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| MEDICAL POLICY | Auricular Electrostimulation (All Lines of Business Except Medicare) |
| Effective Date: 5/1/2021 | Medical Policy Number: 128 |
|  5/1/2021 | Technology Assessment Committee Approved Date: 8/16 Medical Policy Committee Approved Date: 10/17; 8/18; 8/19; 3/2020; 4/2021 |
| Medical Officer | Date |

See Policy HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All Lines of Business Except Medicare

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

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

Link to [Policy Summary](#)

BILLING GUIDELINES

The HCPCS S8930 code is the only code that may be used to bill auricular electrostimulation.

CPT codes 97813 or 97814 are not specific to auricular electrostimulation, therefore, if they are billed for this service they will be denied.

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CPT/HCPCS CODES

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| All Lines of Business Except Medicare | |
| Not Covered | |
| S8930 | Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient |
| Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered . | |
| E1399 | Durable medical equipment, miscellaneous |

DESCRIPTION

Auricular electrostimulation, also known as auricular electro-acupuncture or electrical auriculotherapy, is a type of ambulatory electrical stimulation of acupuncture points on the ear and has been developed to provide continuous or intermittent stimulation over a period of several days for a variety of conditions, including pain, depression, anxiety, nausea/vomiting and weight loss. These devices are disposable, preprogrammed units worn behind the ear and connected to acupuncture needles.

REVIEW OF EVIDENCE

Evaluating the safety and effectiveness of auricular electrostimulation with FDA-approved devices requires randomized controlled trials to isolate the treatment effect of auricular electrostimulation. Randomization is critical in evaluating any intervention in which clinically relevant outcomes consist of subjective, self-reported improvements such as pain, function and disability, as these outcomes may be influenced by nonspecific effects like placebo response and the natural history of the disease. As a result, when randomization is used, differences in reported outcomes between treatment groups may be attributed to the treatment in question. In addition, randomized studies must be sufficiently powered in order to eliminate any spurious results due to chance, must be evaluated in general groups of patients to allow generalizability of results, and must be evaluated against the existing standard of care for the condition being treated. Therefore the evidence review below has focused on randomized controlled trials (RCTs) and systematic reviews that included RCTs.

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of auricular electrostimulation as a treatment for any condition. Below is a summary of the available evidence identified through February 2021.

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Systematic Reviews

- In 2014 (archived 2016), Hayes evaluated auricular electroacupuncture for pain management, including seven randomized controlled trials evaluating the safety and efficacy of the P-Stim device for a number of different indications.¹ Four studies that investigated acute peri- and postoperative pain reported conflicting results. The studies used the P-Stim device for pain from tooth extraction, laparoscopy, intraoperative oocyte retrieval and tonsillectomy. Compared to sham, three studies reported no improvement in pain or use of analgesic medication. Two additional studies reported an improvement with P-Stim for the treatment of chronic cervical pain and low back pain. One trial evaluated patients with rheumatoid arthritis and reported a modest reduction in pain intensity using P-Stim compared with a control treatment. According to Hayes, the overall quality of the evidence was low due to the limited number of studies and small patient populations. Only subjective outcome measures were used and the majority of studies did not report functional outcomes. According to the review, “long-term follow-up data were lacking and it is unclear if use of the P-Stim device results in durable, long-term positive effects on pain. Additional well-designed clinical trials are necessary to confirm the safety and efficacy of auricular electroacupuncture with P-Stim for controlling acute and chronic pain, and to clarify its role as a potential adjunct to traditional forms of pain management, including pharmacologic, rehabilitative, and psychological interventions, in the context of a comprehensive pain management plan.”¹
- In 2014, Yeh et al. published a systematic review of randomized controlled trials to assess the efficacy of auricular therapy compared to sham therapy for pain management, including two studies (out of 22 studies) using auricular electroacupuncture stimulation (EAS) (N=19 patients).² One study evaluated auricular electrostimulation for postoperative nausea and vomiting and patient-controlled epidural analgesia in cesarean section, while the other trials assessed the treatment for perioperative analgesic method during oocyte aspiration in IVF treatment. In the two studies using electroacupuncture stimulation (EAS), EAS was found to be nonsignificant for pain reduction compared to sham or control group.
- In 2014, Tan et al. published the results of a systematic review evaluating adverse events (AEs) resulting from auricular stimulation, including three RCTs on auricular electrostimulation (N=203).³ The size of the trials ranged from 44 -125 patients but were all evaluating the use of auricular electrostimulation for different conditions (obesity, smoking cessation, and rheumatoid arthritis). Two out of three trials reported improved outcomes compared to the control arm. AEs from the use of auricular therapy included: skin irritation; local discomfort and pain; and minor infection. The events were transient, mild and tolerable. No serious adverse events were reported.
- In 2015, Zhao et al. conducted a systematic review of RCTs to assess the safety and efficacy of auricular therapy for the management of chronic pain in adults, including five trials on auricular electrostimulation for the treatment of low back pain, rheumatoid arthritis, neck pain and miscellaneous chronic pain.⁴ Subgroup meta-analysis (four studies; n=131) showed a significant improvement in pain (p=0.01) with auricular electrostimulation compared to the control group

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interventions. However, the lasting effect of auricular therapy began to diminish 3 months after the completion of treatment. Limitations of the studies included: small, heterogeneous patient populations, heterogeneous acupoints and treatment regimens, short-term treatment sessions, and short-term follow up. Due to the significant clinical heterogeneity and methodological flaws identified in the analyzed trials, there is insufficient evidence to support auricular electrostimulation for the treatment of chronic pain management.

- In 2015 Lui et al. conducted a systematic review that evaluated several types of acupuncture for post-operative pain control, including three RCTs (N=128 patients) using auricular electrostimulation.⁵ The meta-analysis showed a significant reduction in VAS scores, although two of the four RCTs found no significant difference due to low pain intensity in intervention groups. The evidence fair quality based on one overall high quality RCT and there was moderate statistical heterogeneity (I²=40%) between the included trials. The reviewers indicated that the body of evidence had several limitations, including heterogeneity of study populations, intervention durations, and timing of outcome measurement; small samples; and lack of follow-up evaluation. In addition, it was noted that, “methods of randomization, blinding, and allocation concealment were not reported or were poorly described in some trials, making quality assessment difficult.”

Randomized Controlled Trials (RCTs)

No additional RCTs evaluating the use of auricular electrostimulation for any condition were identified after the publication of the systematic reviews described above.

CLINICAL PRACTICE GUIDELINES

American College of Chest Physicians (ACCP)

In 2003, the ACCP published a clinical practice guideline that addressed complementary therapies in lung cancer management, stating the following:⁶

“In patients having nausea and vomiting from either chemotherapy or radiation therapy, acupuncture or related techniques is suggested as an adjunct treatment option.” This was a weak recommendation, based on moderate-quality evidence (Grade 2B).

“In patients with cancer related pain and peripheral neuropathy, acupuncture is suggested as an adjunct treatment in patients with inadequate control of symptoms.” This was a weak recommendation, based on very low- to low-quality evidence (Grade 2C).

However, regarding electroacupuncture, the guideline stated, “electroacupuncture has demonstrated benefit for chemotherapy-induced acute vomiting, but studies combining electroacupuncture with state-of-the-art antiemetics and in patients with refractory symptoms are needed to determine clinical

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relevance.” In addition, only two studies on electroacupuncture and one on auricular acupuncture were cited which supported the weak recommendation.

POLICY SUMMARY

There is insufficient evidence that auricular electrostimulation improves health outcomes for any indication for which it has been evaluated as a potential treatment, including but not limited to the treatment of acute and chronic pain. Only a limited number of randomized controlled trials have been published which suffer from the same limitations, including small patient populations (n=14–44), short-term follow up, and heterogeneity in the conditions treated and treatment protocols administered. Studies have reported conflicting outcomes, with insignificant differences between treatment and control groups reported for a number of conditions evaluated. Lastly, no evidence-based clinical practice guidelines strongly support the use of auricular electrostimulation for any indication.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

U.S. Food & Drug Administration (FDA)

Devices used for auricular stimulation are approved by the FDA through the 510(k) process as Class II devices. The devices are classified as electro-acupuncture stimulators under the product code “BWK”. Some devices are “intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points”, while others have a more general indication for use “in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states.” A list of all FDA approved electro-acupuncture stimulation devices can be found on the FDA 510(k) searchable database website, [here](#).

Examples of these devices include:

1. AcuStim (S.H.P. International), approved 2002
2. P-Stim™ System (NeuroScience Therapy), approved 2006
3. E-pulse® (AMM Marketing), approved 2009

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4. Electro Auricular Device (EAD)(Key Electronics), approved 2014
5. P-Stim (Biegler GmbH)
6. ANSiStim® (DyAnsys), approved 2015
7. Stivax System (Biegler GmbH), approved 2016

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Hayes Inc. P-Stim (Biegler GmbH) Auricular Electroacupuncture for Pain Management. <https://evidence.hayesinc.com/report/htb.pstim2362>. Published 2012 (archived 2014). Accessed 2/26/2021.
2. Yeh CH, Chiang YC, Hoffman SL, et al. Efficacy of auricular therapy for pain management: a systematic review and meta-analysis. *Evid Based Complement Alternat Med*. 2014;2014:934670. <https://www.ncbi.nlm.nih.gov/pubmed/25165482>.
3. Tan JY, Molassiotis A, Wang T, Suen LK. Adverse events of auricular therapy: a systematic review. *Evid Based Complement Alternat Med*. 2014;2014:506758. <https://www.ncbi.nlm.nih.gov/pubmed/25435890>.
4. Zhao HJ, Tan JY, Wang T, Jin L. Auricular therapy for chronic pain management in adults: A synthesis of evidence. *Complement Ther Clin Pract*. 2015;21(2):68-78. <https://www.ncbi.nlm.nih.gov/pubmed/25921554>.
5. Liu XL, Tan JY, Molassiotis A, Suen LK, Shi Y. Acupuncture-Point Stimulation for Postoperative Pain Control: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *Evid Based Complement Alternat Med*. 2015;2015:657809. <https://www.ncbi.nlm.nih.gov/pubmed/26568767>.
6. Deng GE, Rausch SM, Jones LW, et al. Complementary therapies and integrative medicine in lung cancer: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. 2013;143(5 Suppl):e420S-e436S. <https://www.sciencedirect.com/science/article/pii/S0012369213603037?via%3Dihub>.