

# MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Acupuncture and Auricular Electrostimulation
Policy Number	8.01.20
Category	Contract Clarification
Original Effective Date	11/29/01
Committee Approval Date	01/23/03, 03/25/04, 04/28/05, 04/27/06, 04/26/07, 04/24/08, 04/23/09, 04/29/10, 04/28/11, 06/28/12, 04/25/13, 04/24/14, 04/23/15, 04/28/16, 06/22/17, 04/26/18, 04/25/19, 04/23/20, 04/22/21, 04/21/22, 04/20/23, 04/18/24
Current Effective Date	04/18/24
Archived Date	
Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> <li>• Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.</li> <li>• 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.</li> <li>• If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.</li> <li>• If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.</li> </ul>

## POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, needle acupuncture (manual or electroacupuncture) is considered **medically appropriate** when performed by an individual state licensed to perform acupuncture and when performed for **ANY** of the following diagnoses:
  - A. adult postoperative nausea and vomiting;
  - B. chemotherapy-related nausea and vomiting;
  - C. pregnancy-related nausea and vomiting;
  - D. carpal tunnel syndrome;
  - E. fibromyalgia;
  - F. headache;
  - G. low back pain;
  - H. menstrual pain;
  - I. myofascial pain;
  - J. osteoarthritis;
  - K. tennis elbow.
- II. Based upon our criteria and assessment of the peer-reviewed literature, acupuncture for patients undergoing rehabilitation following cerebral vascular accidents (stroke) is considered **not medically necessary** as the efficacy of the treatment has not been proven.
- III. Based upon our criteria and assessment of the peer-reviewed literature, acupuncture for **ALL** other conditions, including, but not limited to, the following, has not been medically proven to be effective and, therefore, is considered **investigational**:
  - A. allergic rhinitis;

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- B. irritable bowel syndrome;
- C. substance (e.g., alcohol, cocaine) use disorders.

- IV. Based upon our criteria and assessment of the peer-reviewed literature, electrical stimulation of auricular acupuncture points/auricular electrostimulation has not been medically proven to be effective and, therefore, is considered **investigational**.
- V. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous electrical nerve field stimulation, has not been medically proven to be effective and, therefore, is considered **investigational** for all indications, including but not limited to irritable bowel syndrome.

*Refer to Corporate Medical Policy #8.01.12 Physical Therapy (PT)*

*Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services*

### **POLICY GUIDELINES**

Coverage for acupuncture, as well as the number of covered treatments, is contract dependent.

### **DESCRIPTION**

Acupuncture is the practice of piercing the skin with needles at specific body sites, to induce anesthesia, to relieve pain, to alleviate substance withdrawal symptoms, or treat various non-painful disorders. The placement of needles into the skin is dictated by the location of the meridians. These meridians are thought to mark patterns of energy flow throughout the human body. Acupuncture has four components—the acupuncture needle(s), the target location defined by traditional Chinese medicine, the depth of insertion, and the stimulation of the inserted needle. Acupuncture may be performed with or without electrical stimulation. Acupuncture is a traditional form of Chinese medical treatment that has been practiced for over 3,000 years. Treatment involves inserting four to 15 needles at selected acupuncture points, usually for 10 to 30 minutes. Needles are approximately 37-gauge, stainless steel, and disposable. Needles are manipulated with electricity (electroacupuncture), with heat, or manually. It is thought that acupuncture for analgesia stimulates the small-diameter nerve fibers in muscles that enter the dorsal horn of the spinal cord. An impulse is then sent to other levels within the spinal cord, the midbrain, and the hypothalamic-pituitary system, which then release neurotransmitters that cause analgesia. Thus, when practitioners place a needle in the region of pain, all three centers are activated to provide an analgesic effect. Acupuncture is felt to be helpful for patients who have unsuccessfully exhausted conventional treatment modalities, who experience adverse consequences with conventional approaches, who prefer not to take pharmacological agents for their condition, or whose co-morbidities prevent them from utilizing certain drug therapies.

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.

- I. 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 P-Stim received U.S. Food and Drug Administration (FDA) marketing clearance through the 510(k) process in 2006.
- II. 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. The E-pulse received FDA 510(k) marketing clearance in 2009.

### **Percutaneous Electrical Nerve Field Stimulation (PENFS)**

PENFS is a variation of 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

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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 non-implantable 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.

Auricular percutaneous electrical nerve field stimulation uses an FDA-approved device for pain to deliver stimulation to the auricular branches of the cranial nerves, including the vagus nerve. The vagus nerve mediates the sensation of the auricular tissue that makes up the ear; therefore, auricular stimulation has been used to modulate its activity and treat pain. PENFS is an emerging minimally invasive approach to treat patients with chronic abdominal pain. It modulates central pain pathways through stimulation of the auricular branches of cranial nerves after 4-weeks of treatment, with sustained efficacy (Santucci et al., 2023). Several pediatric studies have demonstrated the benefits of PENFS in children with functional abdominal pain disorders (FAPD). Limitations of these studies include small sample sizes and lack of control groups, resulting in insufficient power to make major inferences from some of the studies finding.

