Regence

Medical Policy Manual Durable Medical Equipment, Policy No. 83.14

External Trigeminal Nerve Stimulation for the Treatment of Attention Deficit Hyperactivity Disorder

Effective: January 1, 2024

Next Review: March 2024
Last Review: December 2023

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

External trigeminal nerve stimulation (eTNS) devices are placed on the forehead (supraorbitally) and stimulate the trigeminal nerve transcutaneously. Trigeminal nerve stimulation is being investigated as a treatment for attention deficit hyperactivity disorder.

MEDICAL POLICY CRITERIA

External trigeminal nerve stimulation devices are considered **investigational** for the treatment of attention-deficit/hyperactivity disorder (ADHD).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Cranial Electrostimulation Therapy (CES), Durable Medical Equipment, Policy No. 83.06

BACKGROUND

Stimulation of the trigeminal nerve is performed using a noninvasive device placed on the

forehead. The device generates an electrical signal that travels across the skin to deliver transcutaneous stimulation of branches of the trigeminal nerve. Trigeminal nerve stimulation has been proposed for the treatment of attention-deficit/hyperactivity disorder (ADHD). The hypothesized mechanism of action involves a signal traveling from the trigeminal nerve to the brain and affecting involved brain areas.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) granted approval for the following device:

- Monarch external Trigeminal Nerve Stimulation (eTNS) System received de novo classification for the April 19, 2019 for the treatment of attention-deficit/hyperactivity disorder (ADHD) as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications.

EVIDENCE SUMMARY

ATTENTION DEFICIT HYPERACTIVITY DISORDER

Systematic Reviews

There are no systematic reviews.

Randomized Controlled Trials

McGough (2019) reported a randomized controlled trial of external trigeminal nerve stimulation (eTNS) for attention-deficit/hyperactivity disorder (ADHD).[1] Sixty-two children aged 8 to 12 with ADHD were randomized 1:1 to receive active or sham eTNS nightly for four weeks. The primary efficacy outcome measure was the clinician completed ADHD-Rating Scales (ADHD-RS) Total Score, based on parental interview and all available clinical information. Patients were assessed at baseline and over subsequent weeks. showed There were statistically significant group-by-time interactions for ADHD-RS total scores (p=0.005), with greater improvement in the active group. The secondary outcome of Clinical Global Impression (CGI) score favored active over sham (p=0.003). No significant group-by-time interactive effects were found for the parent-completed Conners, the MASC-Parent Report, Bedtime Resistance, Sleep Anxiety, and Total Sleep Problems and no significant effects were reported for the other behavioral outcomes assessed, including the MASC Child Report, CDRS-R, BRIEF, remaining CSHQ scales, teacher Conners, and ARI scales. There were no serious adverse events in either group.

Secondary outcomes of cognitive and electroencephalographic (EEG) variables from the original randomized controlled trial (McGough 2019) were analyzed by Loo (2021) as potential predictors of treatment response.[2] Treatment responders (RESP) were defined as those with an ADHD Rating Scale (ADHD-RS) Total score reduction of ≥25%, whereas nonresponders (NR) were those with <25% reduction posttreatment. Data from 51 individuals (25 RESP and 26 NR) with a mean (SD) age of 10.3 (1.4) years were analyzed. Baseline measures that predicted RESP or NR included: lower working memory, lower spelling and mathematics achievement, deficits on behavioral ratings of executive function (BRIEF), and lower resting state EEG power in the right frontal (F4) region (all p values <0.05).

Nonrandomized Studies

In 2015, McGough published an eight-week pilot of eTNS for children with ADHD.[3] eTNS was delivered nightly for eight weeks to 24 participants (7 to 14 years). Statistically significant improvements compared to baseline were reported for the ADHD-IV Rating Scale ($p<0.0001$), the parent-completed Conners Global Index ($p<0.0001$), the majority of scales on the parent-completed Behavior Rating Inventory of Executive Functioning (BRIEF), and the computerized Attention Network Task (ANT) Incongruent Reaction Time ($p=0.006$).

Section Summary

The evidence regarding eTNS is limited. Although the few studies that have been published have reported positive outcomes, including improvement in the ADHD-Rating Scales, the methodological limitations of those studies include small sample size and short duration of follow-up. Additional studies with longer comparative follow-up are needed to permit greater certainty regarding the effect of this treatment on health outcomes.

PRACTICE GUIDELINE SUMMARY

American Academy of Pediatrics

The 2019 guideline from the American Academy of Pediatrics (AAP) on the diagnosis, evaluation, and treatment of ADHD states that eTNS "cannot be recommended as a treatment of ADHD without considerably more extensive study on its efficacy and safety."[4]

SUMMARY

There is not enough evidence to show if or how well external trigeminal nerve stimulation (eTNS) works to treat attention-deficit/hyperactivity disorder (ADHD). In addition, there are no clinical practice guidelines based on evidence that recommend this treatment for ADHD. Therefore, eTNS is considered investigational for the treatment of ADHD.

REFERENCES

1. McGough JJ, Sturm A, Cowen J, et al. Double-Blind, Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder. *J Am Acad Child Adolesc Psychiatry.* 2019;58(4):403-11.e3. PMID: 30768393
2. Loo SK, Salgari GC, Ellis A, et al. Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder: Cognitive and Electroencephalographic Predictors of Treatment Response. *J Am Acad Child Adolesc Psychiatry.* 2021;60(7):856-64 e1. PMID: 33068751
3. McGough JJ, Loo SK, Sturm A, et al. An eight-week, open-trial, pilot feasibility study of trigeminal nerve stimulation in youth with attention-deficit/hyperactivity disorder. *Brain Stimul.* 2015;8(2):299-304. PMID: 25533244
4. Wolraich ML, Hagan JF, Jr., Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. *Pediatrics.* 2019;144(4). PMID: 31570648

CODES

Codes	Number	Description
CPT	None	
HCPCS	A4541	Monthly supplies for use of device coded at e0733
	E0733	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
	~~K1016~~	~~Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve~~ (Deleted 01/01/2024)
	~~K1017~~	~~Monthly supplies for use of device coded at K1016~~ (Deleted 01/01/2024)

Date of Origin: *March 2021*