MEDICAL POLICY

Medical Policy Title	**Cranial and Auricular Neuromodulation**
Policy Number	**1.01.58**
Current Effective Date	**January 1, 2027**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

This policy does not address cranial electrotherapy stimulation for the treatment of behavioral health conditions, or implantable vagus nerve stimulation and vagus nerve blocking therapy.

POLICY STATEMENT(S)

I. The following neuromodulation types are **investigational**:

A. Cranial Electrical Stimulation; (also known as transcranial electrical stimulation [tES] or cranial electrotherapy stimulation for pain (e.g., Alpha Stim-AID, Carvella, CES Ultra);

B. External Trigeminal Nerve Stimulation (eTNS) (e.g., Monarch);

C. Transcutaneous/Non-Implantable Vagus Nerve Stimulation (tVNS) (e.g., GammaCore Sapphire);

D. Transcutaneous Supraorbital Neurostimulation (e.g., Cefaly);

E. Auricular Electrostimulation, including Percutaneous Electrical Nerve Field Stimulation (PENFS) and Transcutaneous Nerve Field Stimulation (e.g., P-Stim, IB-Stim, NSS-2 Bridge device).

RELATED POLICIES

Corporate Medical Policies

1.01.59 Electromagnetic and Pulsed Field Stimulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

1.01.62 Specialized Neuromodulation for Specific Conditions

3.01.09 Transcranial Magnetic Stimulation and Cranial Electrotherapy Stimulation

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

External Trigeminal Nerve Stimulation (eTNS)

The Monarch eTNS system, (NeuroSigma) is classified as a transcutaneous electrical nerve stimulator for attention deficit hyperactivity disorder device type. It is designed to generate and deliver electrical pulses to the trigeminal nerve, which directs signals to the parts of the brain that are believed to be associated with ADHD. The device is connected to a small patch that adheres to a patient's forehead. It is meant for at-home use during sleep and requires caregiver supervision.

Transcutaneous Supraorbital Neurostimulation

The Cefaly device (CEFALY Technology) received FDA approval for the prophylactic treatment of migraines in patients ages 18 years and older. Cefaly is a small, portable, battery-powered, prescription device that resembles a plastic headband worn across the forehead and atop the ears. The user positions the device in the center of the forehead, just above the eyes, using a self-adhesive electrode. The device applies an electric current to the skin and underlying body tissues to stimulate branches of the trigeminal nerve, which has been associated with migraine headaches. The user may feel a tingling or massaging sensation where the electrode is applied. The device should only be worn daily for 20 minutes.

Cranial Electrical Stimulation (CES)

CES is also known as cranial electrotherapy, transcranial electrical stimulation, or electrical stimulation therapy. The most common CES device in the United States, is the Alpha Stim products. Alpha Stim-AID, and Alpha-Stim M is a handheld prescription device that delivers an electronic microcurrent through electrodes placed further from the brain (i.e., earlobes, scalp, eyelids) and delivers a pulsed, low-intensity current to stimulate specific groups of nerve cells. Although the exact mechanism of action is unknown, CES has been approved by the FDA for the treatment of insomnia, depression, and anxiety. The user can select the level of stimulation and increase or reduce as needed, typically for 20- minute sessions. CES is being evaluated for a variety of other conditions including pain, and functional constipation.

Transcutaneous/Non-Implantable Vagus Nerve Stimulation (tVNS)

tVNS is a medical treatment that involves delivering electrical impulses to the auricular or cervical branch of the vagus nerve. It has been proposed as an adjunctive treatment for certain types of treatment-resistant depression, tinnitus, diabetes, endotoxemia, memory, myocardial infarction, headache, pain, intractable epilepsy, and stroke.

The gammaCore-S (electroCore LLC) is a noninvasive vagus nerve stimulation device for the acute treatment of adults with episodic cluster headaches. When the device is applied to the side of the neck by the patient, a mild electrical stimulation of the vagus nerve is carried to the central nervous system. Each stimulation using gammaCore-S lasts two minutes. The patient controls stimulation strength. In 2021, the gamma-Core Sapphire received additional approval for indications for use including the preventative treatment of migraine headache in adolescent (age 12 and older) and

adult patients, the acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients, and for the adjunctive use for the preventative treatment of cluster headache in adults.

Auricular Electrostimulation

Electrical stimulation of auricular acupuncture points, or auricular electrostimulation, involves the stimulation of acupuncture points on the ear. Auricular electrostimulation has been proposed for the treatment of a variety of conditions, including pain, depression, and anxiety. Devices have been developed that provide electrical stimulation to auricular acupuncture sites over a period of several days.

The P-Stim (NeuroScience Therapy Corporation) 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.

The E-pulse, or Electro Acupuncture device, is a microprocessor-controlled, battery-powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96-hour period.