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. The FDA cleared this device in 2017 through the *de novo* premarket review pathway 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 proposed for use in patients 11-18 years old with functional abdominal pain associated with irritable bowel syndrome (IBS). The device is intended for use 120 hours per week for three consecutive weeks. The FDA cleared the IB-Stim through the *de novo* premarket review pathway in June 2019. Because there are few pharmacologic treatments for children and adolescents with IBS, nonpharmacologic options are commonly explored. PENFS is a potential treatment option for these patients.

### **RATIONALE**

The FDA regulates the approval of acupuncture needles and requires manufacturers to label the needles for single use only.

Clinical trials have demonstrated good evidence on the effectiveness of acupuncture in studies on headache, pregnancy-induced nausea and vomiting, chemotherapy-induced nausea and vomiting, and postoperative nausea and vomiting.

The National Institutes of Health (NIH) state that there are other situations where acupuncture may be useful as an adjunct treatment or acceptable alternative, or may be included in a comprehensive management program. These include, but are not limited to menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, and carpal tunnel syndrome.

Studies investigating acupuncture for the treatment of asthma are of poor quality and have conflicting results. The efficacy of acupuncture in the treatment of asthma and in stroke rehabilitation is not supported by clinical trials. Studies investigating the use of acupuncture for substance addiction (e.g., alcohol, opioids) and allergic rhinitis have not demonstrated the efficacy of acupuncture for these conditions. Studies of acupuncture for smoking cessation found that acupuncture is not effective in maintaining abstinence from nicotine addiction. A 2018 case series (Miranda and Taca) reported successful alleviation of opioid withdrawal symptoms; however, this was an uncontrolled, retrospective study with no comparator used, and, therefore, conclusions cannot be drawn from this limited evidence.

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  $\geq 3$  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

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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  $\geq 30\%$  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%;  $p=.33$ ).

### CODES

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
- Code Key: Experimental/Investigational = (E/I), Not Medically Necessary = (NMN)

#### CPT Codes

Code	Description
0720T (E/I)	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (e.g., IB-Stim system)
0783T (E/I)	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
97810	Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
97811	Acupuncture, 1 or more needles; without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s) (List separately in addition to code for primary procedure)
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 re-insertion of needle(s) (List separately in addition to code for primary procedure)

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#### HCPCS Codes

Code	Description
S8930 (E/I)	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient

#### ICD10 Codes

Code	Description
F10.10-F10.99 (E/I)	Alcohol related disorders (code range)
F11.10-F11.99 (E/I)	Opioid related disorders (code range)

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<b>Code</b>	<b>Description</b>
F12.10-F12.99 (E/I)	Cannabis related disorders (code range)
F13.10-F13.99 (E/I)	Sedative, hypnotic, or anxiolytic related disorders (code range)
F14.10-F14.99 (E/I)	Cocaine related disorders (code range)
F15.10-F15.99 (E/I)	Other stimulant related disorders (code range)
F16.10-F16.99 (E/I)	Hallucinogen related disorders (code range)
F17.200-F17.299 (E/I)	Nicotine dependence (code range)
F18.10-F18.99 (E/I)	Inhalant related disorders (code range)
F19.10-F19.99 (E/I)	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 (NMN)	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 (NMN)	Cerebral atherosclerosis
I67.81-I67.82 (NMN)	Other specified cerebrovascular diseases (code range)
I67.89 (NMN)	Other cerebrovascular disease
I67.9 (NMN)	Cerebrovascular disease, unspecified
I68.0 (NMN)	Cerebral amyloid angiopathy
I68.8 (NMN)	Other cerebrovascular disorders in diseases classified elsewhere
J30.1-J30.9 (E/I)	Allergic rhinitis (code range)
K58.0-K58.9 (E/I)	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)
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)

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<b>Code</b>	<b>Description</b>
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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\*Key Article

### **KEY WORDS**

Acupuncture, Alternative Medicine, Auricular Electrostimulation, Electroacupuncture, E-pulse, P-Stim.

**Medical Policy: ACUPUNCTURE AND AURICULAR ELECTROSTIMULATION**

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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There are currently four National Coverage Determinations (NCDs) for acupuncture. Please refer to the following websites for Medicare Members:

Acupuncture (NCD# 30.3):

[<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=11&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=acupuncture&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&=>] accessed 03/13/24.

Acupuncture for Fibromyalgia (NCD# 30.3.1):

[<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=283&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=acupuncture&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&=>] accessed 03/13/24.

Acupuncture for Osteoarthritis (NCD# 30.3.2):

[<https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=284&ncdver=2&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=acupuncture&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&=>] accessed 03/13/24.

Acupuncture for Chronic Lower Back Pain (cLBP) (NCD# 30.3.3):

[<https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=373&ncdver=1&keyword=acupuncture&keywordType=starts&areaId=s41&docType=NCA,CAL,NC D,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact>] accessed 03/13/24.