Cranial Electrotherapy Stimulation (CES) and Auricular Electroacupuncture

Policy Number: 2013M0032A  Effective Date: January 1, 2014

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy describes the use of cranial electrotherapy stimulation and electrical auriculotherapy devices, which are intended to be used for individuals as ambulatory treatment of a variety of conditions including pain, insomnia, depression, and anxiety. These devices provide pulsed, low-intensity current, via clip electrodes attached to the eyelids, frontal scalp, mastoid process, or behind the ears. Other devices provide electrical stimulation with inserted acupuncture needles with caps and wires to acupuncture points on the earlobes. Treatment may be administered once or twice daily for a period of several days to several weeks.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

- The use of Cranial Electrotherapy Stimulation (CET), (also known as Cerebral Electrotherapy, Craniofacial Electrostimulation, Electric Cerebral Stimulation, ElectroSleep, Electrotherapeutic Sleep, Transcerebral Electrotherapy, Transcranial Electrotherapy, Transcranial Direct Electrical Stimulation (tDCS), Neuroelectric Therapy, Craniofacial Electrostimulation, Cranial Transcutaneous Electrical Nerve Stimulation, as well as the Liss Body Stimulator), is considered EXPERIMENTAL AND/OR INVESTIGATIONAL as a treatment for any condition, including the following (not an all inclusive list):
  - Alcoholism
  - Alzheimer's disease
  - Autism
  - Chemical dependency
  - Chronic pain
  - Dementia
  - Depression
  - Headaches
  - Mood (anxiety) and sleep disturbances (insomnia)
  - Parkinson disease
  - Visual rehabilitation

- The use of Auricular Electrostimulation (AES), also known as Auricular Electroacupuncture or Electrical Auriculotherapy, is considered EXPERIMENTAL AND/OR INVESTIGATIONAL for the treatment of any condition, including but not limited to:
  - Acute and Chronic Pain Control (Note: Minnesota DHS covers acupuncture for patients with chronic pain of at least six months duration who tried/failed conservative treatment)
  - Adrenal Disorders
  - Arthritis
  - Depression
  - Headaches
  - High Blood Pressure
  - Inflammation
  - Musculoskeletal Disorders
Obesity
Relaxation
Sciatica
Smoking Cessation
Stress
Substance Abuse
Swelling
Vertigo

There is inadequate evidence that CES or AES is beneficial for health outcomes in patients with any of the conditions listed above. The majority of studies that evaluated CES and AES failed to find evidence of an enduring treatment effect after the initial response, and some of the randomized, sham controlled trials failed to find any significant treatment effect. Methodological concerns have been raised about the scientific evidence, including small sample size, lack of a validated sham comparison in randomized controlled trials, and variable use of the outcome measures. Further well designed clinical trials with long-term follow-up are required to establish the benefits and health outcomes. Additional evidence is also needed to determine optimal patient selection criteria.

Clinical Considerations:
- Cranial electrical stimulation (CET) refers to any small electrical current that is passed through the head for therapeutic purposes.
- Auricular electroacupuncture is generally administered by a licensed acupuncturist or chiropractor, or by an allopathic or osteopathic physician who practices medical acupuncture in an outpatient setting without the need for anesthesia. The electrodes are placed on different parts of the earlobes so that the microcurrent will trace a direct path through the area of pain. The treatment usually lasts for 20 minutes per session, and is done either daily or every other day.
- CET and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, and anxiety.
- Contraindications for the use of electroacupuncture include anticoagulation therapy, pregnancy, recent organ transplants, bleeding disorders, history of cardiac disease, history of seizure disorders, immunodeficiency, presence of a pacemaker, concomitant use of transcutaneous electrical nerve stimulation, skin infection, and psoriasis.
- Minimal complications have been reported to date following the use of the P-Stim device. P-Stim can be associated with a minor risk of infection, particularly if proper sanitary procedures are not followed.

BACKGROUND:

Transcutaneous Electrical Nerve Stimulation (TENS) is the application of an electrical current through electrodes attached to the skin, and is most commonly used for pain relief. It has also been employed for the treatment of a range of neurological and psychiatric conditions such as alcohol and drug dependence, depression, as well as headaches. The use of TENS for these indications entails peripherally applied TENS as well as TENS applied to the head, also known as Cranial Electrical Stimulation (CES), Transcranial Electrical Stimulation Therapy, Electrodesleep, and Neuroelectric Therapy,
Interest in Cranial Electrotherapy Stimulation (CES) began in the early 1900s with the theory that weak pulses of electrical current would lead to a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression, and use of CES later spread to Western Europe and the U.S. as a treatment for a variety of psychological and physiological conditions. Although the mechanism of action is not clearly understood, it is hypothesized that electrical currents emitted from CES may positively impact the limbic system, the reticular activating system and/or the hypothalamus, resetting the brain to improved homeostasis levels. This therapy is not to be confused with transcranial magnetic stimulation or vagus nerve stimulation. CES has been proposed for the treatment of anxiety, depression, insomnia, substance abuse, fibromyalgia, Alzheimer’s, attention-deficit/hyperactivity disorder (ADHD), asthma, spastic colitis, tension headaches, hypertension, chemotherapy symptoms in cancer patients, burn patients, and other pain-related disorders. Because many of these indications require long-term therapy with medications, which may be costly, CES has been proposed as a cost-effective, non-invasive alternative to standard treatment.

