Name of Policy:
Cranial Electrical Stimulation

Policy #: 021
Category: DME

Latest Review Date: February 2007
Policy Grade: C

Background:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Coding:

The correct code to report the cranial electrical stimulation device is E1399, unlisted DME. Narrative identifying this device should be placed to the right of the CPT code. The manufacturers are encouraging the suppliers to use procedure code E0730 TENS four lead, larger area/multiple nerve stimulation. Please note that E0730 is not the correct code to report ~~the Alpha Stim or~~ ~~other~~ cranial electrical devices.

Description of Procedure or Service:

Most cranial electrical utilization kits include several component parts. These parts would include the electrical stimulator console unit, one set of ear clip electrodes, felt pads, conducting solution for moistening the electrodes, 9-volt batteries, an owner's manual, and a carrying case that can be worn on the belt during treatment time. The manufacturer states cranial electrical stimulation therapy is based on the concept that the biophysics underlying the body's chemistry also plays a significant role in regulating all of life's processes. The waveforms produced by the electrical stim device are similar to the body's own electrical waves. This is hypothesized to bridge cellular communications while establishing the normal electrical flow. The cranial

electrical therapy device is used to assist with relieving anxiety, depression, insomnia and headaches. The cranial electrical therapy stimulation can be used anywhere from 20-60 minutes every day, every other day or on an as needed basis.

The U.S. Food and Drug Administration (FDA) has awarded several cranial electrotherapy stimulators the 510K premarket approval for the treatment of insomnia, depression or anxiety.

Policy:

Cranial electrical therapy stimulation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**. ~~for any indication due to the fact that it does not meet the definition of durable medical equipment as defined in the member's contract. Blue Cross and Blue Shield of Alabama written contracts define durable medical equipment as, "Equipment we approve as medically necessary to diagnose or treat an illness or injury or to prevent a condition from becoming worse. To be durable medical equipment, an item must be made to withstand repeated use, be for a medical purpose rather than for comfort or convenience, be useful only if you are sick or injured, and be related to your condition and prescribed by your physician to use in your home."~~

The purpose of Blue Cross and Blue Shield of Alabama's medical policy is to provide a guide to coverage. Medical policy is not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

Key Points:

In a recent study by Southworth, it has been evaluated that using cranial electrical stimulation (LES) may enhance attention and ability to learn a new task in a normal population. This study used a continuous performance test as the measure of attention. The follow-up consisted of 21 subjects who received the placebo treatment with experimental group of 31 subjects who received 20 minutes of the cranial electrical stimulation. The results of the study showed that 31% of the experimental group improved versus 4% of the control group. This indicates that the use of CES as a method of increasing attention could possibly be promising and should require further investigation.

A recent study was completed at Robert Wood Johnson Medical School for the use of cranial electric stimulation for the treatment of fibromyalgia. In this double-blinded, placebo-control study, 60 randomly assigned patients were given 3 weeks of subsensational cranial electric stimulation for one hour daily, a sham treatment, or served as controls for any placebo effect in the sham treated patients. The treated patient showed a significant improvement in tender point scores with a P value of <.001 and a significant improvement of self-rated scores of general pain level with a P value of <.005. Upon completion of the double-blinded study, 23 of the 40 control patients opted for actual treatment in an open clinical trial where they could increase the current in accordance with the standard clinical protocols for the Alpha-Stim cranial electrical stimulator. The authors concluded that the stimulation is as effective as drug therapies, with no negative side effects, and deserves further consideration for the treatment of fibromyalgia.

Tan G. et al reported on the use of cranial electrotherapy stimulation (CES) for pain in association with spinal cord injury (SCI). Thirty-eight males with SCI were randomized to receive active CES or sham CES treatment for 21 days. The active group (n=18) reported significantly decreased daily pain intensity compared with the sham CES group (n=20). The active group also reported significantly decreased pain interference in contrast to the nonsignificant decrease in the sham group. The authors concluded that CES can effectively treat chronic pain in persons with SCI. There is no FDA approval for these indications.

There is insufficient published peer-reviewed literature to determine the possible benefits of this treatment and therefore is considered investigational.

Key Words:

Alpha-Stim, cranial electrotherapy, cranial electrical stimulation

Approved by Governing Bodies:

Several Cranial Electrotherapy Stimulators have 510K premarket approvals. Some devices are intended for use by or on the order of a licensed health care practitioner and a trained technician will administer actual treatment.
~~Per manufacturer's information listed as Class IIA, Type B medical device~~.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
BellSouth contracts: Considers investigational
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: No special provisions apply

References:

1. Cameron M, et al. *Transcutaneous electrical nerve stimulation (TENS) for dementia*, Cochrane Database Syst Rev, January 2003(3): CD004032.
2. Kirsch, Daniel L. and Smith, Ray B. *The use of cranial electrotherapy stimulation in the management of chronic pain: A review*, NeuroRehabilitation, 14(2):85-95, 2000.
3. Lichtbroun, Alan S., et al. *The treatment of fibromyalgia with cranial electrotherapy stimulation*, Journal of Clinical Rheumatology, 7(2):72-78, 2001.
4. Southworth, S. *A study of the effects of cranial electrical stimulation on attention and concentration*, Integr Physiol Behav Sci, Jan-Mar 1999; 34(1):43-53.
5. http://www.alpha-stim.com.

Policy History:

Medical Policy Manual, April 1982
Re-Evaluated 1989
Medical Policy Group, September 7, 2001

Medical Policy Group, January 2003
Medical Policy Group, February 2004
Medical Policy Group, February 2006 **(1)**
Medical Policy Group, February 2007 **(1)**

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review)in Blue Cross and Blue Shield's administration of plans contracts.