Corporate Medical Policy

Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

File Name: cranial_electrotherapy_stimulation_and_auricular_electrostimulation
Origination: 11/2012
Last Review: 5/2023

Description of Procedure or Service

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 the stimulation of acupuncture points on the ear. Devices, including the P-Stim™ and E-pulse, have been developed to 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 U.S. 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 U.S. 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 a period of 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 pre-programmed 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 received marketing clearance through the U.S. Food and Drug Administration's (FDA) 510(k) process. The Alpha-Stim® CES device (Electromedical Products International) received marketing clearance in 1992 for the treatment of anxiety, insomnia, and depression. Other FDA-cleared devices for Cranial Electrotherapy Stimulation include the the Cranial Electrical Nerve Stimulator (Johari Digital Healthcare, 2009), the Elexoma Medic™ (Redplane AG, 2008), CES Ultra™ (Neuro-Fitness, 2007), Net-2000 Microcurrent Stimulator (Auri-Stim Medical, 2006), and the Transcranial Electrotherapy Stimulator-A, Model TESA-1 (Kalaco Scientific, 2003). In March 2019, the Cervella device (Innovative Neurological Devices) received clearance from FDA for treatment of anxiety, insomnia, and depression.

Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

The P-Stim™ (NeuroScience Therapy Corp) received marketing clearance through the FDA's 510(k) process in 2006. The P-Stim™ is intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points.

The E-pulse® received 510(k) marketing clearance in 2009, listing the P-Stim™ as a predicate device. The E-pulse is a microprocessor-controlled battery-powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96-hour period.

Other FDA-cleared Electroacupuncture Devices for Auricular Acupuncture Points include ANSiStim® (DyAnsys, 2015), Stivax System (Beigler, 2016), and NSS-2 Bridge (Innovative Health Solutions, 2017). Drug Relief (DyAnsys) is an electroacupuncture device for auricular acupuncture points that was cleared by FDA in 2018 to reduce symptoms of opioid withdrawal. The AXUS ES-5 Electro-Acupuncture Device (Lhasa OMS, INC.), the Drug Relief V1 (DyAnsys Inc), and the Sparrow Therapy System (Spark Biomedical, Inc.) received FDA clearance in 2021.

Related Policies:
TENS (Transcutaneous Electrical Nerve Stimulation)
Percutaneous Electrical Nerve Stimulation (PENS) or Neuromodulation Therapy and Percutaneous Electrical Nerve Field Stimulation (PENFS)
Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Cranial electrotherapy stimulation and auricular electrostimulation are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

Most benefit plans exclude acupuncture services as non-covered.

When Cranial Electrotherapy Stimulation and Auricular Electrostimulation are covered

Not applicable.

When Cranial Electrotherapy Stimulation and Auricular Electrostimulation are not covered

Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is considered investigational.

Electrical stimulation of auricular acupuncture points is considered investigational.

Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

Policy Guidelines

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. Systematic reviews of randomized trials evaluated CES for headache and chronic pain. Pooled analyses found marginal benefits for headache with CES and no benefits for chronic pain with CES. A subsequent sham-controlled trial of remotely supervised CES via secure videoconferencing found a significant benefit with CES for pain reduction, but it had important relevance and conduct and design limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric, behavioral, or neurologic conditions (depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four randomized controlled trials (RCTs) evaluated CES for depression and anxiety. One RCT each found a significant benefit with CES for anxiety or depression, but both had important relevance limitations. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease, smoking cessation, and tic disorders do not support the use of CES for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

Auricular Electrostimulation
For individuals who have acute or chronic pain (acute pain from surgical procedures, chronic pain from osteoarthritis or rheumatoid arthritis, chronic back pain) 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 that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive auricular electrostimulation, the evidence includes small RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCTs reported inconsistent results and used different treatment protocols. The systematic reviews are limited by high heterogeneity with respect to the interventions used, participants included, treatment period, and outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have opioid withdrawal symptoms who receive auricular electrostimulation, the evidence includes two observational studies. Relevant outcomes are symptoms, morbid

events, functional outcomes, and treatment-related morbidity. Both studies 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 that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *A4596, 0783T*, *K1002, S8930*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 9/13/2012

Senior Medical Director – 10/2012

Specialty Matched Consultant Advisory Panel – 5/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 8/8/2013

Specialty Matched Consultant Advisory Panel – 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 8/14/14

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 8/13/15

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 2/11/16

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 2/9/17

Specialty Matched Consultant Advisory Panel – 5/2017

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 6/14/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 2/14/2019

Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 2/13/2020

Specialty Matched Consultant Advisory Panel – 5/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.58, 2/11/2021

Specialty Matched Consultant Advisory Panel – 5/2021

Price L, Briley J, Haltiwanger S, et al. A meta-analysis of cranial electrotherapy stimulation in the treatment of depression. J Psychiatr Res. Mar 2021; 135: 119-134

Specialty Matched Consultant Advisory Panel – 5/2022

Ching PY, Hsu TW, Chen GW, et al. Efficacy and Tolerability of Cranial Electrotherapy Stimulation in the Treatment of Anxiety: A Systemic Review and Meta-Analysis. Front Psychiatry. 2022; 13: 899040. PMID 35757229

Patel S, Boutry C, Patel P, et al. A randomised controlled trial investigating the clinical and cost-effectiveness of Alpha-Stim AID cranial electrotherapy stimulation (CES) in patients seeking treatment for moderate severity depression in primary care (Alpha-Stim-D Trial). Trials. Apr 04 2022; 23(1): 250. PMID 35379314

Specialty Matched Consultant Advisory Panel – 5/2023

Policy Implementation/Update Information

11/27/12 New policy. Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is considered investigational. Electrical stimulation of auricular acupuncture points is considered investigational. Reviewed by Senior Medical Director 11/3/12. Notification given 11/27/12. Policy effective 2/26/13.(btw)

7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No change to policy. (btw)

10/1/13 Reference added. (btw)

6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. No change to policy. (btw)

11/11/14 Reference added. (sk)

7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. (sk)

10/1/15 Reference added. (sk)

7/1/16 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)

3/31/17 Reference added. (sk)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)

6/29/18 Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)

9/7/18 Reference added. Regulatory Status and Policy Guidelines updated. (sk)

6/11/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)

12/31/19 HCPCS code K1002 added to Billing/Coding section. (sk)

6/9/20 Reference added. Cervella device added to Regulatory Status section. Specialty Matched Consultant Advisory Panel review 5/20/2020. (bb)

6/1/21 Reference added. Related policy added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/19/2021. (sk)

6/14/22 Reference added. Regulatory Status updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/18/2022. (sk)

9/30/22 Added code A4596 to Billing/Coding section. (sk)

12/30/22 Added code 0783T to Billing/Coding section. (sk)

6/30/23 References added. Specialty Matched Consultant Advisory Panel review 5/17/2023. (sk)