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Medical Policy Manual

Topic: Auricular Electrostimulation

Date of Origin: March 2012

Section: Medicine

Approved Date: February 2014

Policy No: 146

Effective Date: May 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Auricular electrostimulation is a type of ambulatory electrical stimulation of acupuncture points on the ear. Devices, including the P-Stim™ and E-pulse, have been developed to provide continuous or intermittent stimulation over a period of several days. Also known as auricular electro-acupuncture, this type of electrostimulation, is being evaluated for a variety of conditions, including pain, depression, and anxiety.

Regulatory Status

Both the P-Stim (NeuroScience Therapy Corp) and the E-pulse (AMM Marketing LLC) devices have received marketing clearance through the U.S. Food and Drug Administration's (FDA) 510(k) process for use in treating acute or chronic pain by a qualified practitioner of acupuncture.

Note: This policy does not address Cranial Electrostimulation Therapy, which is considered separately in Durable Medical Equipment, Policy No. 83.06.

MEDICAL POLICY CRITERIA

Electrical stimulation of auricular acupuncture points is considered **investigational** for all indications, including but not limited to chronic and acute pain.

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of pain due to any cause may include: relief of pain, improved functional level, and return to work. Relief of pain is a subjective outcome that is typically associated with a placebo effect. Therefore, data from adequately powered, blinded, randomized, sham-controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect from an auricular electrostimulation device provides a significant advantage over the placebo.

Treatment with an auricular electrostimulation device must also be evaluated in general groups of patients against the existing standard of care for the condition being treated. For example, in patients with pain symptoms, treatment with an auricular electrostimulation device should be compared to other forms of conservative therapy such as rest, non-steroidal anti-inflammatory medications, physical therapy, or steroid injections.

Literature Appraisal

Several randomized controlled trials (RCTs) have been reported on the use of the P-stim device and are the focus of this policy.

- 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).[1] 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.[2]

- In 2008, Bernateck et al. reported the use of the P-Stim device in a RCT of 44 patients with rheumatoid arthritis.[3] 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.

- A 2011 randomized trial tested the efficacy of the P-Stim in 40 female patients undergoing gynecologic surgery.[4] 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, 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 this small study, use of the P-stim device was not associated with improved pain management following gynecologic surgery, although the study size may have been too small to find differences between groups where they existed.

Clinical Practice Guidelines

There are no evidence-based clinical practice guidelines that recommend the use of auricular electrostimulation devices for any indication.

Summary

The evidence available at this time is insufficient to evaluate the effect of auricular electrostimulation on health outcomes, including acute and chronic pain. 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.

REFERENCES

1. Sator-Katzenschlager, SM, Scharbert, G, Kozek-Langenecker, SA, et al. The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture. *Anesth Analg*. 2004 May;98(5):1359-64, table of contents. PMID: 15105215
2. Sator-Katzenschlager, SM, Szeles, JC, Scharbert, G, et al. Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study. *Anesth Analg*. 2003 Nov;97(5):1469-73. PMID: 14570667
3. Bernateck, M, Becker, M, Schwake, C, et al. Adjuvant auricular electroacupuncture and autogenic training in rheumatoid arthritis: a randomized controlled trial. Auricular acupuncture and autogenic training in rheumatoid arthritis. *Forsch Komplementmed*. 2008 Aug;15(4):187-93. PMID: 18787327
4. Holzer, A, Leitgeb, U, Spacek, A, Wenzl, R, Herkner, H, Kettner, S. Auricular acupuncture for postoperative pain after gynecological surgery: a randomized controlled trail. *Minerva Anestesiol*. 2011 Mar;77(3):298-304. PMID: 21441884
5. BlueCross BlueShield Association Medical Policy Reference Manual "Cranial Electrotherapy Stimulation (CES) and Auricular Electrostimulation." Policy No. 8.01.58

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	S8930	Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient