MEDICAL POLICY

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

Effective Date:	1/1/2024

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.

External trigeminal nerve stimulation to treat ADHD is considered **investigational** as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Percutaneous Electrical Nerve Field Stimulator (PENFS) for the treatment of functional abdominal pain is considered **not medically necessary**.

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 Blue Cross and subject to benefit variations as discussed in Section VI. 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

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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, 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 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 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.

Percutaneous Electrical Nerve Field Stimulation (PENFS) has been proposed as a treatment of functional abdominal pain secondary to inflammatory bowel disease in children and adolescents. The IB-Stim is intended to be used for 120 hours per week up to 3 consecutive weeks, through application to auricular branches of cranial nerves V, VII, IX, and X, and the occipital nerves identified by transillumination. Once the desired neurovascular bundles are visualized by transillumination, the electrode needle is secured and implanted percutaneously with gentle pressure. The four-needle electrode array, attached to the white wire, is placed on the ventral side of the ear lobe.

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. 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
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
Needle Stimulator	Wuxi Jiajian Medical Instrument	8/27/2021	K202861	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states

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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 practitioners as determined by the states
Pantheon Electrostiumulator	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 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

In 2019, the FDA permitted marketing of the first medical device to treat attention deficit hyperactivity disorder (ADHD) - the Monarch® external Trigeminal Nerve Stimulation (eTNS) System by NeuroSigma.[7,] The FDA reviewed the system through the de novo premarket review pathway. This prescription only TENS device is indicated for patients 7 to 12 years of age who are not currently taking prescription ADHD medication. The Monarch eTNS System is intended to be used in the home under the supervision of a caregiver. The device generates a low-level electrical pulse and connects via a wire to a small patch that adheres to a patient's forehead, just above the eyebrow.

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 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 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, 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.

External trigeminal nerve stimulation

For individuals who have attention deficit hyperactivity disorder (ADHD) who receive external trigeminal nerve stimulation, the evidence includes one RCT. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the RCT concluded that TENS is an effective and safe treatment option for pediatric patients with ADHD. However, the study included a small patient sample and was of short duration. Further studies comparing TENS to standard of care therapy for ADHD are needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Percutaneous Electrical Nerve Field Stimulation (PENFS)

For children and adolescents who have functional abdominal pain secondary to inflammatory bowel disease, the evidence includes small RCTs. While initial findings of the Kovacic (2017) RCT are promising, additional studies are necessary to confirm the results of the study. Given the chronic nature of abdominal pain-related functional gastrointestinal disorders, a longer assessment period is also needed to determine the durability of efficacy. Additionally, the clinical significance of the purported effects of the PENFS is difficult to assess based on current findings.

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 Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross'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 Blue Cross' Provider Services or Member Services. Capital Blue Cross 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.

Not medically necessary for the treatment of functional abdominal pain:

Procedure Codes								
E1399	64999	0720T						

Investigational; therefore, not covered for all other indications:

Procedure Codes								
A4596	E0732	E0733	S8930	64999	0783T			

IX. REFERENCES

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X. POLICY HISTORY

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MP 2.092	**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.
	3/10/2021 Consensus review. No changes to policy statement. References updated and coding reviewed. Background/Description section updated.
	5/27/2021 Added new codes K1016 and K1017, updated Background/Description and References
	9/20/2021 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.
	5/11/2022 Consensus review. Updated coding and references.
	6/10/2022 Administrative update. Added procedure code 0720T effective 7/1/2022.
	9/12/2022 Administrative update. Added procedure code A4596 effective 10/1/2022.
	11/29/2022 Administrative update. Added procedure code 0783T
	4/6/2023 Consensus review. Updated background, rationale, and references.
	12/12/23 Administrative review. Deleted K1002, K1016, K1017. Added E0732-E0733.

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