Protocol

Cranial Electrotherapy Stimulation and Auricular Electrostimulation

(80158)

Medical Benefit		**Effective Date**: 01/01/19	**Next Review Date**: 09/20
Preauthorization	No	**Review Dates**: 09/18, 09/19	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With acute or chronic pain	Interventions of interest are: • Cranial electrotherapy stimulation	Comparators of interest are: • Medical management • Other conservative therapies	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With psychiatric, behavioral, or neurologic conditions	Interventions of interest are: • Cranial electrotherapy stimulation	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With functional constipation	Interventions of interest are: • Cranial electrotherapy stimulation	Comparators of interest are: • Medication • Biofeedback • Behavior modification	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With acute or chronic pain	Interventions of interest are: • Auricular electrostimulation	Comparators of interest are: • Medical management • Other conservative therapies	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With obesity	Interventions of interest are: • Auricular electrostimulation	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Treatment-related morbidity
Individuals: • With opioid withdrawal symptoms	Interventions of interest are: • Auricular electrostimulation	Comparators of interest are: • Standard therapy	Relevant outcomes include: • Symptoms • Morbid events • Functional outcomes • Treatment-related morbidity

DESCRIPTION

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES is being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and functional constipation. Auricular electrical stimulation is being evaluated for pain, weight loss, and opioid withdrawal.

SUMMARY OF EVIDENCE

CRANIAL ELECTROTHERAPY STIMULATION

For individuals who have acute or chronic pain who receive CES, the evidence includes a number of small sham-controlled randomized trials, and pooled analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Three trials studied headache and CES, and five trials studied chronic pain and CES. Pooled analyses found marginal benefits for a headache with CES and no benefits for chronic pain with CES. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have psychiatric, behavioral, or neurologic conditions (e.g., depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Three randomized controlled trials (RCTs) evaluated CES for depression and anxiety and reported inconsistent outcomes. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease and smoking cessation do not support the use of CES for these conditions. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have functional constipation who receive CES, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The single RCT reported positive results for the treatment of constipation with CES. However, the trial was unblinded, and most outcomes were self-reported. The evidence is insufficient to determine the effects of the technology on health outcomes.

Auricular Electrostimulation

For individuals who have acute or chronic pain (e.g., acute pain from surgical procedures, chronic back pain, chronic pain from osteoarthritis or rheumatoid arthritis) who receive auricular electrostimulation, the evidence includes a limited number of trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Studies evaluating the effect of electrostimulation technology on acute pain are inconsistent, and the small amount of evidence on chronic pain has methodologic limitations. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham-control group, and, in a study of rheumatoid arthritis, auricular electrostimulation was compared with autogenic training and resulted in a small improvement in visual analog scale pain scores of unclear clinical significance. Overall, the few published studies have small sample sizes and methodologic limitations. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obesity who receive auricular electrostimulation, the evidence includes small RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The

RCTs reported inconsistent results and used different treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have opioid withdrawal symptoms who receive auricular electrostimulation, the evidence includes two case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Both case series report positive outcomes for the use of CES to treat opioid withdrawal symptoms. The studies used different treatment protocols and no comparators, limiting conclusions drawn from the results. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) is **investigational** in all situations.

Electrical stimulation of auricular acupuncture points is **investigational** in all situations.

BACKGROUND

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves stimulation of acupuncture points on the ear. Devices, including the P-Stim and E-pulse, provide ambulatory auricular electrical stimulation over a period of several days. CES and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, weight loss, and opioid withdrawal.

Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression and use of CES later spread to Western Europe and the United States as a treatment for various psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system. One device used in the United States is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. Treatments may be administered once or twice daily for several days to several weeks.

Other devices provide electrical stimulation to auricular acupuncture sites over several days. One device, the P-Stim, is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify three auricular acupuncture points. The P-Stim device connects to three inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

REGULATORY STATUS

A number of devices for CES have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1992, the Alpha-Stim® CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Devices cleared since 2000 are summarized in Table 1. FDA product code: JXK.

Table 1. Cranial Electrotherapy Stimulation (CES) Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	05/29/2009	K090052	Insomnia, depression, anxiety
Elexoma Medic™	Redplane AG	05/21/2008	K070412	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	04/05/2007	K062284	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	10/13/2006	K060158	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	07/21/2003	K024377	Insomnia, depression, anxiety

FDA: Food and Drug Administration.

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing by FDA through the 510(k) process. Devices cleared since 2000 are summarized in Table 2. FDA product codes: BWK, PZR.

Table 2. FDA-Cleared Electroacupuncture Devices for Auricular Acupuncture Points

Device Name	Manufacturer	Cleared	Indications
Drug Relief	DyAnsys Inc.	05/02/2018	Reduce symptoms of opioid withdrawal
NSS-2 Bridge	Innovative Health Solutions	2017	Substance use disorders
Stivax System	Biegler	05/26/2016	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim®	DyAnsys	05/15/2015	Practice of acupuncture by qualified practitioners as determined by the states
Bridge Neurostimulation System	Innovative Health Solutions	2014	Practice of acupuncture by qualified practitioners as determined by the states
e-Pulse®	AMM Marketing	12/07/2009	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim™	NeuroScience Therapy	3/30/2006	Practice of acupuncture by qualified practitioners as determined by the states
AcuStim	S.H.P. International	6/12/2002	As an electroacupuncture device

FDA: Food and Drug Administration.

RELATED PROTOCOLS

Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

Transcutaneous Electrical Nerve Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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