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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.

• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.

• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:

- I. Based upon our criteria, assessment of peer-reviewed literature, acupuncture is **medically appropriate** when performed by an individual licensed by New York State to perform acupuncture and when performed for 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; or
 - L. Tennis elbow.
- II. Based upon our criteria and review of the peer-reviewed literature, acupuncture for patients undergoing rehabilitation following cerebral vascular accidents (stroke) is **not medically necessary** as the efficacy of the treatment has not been proven.
- III. Based upon our criteria and review of the peer-reviewed literature, acupuncture for all other conditions, including but not limited to the following, has not been proven to be effective and is, therefore, considered **investigational**:
 - A. allergic rhinitis,
 - B. irritable bowel syndrome, and
 - C. substance (e.g., alcohol, cocaine) dependence.
- IV. Based upon our criteria and review of the lack of peer-reviewed literature, electrical stimulation of auricular acupuncture points/auricular electrostimulation is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

- I. Coverage for acupuncture, as well as the number of covered treatments, is contract dependent. Please refer to your Customer (Member/Provider) Service Department for determination of contract benefits.
- II. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Acupuncture is the stimulation of certain points on the surface of the body using needles to treat illness and promote health. Practitioners trained in Chinese Medicine believe that a vital energy called "Qi" circulates in the body through 12 main pathways called medians. When there is balance, the energy flows smoothly and there is vibrant health. When the

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body is imbalanced, blockages arise and create illness. There are both surface and internal projections for each median. The surface projections contain sites called acupuncture points. Chinese Medicine practitioners insert needles into these points to influence the body's "Qi" to restore health.

Treatment involves inserting 4 to 15 needles at selected acupuncture points for usually 10-30 minutes. Needles are approximately 37 gauge, stainless steel and disposable. Needles are manipulated with electricity (electroacupuncture), 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 the conventional treatment modalities, who experience adverse consequences with conventional approaches, who prefer to not 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 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 Corp) 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. The P-Stim™ received marketing clearance through the U.S. Food and Drug Administration's (FDA) 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 510(k) marketing clearance in 2009.

RATIONALE:

The U.S. Food and Drug Administration (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 Institute of Health (NIH) states there are other situations where acupuncture may be useful as an adjunct treatment, an 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.

Auricular electrostimulation:

A 2011 randomized trial from Europe tested the efficacy of the P-Stim in 40 female patients undergoing gynecologic surgery. Patients were randomly assigned to receive auricular acupuncture or sham stimulation. Patients in the control group received electrodes without needles and the P-Stim devices were applied without electrical stimulation. The P-Stim device was placed behind the ear at the end of the operation on all patients while they were still under general anesthesia.

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and the dominant ear was completely covered with identical dressing in both groups to maintain blinding. Postoperatively, patients received 1,000 mg paracetamol every 6 hours with additional piritramide given on demand. Needles and devices were removed 72 hours postoperatively. A blinded observer found no significant difference between the 2 groups in consumption of piritramide during the first 72 hours postoperatively (acupuncture vs. placebo: 15.3 mg vs. 13.9 mg, respectively) or on VAS scores taken at 0, 2, 24, 48, and 72 hours (average of 2.32 vs. 2.62, acupuncture vs. placebo, respectively).

In a European study from 2008, Bernateck et al. reported the use of the P-Stim device in a randomized controlled trial of 44 patients with rheumatoid arthritis. The control group received autogenic training, a psychological intervention in which participants learn to relax their limbs, breathing, and heart. Electro-acupuncture (continuous stimulation for 48 hours at home) and lessons in autogenic training were performed once weekly for 6 weeks. In addition, the control patients were encouraged to use an audiotape to practice autogenic training every day. The needles and devices were removed after 48 hours. Seven patients withdrew from the study before beginning the intervention; the 37 remaining patients completed the study through 3 months of follow-up. The primary outcome measures were the mean weekly pain intensity and the disease activity score (DAS-28). At the end of treatment and at 3-month follow-up, a statistically significant improvement was observed in all outcome measures for both groups. There was greater improvement in the electro-acupuncture group than the control group (e.g., VAS pain 2.79 vs. 3.95) during the treatment period. This difference did not persist at the 3-month follow-up. The clinical significance of a 1-point difference in VAS from this small trial is unclear.

In a 2007 review, Sator-Katzenschlager and Michalek-Suberer found that studies on the use of the P-Stim in acute pain (e.g., oocyte aspiration and molar tooth extraction) are contradictory.

In 2004, Sator-Katzenschlager et al. reported a randomized double-blind controlled study of auricular electro-acupuncture compared to conventional manual auricular acupuncture in 61 patients with chronic low back pain (duration of at least 6 months). All needles were connected to the P-Stim device; in the control group, devices were applied without electrical stimulation. Treatment was performed once weekly for 6 weeks, with needles withdrawn 48 hours after insertion. Patients received questionnaires assessing pain intensity and quality, psychological well-being, activity level, and quality of sleep using visual analog scale (VAS). There was a significant improvement in pain at up to 18 weeks' follow-up. Auricular electro-acupuncture resulted in greater improvement in the outcome measures than that of the control group. For example, at 18-week follow-up, VAS pain intensity was less than 5 in the control group and less than 2 in the electro-acupuncture. This study is limited by the small number of participants. In 2003, this group of investigators had reported similar effects in a small randomized study of 21 patients with chronic cervical pain.