Percutaneous Electrical Nerve Field Stimulation (PENFS)

Auricular PENFS is a variation of peripheral electrical nerve stimulation (PENS) in that it uses a low-frequency electrical current to stimulate the skin and underlying tissues in a general area of pain rather than targeting a specific nerve. PENFS devices are thought to work by sending electrical stimulation of peripheral cranial neurovascular bundles in the external ear to help modulate central pain pathways, however, the exact mechanism responsible for the analgesic effects remains unknown. PENFS involves a nonimplantable device that stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal and neuropathic pain conditions, and patients with opioid withdrawal.

The NSS-2 Bridge device (Innovative Health Solutions, Inc.) is a small electrical nerve stimulator placed behind the ear that emits electrical pulses to stimulate branches of certain cranial nerves, which may provide relief from opioid withdrawal symptoms. This device was approved for use in reducing the symptoms of opioid withdrawal.

The IB-Stim (Innovative Health Solutions, Inc.) is a disposable, battery-powered, percutaneous electrical nerve field stimulator (PENFS) system placed behind the ear. The device has four percutaneously placed electrodes (three frontal and one dorsal) applied to auricular areas innervated by branches of four cranial nerves (CN V, VII, IX, and X). It is intended for patients 11-18 years old with functional abdominal pain disorders (FAPD) associated with irritable bowel syndrome (IBS). The device is to be used 120 hours per week for three consecutive weeks.

SUPPORTIVE LITERATURE

External Trigeminal Nerve Stimulation (eTNS)

McGough et al (2019) assessed the efficacy and safety of eTENS in a double-blind, sham-controlled pilot study of pediatric patients with attention deficit hyperactivity disorder (ADHD). The study was a four -week trial followed by one blinded week without intervention. Clinical assessments included weekly clinician-administered ADHD-Rating and Clinical Global Impression (CGI) scales, and quantitative electroencephalography (EEG) at baseline as well as at week four. The primary outcome measure was the clinician completed ADHD-Rating Scale total score. Results revealed that ADHD-Rating Scale totals showed significant group-by-time interactions, demonstrating a differential treatment effect ($F=8.12$; $df=1/228$; $p=.005$). The CGI-Improvement scale also favored active treatment over sham ($p=.003$). Quantitative EEG readings were obtained in both groups but there were no participant specific correlations to other outcomes. No serious adverse events were observed in either group, and no patient withdrew from the study due to adverse events. Significant increases in weight and pulse were seen with active eTENS over the trial period; however, no differences between active and sham eTENS with regard to blood pressure were seen. Conclusions were that eTENS therapy is efficacious and well-tolerated in pediatric patients with ADHD. Limitations cited were the small sample size and relatively short duration of treatment and follow-up.

Transcutaneous Supraorbital Neurostimulation

Schoenen et al (2013) reported the results from the Prevention of Migraine (PREMICE) trial, a multi-center, randomized, sham controlled trial. They assessed the efficacy and safety of supraorbital transcutaneous neurostimulation (STNS) in migraine prophylaxis with the Cefaly device. The trial consisted of 67 patients randomized to receive the Cefaly device or sham treatment daily for 20 minutes for three months. After the first month of treatment both the treatment and sham groups showed a decrease in migraine days by an average of 20%. This decrease disappeared in the sham group by the second and third month but continued in the treatment group. The 50% responder rate was greater in the treatment group, and the therapeutic gain of effective stimulation over sham was 26%. The monthly attack frequency from the first to the third month was reduced by 18.8% in the treatment group and by only 3.5% in the sham group. Headache severity and the monthly intake of anti-migraine medications was also reduced in the treatment group. No adverse events or side effects were found for either the treatment or sham group. Compliance was moderately satisfactory in both groups. The responder rate for electrical stimulation was within the range of those reported for other migraine treatment modalities. However, the study size was small, and the individuals in the selected cohort were not severely disabled by their migraines.

Cranial Electrical Stimulation (CES)

CES has been investigated for individuals with headache, chronic pain, depression, and Parkinson disease. Trials that studied headache found only marginal benefits. Trials studied for chronic pain did not show a benefit. The evidence for the use of CES for psychiatric, behavioral, or neurologic conditions include a systematic review and a number of small sham controlled randomized controlled trials (RCTs), only one of which (Barclay 2014) found a significant benefit for its use in depression, but the sample size was small with strong potential placebo effects. Additionally, studies had significant heterogeneity in study populations and treatment protocols.

