BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation

Policy #: 021
Latest Review Date: February 2022
Category: DME/Medical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **cranial electrical therapy stimulation (also known as cranial electrostimulation therapy or CES)** as a **non-covered** benefit and as **investigational**.

Blue Advantage will treat **electrical stimulation of auricular acupuncture points** as a **non-covered** benefit and as **investigational.**

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcraial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid process, 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 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.

Interest in cranial electrotherapy stimulation (CES) began in the early 1900s with the theory that weak pulses of electrical current would lead to 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 a variety of psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in the brain networks by direct action in the hypothalamus, limbic system and/or the reticular activation 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.

KEY POINTS:

The most recent literature review was updated through December 10, 2021.

Summary Of Evidence:

Cranial Electrotherapy Stimulation

For individuals who have acute or chronic pain, who receive cranial electrotherapy stimulation, the evidence includes a number of randomized, small sham-controlled trials, along with several systematic reviews and pooled analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Three trials studied headache and CES and 5 trials studied chronic pain and CES. Pooled analyses found marginal benefits for headache with CES and no benefits for chronic pain with CES. 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 (e.g., depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and a systematic review. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four randomized controlled trials (RCTs) evaluated CES for depression and anxiety. Only 1 RCT found a significant benefit with CES for depression, but it had important relevance gaps. 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 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 (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 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 1 systematic review. 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 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 2 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 that the technology results in an improvement in the net health outcome.

Practice Guidelines And Position Statements:
No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations:
Not applicable.

KEY WORDS:

Cranial electrotherapy stimulation (CES), cranial electrical stimulation, transcranial electrical stimulation, electrical stimulation therapy, Alpha-Stim®, Auricular electrostimulation, Stim™, E-pulse™, NSS-2 Bridge, Bridge Neurostimulation system, P-Stim, AcuStim, Stivax system, Ansistem-Pp, Cervella,AXUS ES-5, Drug Relief V1, Sparrow Therapy

APPROVED BY GOVERNING BODIES:

A number of devices for cranial electrotherapy stimulation (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. Those devices cleared since 2000 are summarized in Table 1.

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

Device Name	Manufacturer	Date Cleared	Indications
Cervella	Innovative Neurological Devices	2019	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	2009	Insomnia, depression, anxiety
Elexoma Medic™	Redplane AG	2008	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness	2007	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical	2006	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	2003	Insomnia, depression, anxiety

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing through the 510(k) process. Those cleared since 2000 are summarized in Table 2.

Table 2: Cranial Electrotherapy Stimulation Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Year Cleared	Indications
AXUS ES-5 Electro-AcupunctureDevice	Lhasa OMS, INC.	02/03/2021	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1	DyAnsys Inc	11/05/2021	Reduce symptoms of opioid withdrawl

Sparrow Therapy System	Spark Biomedical, Inc	01/02/2021	Reduce symptoms of opioid withdrawal
Drug Relief	DyAnsys Inc	05/02/2018	Reduce symptoms of opioid withdrawal
Ansistem-Pp	DyAnsys Inc	2017	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	2017	Substance use disorders
Stivax System	Biegler	2016	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
ANSiStim®	DyAnsys, Inc	2015	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Pantheon Electrostimulator	Pantheon Research	2014	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Electro Auricular Device	Navigant Consulting, Inc	2014	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Biegler GMBH	2014	Practice of acupuncture by qualified practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	2013	Practice of acupuncture by qualified practitioners as determined by the states

JiaJian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	2013	Practice of acupuncture by qualified practitioners as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	2010	Unknown - Summary not provided
Electro-Acupuncture: Aculife/Model ADOC-01	Inno-Health Technology, Inc	2010	Practice of acupuncture by qualified practitioners as determined by the states
e-Pulse®	AMM Marketing	2009	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Model ES-130	Ito Co., LTD	2008	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
P-Stim™	NeuroScience Therapy Corp.	2006	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Aculife	Inno-Health, Technology	2006	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
AcuStim	S.H.P. International	2002	As an electroacupuncture device

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

The manufacturers are encouraging the suppliers to use procedure code E0730 TENS four lead, larger area/multiple nerve stimulation.

Please note that E0730 is not the correct code to report cranial electrical devices.

CPT:

97813	Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97814	; with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with reinsertion of needle(s) (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system

HCPCS:

A4596	Cranial electrotherapy stimulation (ces) system supplies and accessories, per month (Effective 10/01/22)
E1399	Durable Medical Equipment Miscellaneous
K1002	Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type
S8930	Electrical stimulation of auricular acupuncture points; each 15 Minute of personal one-on-one contact with the patient

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POLICY HISTORY:

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Medical Policy Group, February 2006
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Medical Policy Group, July 2018 **(6)**: Added coding 64999.
Medical Policy Group, February 2019
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Medical Policy Group, September 2022: 2022 Quarterly Coding Update, added new HCPCS code A4596 to the Current Coding section.

common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.