The available evidence is insufficient to evaluate the effect of auricular electrostimulation on health outcomes. Additional randomized studies with a larger number of subjects are needed to evaluate the efficacy of this treatment approach. Therefore, auricular electrostimulation is considered investigational.

CODES: **Number** **Description**

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.

<u>CPT:</u>	97810	Acupuncture, one or more needles; without electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient
	97811	without electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)
	97813	with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient

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97814 with electrical stimulation, each additional 15 minutes of personal one-on-one contact with the patient, with re-insertion of needle(s)

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<u>HCPCS:</u>	S8930 (E/I)	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient
<u>ICD9:</u>		
	307.81	Tension headache
	350.1	Trigeminal neuralgia
	350.2	Atypical face pain
	351.8	Other facial nerve disorders
	354.0	Carpal tunnel syndrome
	388.70-388.72	Otalgia (code range)
	436	Acute, but ill-defined cerebrovascular disease-stroke
	437.1, 437.8, 437.9	Other and ill-defined cerebrovascular disease
	524.62	Arthralgia of TMJ
	564.3	Vomiting following GI surgery
	611.71	Mastodynia (breast)
	625.3	Dysmenorrhea
	643.00-643.03	Mild hyperemesis gravidarum (code range)
	643.10-643.13	Hyperemesis gravidarum with metabolic disturbance (code range)
	643.20-643.23	Late vomiting of pregnancy (code range)
	643.90-643.93	Unspecified vomiting of pregnancy (code range)
	715.00-715.98	Osteoarthritis (code range)
	719.40	Disorders of joints, joint pain
	719.41	shoulder
	719.42	elbow
	719.43	wrist
	719.44	hand
	719.45	hip, pelvic region
	719.46	knee
	719.47	ankle, foot
	719.48	specified site NEC
	719.49	multiple sites
	723.1	Cervicalgia
	723.3	Cervicobrachial syndrome
	724.1	Pain in thoracic spine

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724.2	Lumbago, low back
724.3	Sciatica
724.4	Thoracic or lumbosacral neuritis or radiculitis, unspecified
724.5	Backache
724.6	Disorders of sacrum
724.70-724.79	Disorders of coccyx (code range)
724.8	Other symptoms referable to back
724.9	Other unspecified back disorders
726.32	Tennis elbow
729.0	Rheumatism
729.1	Myalgia
729.2	Neuralgia
729.5	Pain in limb
733.90	Disorders of bone and cartilage
784.0	Headache, facial pain
<u>ICD10:</u>	
G44.1	Vascular headache, not elsewhere classified
G44.209	Tension-type headache, unspecified, not intractable
G46.3-G46.8	Vascular syndromes of brain in cerebrovascular diseases (code range)
G50.0-G50.1	Disorders of trigeminal nerve (code range)
G51.2-G51.8	Facial nerve disorders (code range)
G56.00-G56.02	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
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)

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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)
M26.62	Arthralgia of temporomandibular joint
M43.20-M43.28	Fusion of spine (code range)
M43.8x9	Other specified deforming dorsopathies, site unspecified (code range)
M51.14-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
M53.80	Other specified dorsopathies, site unspecified
M53.84-M53.9	Other specified dorsopathies (code range)
M53.9	Dorsopathy, unspecified
M54.03-M54.09	Panniculitis affecting regions of neck and back (code range)
M54.10	Radiculopathy, site unspecified
M54.14-M54.18	Radiculopathy (code range)
M54.2	Cervicalgia
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.5	Low back pain
M54.6	Pain in thoracic spine
M54.89-M54.9	Dorsalgia (code range)
M60.80-M60.9	Other myositis (code range)
M62830	Muscle spasm of back
M77.10-M77.12	Lateral epicondylitis (code range)
M79.0	Rheumatism, unspecified
M79.1	Myalgia
M79.2	Neuralgia and neuritis, unspecified
M79.601-M79.67	Pain in limb, hand, foot, fingers and toes (code range)
M79.7	Fibromyalgia
M85.9	Disorder of bone density and structure, unspecified
M89.9	Disorder of bone, unspecified

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M94.9	Disorder of cartilage, unspecified
N64.4	Mastodynna
N94.4-N94.6	Dysmenorrhea (code range)
O21.0-O21.1	Hyperemesis gravidarum (code range)
O21.2	Late vomiting of pregnancy
O21.9	Vomiting of pregnancy, unspecified
R51	Headache

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KEY WORDS:

Acupuncture, Alternative medicine, Auricular electrostimulation, Electroacupuncture, E-pulse, P-Stim™.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

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

Acupuncture:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDID=11&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&KeyWord=acupuncture&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&>

Acupuncture for Fibromyalgia: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDID=283&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&KeyWord=acupuncture&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&>

Acupuncture for Osteoarthritis:

<http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDID=284&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York++Upstate&KeyWord=acupuncture&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAA&>