MEDICAL POLICY

POLICY TITLE	CRANIAL ELECTROTHERAPY STIMULATION (CES) AND AURICULAR ELECTROSTIMULATION
POLICY NUMBER	MP-2.092

Original Issue Date (Created):	**6/1/2013**
Most Recent Review Date (Revised):	**7/1/2020**
Effective Date:	**10/1/2020**

I. POLICY

Cranial electrotherapy stimulation (also known as cranial electrostimulation therapy or CES) is **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Electrical stimulation of auricular acupuncture points is **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:
MP-6.020 Transcutaneous Electrical Nerve Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO- Refer to FEP Benefit Brochure for information on CRANIAL ELECTROTHERAPY STIMULATION (CES) AND AURICULAR ELECTROSTIMULATION:
https://www.fepblue.org/benefit-plans/benefit-plans-brochures-and-forms
Note* - The Federal Employee Program (FEP) Service Benefit Plan does not have a medical policy related to these services.

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III. DESCRIPTION/BACKGROUND

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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 and weight loss.

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 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 have been developed that 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 3 auricular acupuncture points. The P-Stim™ device connects to 3 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 cranial electrotherapy stimulation 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. FDA product code: JXK.

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Table 1: FDA-Cleared Devices for Cranial Electrotherapy Stimulation

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Device Name	Manufacturer	Year Cleared	**510(k) No**	Indications
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare (Boranada, India)	5/29/2009	K090052	Insomnia, depression, anxiety
Elexoma Medic™	Redplane AG (Zug, Switzerland)	5/21/2008	K070412	Insomnia, depression, anxiety
CES Ultra™	Neuro-Fitness (Snoqualmie, WA)	4/5/2007	K062284	Insomnia, depression, anxiety
Net-2000 Microcurrent Stimulator	Auri-Stim Medical (Boulder, CO)	10/13/2006	K060158	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific (San Carlos, CA)	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 through the 510(k) process. Devices cleared since 2000 are summarized in Table 2. FDA product code: BWK, PZR.

Table 2. Cranial Electrotherapy Stimulation (CES) Devices Cleared by the US Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
Drug Relief	DyAnsys Inc	05/02/2018	K173861	Reduce symptoms of opioid withdrawal
NSS-2 Bridge	Innovative Health Solutions	2017		Substance use disorders
Stivax System	Biegler Gmbh	05/26/2016	K152571	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim®	DyAnsys Inc	05/15/2015	K141168	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®	Medevice Corporation	12/07/2009	K091875	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim™	Neuroscience Therapy Corp.	03/30/2006	K050123	Practice of acupuncture by qualified practitioners as determined by the states
AcuStim	S.H.P. Intl. Pty., Ltd.	06/12/2002	K014273	As an electroacupuncture device

FDA: Food and Drug Administration.

IV. RATIONALE

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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 5 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 (eg, 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 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 (eg, acute pain from surgical procedures, chronic back pain, and 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 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 the effects of the technology on health outcomes.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member’s health benefit plan governs which services are covered, which are

excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

CPT Codes®								
64999								

HCPCS Code	Description
K1002	Cranial electrotherapy stimulation (ces) system, includes all supplies and accessories, any type
S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with patient

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.092	**CAC 1/29/13 New policy.** BCBSA adopted. Both cranial electrotherapy Stimulation (CES) and auricular electrostimulation are considered investigational. FEP variation added. Policy coded 11/13/12
	CAC 1/28/14 Consensus. No change to policy statements. Rationale section added. References updated.
	CAC 1/27/15 Consensus review. No changes to the policy statements. References and rationale updated**.** Codes reviewed.
	6/22/15 Administrative update. Corrected rationale section.
	1/26/16 Consensus review. No change to policy statements. References and rationale updated**.** Coding reviewed.
	9/23/16 Administrative update. Medicare update. Added LCA A55240 Auricular Peripheral Nerve Stimulation (Electro-Acupuncture) to reference list. Coding reviewed.
	11/10/16 Administrative update. Variation Reformatting
	CAC 1/31/17 Consensus review. No change to policy statements. Rationale and references updated. Coding Reviewed.
	12/1/17 Consensus review. No change to policy statements. References and rationale updated. Coding Review completed 3/13/18.
	11/12/18 Consensus review. No change to the policy statements. References updated. Rationale revised**.**
	8/15/2019 Consensus Review. Policy statement unchanged. Tables under Background/Description section updated. References Updated.
	1/1/2020 Administrative update. Added new code K1002.
	07/1/2020 Consensus review. No changes. References updated and coding reviewed.

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