. Policy updated with literature review through September 27,
	2023, references added. Removed outdated clinical input. Separated out evidence

	on migraine from the chronic pain and acute pain sections. Added new policy
	statement to clarify that TENS is investigational for both prevention and treatment of
	migraine headache. Other policy statements unchanged
1/2023	Annual policy review. Description, summary, and references updated. Policy
	statement unchanged.
5/2022	Policy revised. New investigational indications described for TENS devices for
	essential tremor and attention deficit hyperactivity disorder. Effective 5/1/2022.
1/2021	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for
	local coverage determination and national coverage determination reference.
1/2020	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged.
1/2019	Annual policy review. Description, summary, and references updated. Policy
	statements unchanged. Clarified coding information.
1/2018	Annual policy review. New references added.
1/2018	Clarified coding information.
8/2016	Clarified coding information.
12/2015	Annual policy review. New references added.
12/2015	Added coding language.
6/2015	Annual policy review. New references added.
9/2014	Annual policy review. New investigational indications described. Coding information
	clarified. Effective 9/1/2014.
5/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective
	10/2015.
12/2013	Medically necessary indications clarified.
10/2013	Annual policy review. New references added
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No
	changes to policy statements.
	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to
1/2012	policy statements.
	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
6/2011	Rheumatology. No changes to policy statements.
	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to
1/2011	policy statements.
	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
7/2010	Rheumatology. No changes to policy statements.
3/2010	Annual policy review. Changes to policy statements.
2/2010	Annual policy review. Changes to policy statements.
7/2009	Annual policy review. Changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use Managed Care Guidelines Indemnity/PPO Guidelines Clinical Exception Process Medical Technology Assessment Guidelines

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