A number of cranial electrical stimulators are available on the market. One device used in the U.S. is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. These devices are generally similar in size and appearance to transcutaneous electrical stimulators, but produce different wave forms at a much lower level. Treatments may be administered once or twice daily for a period of several days to several weeks.

Auricular electroacupuncture is a complementary and alternative treatment method used to treat a variety of acute and chronic pain conditions by electrically stimulating appropriate acupuncture points through a self-adhesive electrode patch which is worn behind the ear. A selection stylus that measures electrical resistance is used to identify 3 auricular acupuncture points. Specifically, electrical stimulation of acupoints is believed to increase the analgesic effects of acupuncture. The hypothesis that acupuncture activates the endogenous opioid system has led researchers to treat various pain syndromes with acupuncture. Acute and chronic pain conditions include peri- and postoperative pain, tension-type and migraine headaches, low back pain, and rheumatoid arthritis. Auricular electroacupuncture is generally administered by a licensed acupuncturist, chiropractor, or by an allopathic or osteopathic physician who practices medical acupuncture in an outpatient setting without the need for anesthesia.

REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

   A number of devices for CES have received marketing clearance through the FDA 510(k) process. Some of these devices are approved for use by the patient at home.
   - **Alpha-Stim® CES** (Electromedical Products International): This device received marketing clearance in 1992 for the treatment of anxiety, insomnia, and depression.
   - **P-Stim™** (Biegler GmbH): This device received marketing clearance through the FDA’s 510(k) process in 2006. The P-Stim™ is intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points.
   - **E-pulse** (E Pulse Magnetics, Inc): This device received 510(k) marketing clearance in 2009, listing the P-Stim™ as a predicate device. The E-pulse is a microprocessor-controlled battery-powered unit.
designed to administer auricular point nerve stimulation treatment for pain therapy over a 96 hour period.

- CES Ultra (Neuro-Fitness LLC.): This device received 510(k) marketing clearance, listing the P-Stim™ as a predicate device.
- Magnetic Black Belt by Orion Medical Group.
- HealthPax by Health Directions, Inc.
- Neurotone by Neurotone Systems, Inc.
- Liss Cranial Stimulator.
- Transcranial Electrotherapy Stimulator-A (TESA) by Kalaco Scientific, Inc.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
Medicare does not have a National Coverage Determination (NCD) or Local Coverage Determination (LCD) for the use of Cranial Electrotherapy Stimulation.


3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
Minnesota DHS does not have a policy statement regarding Transcranial Electrotherapy Stimulation or Auricular Electroacupuncture in its Provider Manual or other specific provider references.

However, Minnesota DHS in its Provider Manual, indirectly addresses Auricular Electroacupuncture under Acupuncture Services for recipients of Medical Assistance (MA) and MinnesotaCare programs. Available at http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&dId=129485

CLINICAL EVIDENCE:

Summary
CES and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, and anxiety. The literature on CES consists of a number of randomized controlled trials and systematic reviews, which provide little support for the efficacy of this treatment approach. In spite of the number of trials, there is a lack of evidence for improvement of health outcomes. Studies evaluating the effect of this technology on acute pain are contradictory, and evidence on chronic pain is limited. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham-control group. In another study, auricular electrostimulation was
compared with autogenic training and resulted in a small improvement in VAS pain scores of unclear clinical significance. The evidence available at this time is insufficient to evaluate the effect of CES and auricular electrostimulation on health outcomes, including acute and chronic pain.

APPLICABLE CODES:
The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<tr>
<td>S8930</td>
<td>Electrical stimulation of auricular acupuncture points; each 15 minutes of personal one-on-one contact with the patient.</td>
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<tr>
<td>97810</td>
<td>Acupuncture, 1 or more needles; without electrical stimulation, initial 15 minutes, one-to-one contact with patient</td>
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<tr>
<td>97811</td>
<td>Without electrical stimulation, each additional 15 minute, one-to-one contact with patient</td>
</tr>
<tr>
<td>97813</td>
<td>Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient</td>
</tr>
<tr>
<td>97814</td>
<td>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)</td>
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REFERENCES:

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<td>07/25/2013</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
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<tr>
<td>11/15/2013</td>
<td>Published to UCare.org</td>
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