Ahn et al (2020) published a double-blind, randomized, sham-controlled pilot study of the feasibility and efficacy of remotely supervised CES via secure videoconferencing in 30 older adults with chronic pain due to knee osteoarthritis. Mean age was 59.43 years. CES was delivered via the Alpha-Stim M Stimulator, which was preset at 0.1 mA at a frequency of 0.5 Hz and applied for one hour daily on weekdays for two weeks. The sham electrodes were identical in appearance and placement, but the stimulator did not deliver electrical current. The study was conducted in a single center in Houston. All 30 participants completed the study and were included in the outcome analyses. For the primary outcome of clinical pain at two weeks as assessed by a Numeric Rating Scale, a significantly greater reduction occurred in the active CES group (-17.00 vs. +5.73; p<.01). No patients reported any adverse effects. Important relevancy limitations include lack of assessment of important health outcomes or long-term efficacy. An important conduct and design limitation is that it is unclear how convincing the sham procedure was as it did not involve any feature designed to simulate a tingling sensation and give the patient the feeling of being treated (i.e., subtherapeutic amplitude, initial current slowly turned to zero). Therefore, findings may be subject to the placebo effect. This trial was also limited by the small number of participants. These limitations preclude drawing conclusions based on these findings.

Wu et al (2020) published a double-blind, randomized, sham-controlled trial of the efficacy and safety of CES as an add on treatment for tic disorders in 62 children and adolescents who lacked a clinical response to prior treatment of four weeks of pharmacotherapy. Cranial electrotherapy stimulation was delivered via the CES Ultra stimulator (American Neuro Fitness LLC) at 500 µA-mA and applied for 30 minutes daily on weekdays for 40 days. The sham CES was delivered at lower than 100 µA. The study was conducted at a single academic medical center in China. A total of nine participants (14.5%) discontinued the intervention early and were excluded from the analyses. There was no significant difference between the active CES and sham groups in the change in Yale Global Tic Severity Scale (YGTSS) score (-31.66% vs. 23.96%; p=.13).

Transcutaneous Vagus Nerve Stimulation (tVNS)

The evidence for tVNS stimulation in individuals who have epilepsy, depression, schizophrenia, headache, or impaired glucose tolerance includes at least one randomized controlled trial and case series for some of the conditions. The RCTs are small and have various methodologic problems. Definitive efficacy of tVNS in improving outcomes among patients has not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

Percutaneous Electrical Nerve Field Stimulation (PENFS)

Kovacic et al (2017) conducted an RCT comparing the Neuro-Stim PENFS device with a sham device in adolescent patients with abdominal pain-related functional gastrointestinal disorders including IBS. Patients 11 to 18 years of age with abdominal pain (pain score ≥3 on an 11-point scale) occurring at least twice weekly for at least two (2) months were included. The devices were worn for five (5) days each week for four (4) weeks. Baseline medications were continued except for antispasmodics which were not allowed during the study period. Enrolled patients were primarily female (91%) and White (90%). Pain, as measured on the Pain Frequency-Severity-Duration (PFSD), was the primary outcome. The PFSD scale incorporates several aspects of the pain experience and is generally calculated over 14 days but was modified as a weekly score in this trial with a high composite score

of 70. Both "worst pain" and median PFSD composite scores were better with PENFS than placebo. The Symptom Response Scale (-7 to +7 [with negative scores as worse and positive scores as better]) was used to assess the overall symptoms. Although the authors reported statistically significantly improved scores with the Neuro-Stim device at 3 weeks, numerical differences between groups were small. Longer-term pain scores obtained at a median of 9.2 weeks after treatment remained improved from baseline in the active treatment group with a decrease of composite PFSD scores of -8.4 compared with 0.0 in the sham group. Adverse events including ear discomfort and adhesive allergy were similar between groups. The study is limited by the small sample size, the heterogeneous population of gastrointestinal disorders, the lack of bowel habit measurement, and the short duration of follow-up. Krasaelap et al (2020) evaluated a subgroup of 50 patients with IBS from the Kovacic et al (2017) RCT. At three (3) weeks there were more responders with the active treatment (response defined as ≥30% reduction in worst abdominal pain) than with the sham device. At the extended follow-up (8-12 weeks), the percentage of responders was similar between groups (32% vs. 18%; p=.33).

PROFESSIONAL GUIDELINE(S)

In 2024, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition/North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Guideline Development Group (ESPGHAN/NASPGHAN GDG) published recommendations for the treatment of abdominal pain-related disorders of gut-brain interaction such as irritable bowel syndrome and functional abdominal pain-not otherwise specified in children, based upon a systematic review and comprehensive synthesis of the available literature. After evaluation of the benefits and harms of PENFS, the GDG made a conditional recommendation with a moderate certainty of evidence for its use in the reduction of pain intensity. The GDG acknowledged that the recommendation came from a single-institution study, and that the treatment comes at a relatively high initial cost, requiring weekly new device placement for the entirety of the treatment course.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 26]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 26]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0783T (E/I)	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
64567 (E/I)	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (e.g., IB-Stim) (Effective 1/1/26)

