MEDICAL POLICY

POLICY TITLE	**CRANIAL ELECTROTHERAPY STIMULATION AND AURICULAR ELECTROSTIMULATION**
POLICY NUMBER	**MP 2.092**

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective date:	**7/1/2026**

POLICY

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

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

Cross-References:
MP 2.397 Percutaneous Electrical Nerve Field Stimulation for Irritable Bowel Syndrome
MP 6.020 Transcutaneous Electrical Nerve Stimulation
MP 6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT)

PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

DESCRIPTION/BACKGROUND

The 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, provide ambulatory auricular electrical stimulation over a period of several days. Cranial electrotherapy stimulation 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 3 auricular acupuncture points. The P-Stim device connects to 3 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: QJQ.

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

Device Name	Manufacturer	Year Cleared	510(k) No	Indications
Modius Stress	Neurovalens Limited	3/27/2024	K232253	Anxiety
Modius Sleep	Neurovalens Limited	10/27/2023	K230826	Insomnia
Cervella™	Innovative Neurological Devices	03/07/2019	K182311	Insomnia, depression, anxiety

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

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. Auricular Electrostimulation Devices Cleared by the US Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
NET Device™	Net Recovery	05/29/2024	K233166	Reduce symptoms of opioid withdrawal
Sparrow Ascent	Spark Biomedical, Inc	6/20/2023	K230796	Reduce symptoms of opioid withdrawal
Drug Relief v1	DyAnsys, Inc	6/6/2022	K221231	Reduce symptoms of opioid withdrawal
Needle Stimulator	Bozhou Rongijan Medical Appliance Co., Ltd	3/18/2022	K220153	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
Needle Stimulator	Wuxi Jiajian Medical Instrument	8/27/2021	K202861	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
AXUS ES-5 Electro-Acupuncture Device	Lhasa OMS, INC.	02/03/2021	K200636	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1	DyAnsys Inc	11/05/2021	K211971	Reduce symptoms of opioid withdrawal
Sparrow Therapy System	Spark Biomedical, Inc.	01/02/2021	K201873	Reduce symptoms of opioid withdrawal
Drug Relief	DyAnsys Inc	05/02/2018	K173861	Reduce symptoms of opioid withdrawal
Ansistem-Pp	DyAnsys Inc	03/09/2017	K170391	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	2017	N/A[a]	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

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
				practitioners as determined by the states
Pantheon Electrostimulator	Pantheon Research	1107/2014	K133980	Practice of acupuncture by qualified practitioners as determined by the states
Electro Auricular Device	Navigant Consulting, Inc.	10/02/2014	K140530	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Biegler GMBH	06/27/2014	K140788	Practice of acupuncture by qualified practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	08/16/2013	K130768	Practice of acupuncture by qualified practitioners as determined by the states
JiaJian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	04/11/2013	K122812	Practice of acupuncture by qualified practitioners as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	08/05/2010	K093322	Unknown - Summary not provided
Electro-Acupuncture: Aculife/Model ADOC-01	Inno-Health Technology, Inc.	04/02/2010	K091933	Practice of acupuncture by qualified practitioners as

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
				determined by the states
e-Pulse	Medevice Corporation	12/07/2009	K091875	Practice of acupuncture by qualified practitioners as determined by the states
Model ES-130	Ito Co., Ltd.	11/24/2008	K081943	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
Aculife	Inno-Health Technology, Inc.	03/28/2006	K051197	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

[a] "FDA cleared the NSS-2 Bridge Device for Substance Use Disorders through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed predicate device to which the device can claim substantial equivalence"
N/A: Not applicable

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RATIONALE

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 trial, 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 (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 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 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, 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.

DEFINITIONS

NA

DISCLAIMER

Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

CODING INFORMATION

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:

Procedure Codes								
A4543	A4596	E0721	E0732	S8930	0783T	64999		

REFERENCES

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marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal. November 15, 2017. Accessed January 9, 2025.

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POLICY HISTORY

MP 2.092	**08/15/2019 Consensus Review**. Policy statement unchanged. Tables under Background/Description section updated. References Updated.
	01/01/2020 Administrative Update. Added new code K1002.
	07/01/2020 Consensus Review. No changes. References updated and coding reviewed.
	03/10/2021 Consensus Review. No changes to policy statement. References updated and coding reviewed. Background/Description section updated.
	05/27/2021 Consensus Review. Added new codes K1016 and K1017, updated Background/Description and References
	09/20/2021 Minor Review. Added Percutaneous Electrical Nerve Field Stimulator to MP as NMN. Added CPT code 64999 and HCPC code E1399 as NMN for treatment of functional abdominal pain.
	05/11/2022 Consensus Review. Updated coding and references.
	06/10/2022 Administrative Update. Added procedure code 0720T effective 07/01/2022.

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	09/12/2022 Administrative Update. Added procedure code A4596 effective 10/01/2022.
	11/29/2022 Administrative Update. Added procedure code 0783T
	04/06/2023 Consensus Review. Updated background, rationale, and references.
	11/29/2023 Minor Review. Added MN criteria for the IB-stim device. Updated background, rationale, coding table, and references.
	12/12/2023 Administrative Update. Deleted K1002, K1016, K1017. Added E0732-E0733.
	04/17/2024 Consensus Review. Updated background, rationale, and references. No changes to coding.
	09/03/2024 Administrative Update. Revised description of K58.9 per New Code Process. Effective 10/01/2024.
	09/18/2024 Administrative Update. New codes A4543, E0721 effective 10/01/2024.
	06/30/2025 Minor Review. Title change; formerly Percutaneous Electrical Nerve Field Stimulation, Cranial Electrotherapy Stimulation, Auricular Electrostimulation, and External Trigeminal Nerve Stimulation. Removed PENFS statement and associated code and placed into New Policy MP 2.397. Removed trigeminal nerve statement and code as this device is already addressed in MP 6.020. Updated all sections.
	03/09/2026 Consensus Review. No changes to coding.