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HCPCS Codes

Code	Description
A4541	Monthly supplies for use of device coded at E0733
A4543 (E/I)	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4596 (E/I)	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
E0720 (*E/I)	TENS, two lead, localized stimulation (*E/I when used for Cefaly device)
E0721 (E/I)	Transcutaneous electrical nerve stimulator for nerves in the auricular region (e.g., Sparrow Ascent)
E0732 (E/I)	Cranial electrotherapy stimulation (CES) system, any type
E0733 (E/I)	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve (e.g., Monarch, Cefaly)
E0735 (E/I)	Noninvasive Vagus Nerve Stimulator

ICD10 Codes

Code	Description
F10.10-F10.99	Alcohol related disorders (code range)
F11.10-F11.99	Opioid related disorders (code range)
F12.10-F12.99	Cannabis related disorders (code range)
F13.10-F13.99	Sedative, hypnotic, or anxiolytic related disorders (code range)
F14.10-F14.99	Cocaine related disorders (code range)
F15.10-F15.99	Other stimulant related disorders (code range)

Code	Description
F16.10-F16.99	Hallucinogen related disorders (code range)
F17.200-F17.299	Nicotine dependence (code range)
F18.10-F18.99	Inhalant related disorders (code range)
F19.10-F19.99	Other psychoactive substance related disorders (code range)
G43.001-G43.019	Migraine without aura (code range)
G43.101-G43.419	Migraine with aura (code range)
G43.701-G43.719	Chronic migraine without aura (code range)
G43.B0-G43.B1	Ophthalmoplegic migraine (code range)
G43.801-G43.919	Other types of migraines (code range)
G44.1	Vascular headache, not elsewhere classified
G44.201-G44.209	Tension-type headache, unspecified (code range)
G44.211-G44.219	Episodic tension-type headache (code range)
G44.221-G44.229	Chronic tension-type headache (code range)
G44.301-G44.309	Post-traumatic headache, unspecified (code range)
G44.321-G44.329	Chronic post-traumatic headache (code range)
G46.0-G46.8	Vascular syndromes of brain in cerebrovascular diseases (code range)
G50.0-G50.9	Disorders of trigeminal nerve (code range)
G51.2-G51.9	Facial nerve disorders (code range)
G56.00-G56.03	Carpal tunnel syndrome (code range)
H92.01-H92.09	Otalgia (code range)
I67.2	Cerebral atherosclerosis
I67.81-I67.82	Other specified cerebrovascular diseases (code range)
I67.89	Other cerebrovascular disease
I67.9	Cerebrovascular disease, unspecified
I68.0	Cerebral amyloid angiopathy
I68.8	Other cerebrovascular disorders in diseases classified elsewhere
J30.1-J30.9	Allergic rhinitis (code range)
K58.0-K58.9	Irritable bowel syndrome (code range)
K91.0	Vomiting following gastrointestinal surgery
M15.0-M15.9	Polyosteoarthritis (code range)
M16.0-M16.9	Osteoarthritis of hip (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M18.0-M18.9	Osteoarthritis of first carpometacarpal joint (code range)

Code	Description
M19.011-M19.079	Primary osteoarthritis (code range)
M19.111-M19.179	Post-traumatic osteoarthritis (code range)
M19.211-M19.279	Secondary osteoarthritis (code range)
M19.90-M19.93	Osteoarthritis, unspecified site (code range)
M25.50-M25.579	Pain in joint (code range)
M26.621-M26.629	Arthralgia of temporomandibular joint (code range)
M43.26-M43.28	Fusion of spine (code range)
M43.8x6-M43.8x9	Other specified deforming dorsopathies (code range)
M51.16-M51.17	Intervertebral disc disorders with radiculopathy (code range)
M53.1	Cervicobrachial syndrome
M53.2x7	Spinal instabilities, lumbosacral region
M53.2x8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies (code range)
M53.9	Dorsopathy, unspecified
M54.06-M54.09	Panniculitis affecting regions of neck and back (code range)
M54.16-M54.18	Radiculopathy (code range)
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.5	Low back pain
M60.80-M60.9	Other myositis (code range)
M62.830	Muscle spasm of back
M77.10-M77.12	Lateral epicondylitis (code range)
M79.0	Rheumatism, unspecified
M79.10-M79.18	Myalgia (code range)
M79.2	Neuralgia and neuritis, unspecified
M79.601-M79.676	Pain in limb, hand, foot, fingers and toes (code range)
M79.7	Fibromyalgia
N64.4	Mastodynia
N94.4-N94.6	Dysmenorrhea (code range)
O21.0-O21.9	Excessive vomiting in pregnancy (code range)
R51	Headache
T45.1x5A-T45.1x5S	Adverse effect of antineoplastic and immunosuppressive drugs (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cranial and Auricular Neuromodulation are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date