Molina Clinical Policy
Monarch Trigeminal Nerve Stimulation (eTNS) System: Policy No. 392

Last Approval: 12/14/2022
Next Review Due By: December 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Attention deficit hyperactivity disorder (ADHD) is a developmental condition of inattention and distractibility, with or without accompanying hyperactivity. ADHD is one of the most commonly diagnosed psychiatric disorders in children and adolescent and is estimated to affect 9.5% of school-age children in the United States, or about 6.1 million American children between the ages of 2 and 17 (Journal of Clinical Child and Adolescent Psychology, 2018). ADHD is defined in the Diagnostic and Statistical Manual, Fifth Edition (DSM-5) (American Psychiatric Association, 2013) as three basic forms: inattentive; hyperactive-impulsive; and combined. Treatment options for ADHD include pharmacological, non-pharmacological or multiple treatment methods. Non-pharmacological treatments for ADHD may involve behavioral, psychological, social, educational and lifestyle interventions. About two-thirds of people with ADHD are currently receiving medication, less than half have received behavioral therapy for ADHD, and nearly 25% have not received treatment. Non-pharmacological treatment with minimal side-effects offers an alternative to ADHD patients who do not respond to or have experienced undesirable side effects to pharmacologic therapy.

According to the Food and Drug Administration (FDA), the Monarch External Trigeminal Nerve Stimulation (eTNS) is a non-invasive device that uses electrical signals to therapeutically stimulate the largest cranial nerve, the trigeminal nerve. Although the exact mechanism of eTNS is unclear, neuroimaging studies have shown that eTNS enhances activity in brain regions known to be important for regulating attention, mood, and behavior. The device consists of two primary components: the external pulse generator and the external (cutaneous) electrical patches, which are single use disposable patches worn on the forehead (FDA, 2019). The small stimulator, powered by a 9-volt battery, is worn on the clothes during sleep and removed in the morning. The stimulator device emits a low-level current through thin wires connected to an adhesive electrode patch that is worn across the forehead delivering the low-level electrical stimulation to the branches of the trigeminal nerve sending therapeutic signals to the parts of the brain thought to be involved in ADHD. The stimulation, described as mild to the skin and barely perceptible to the child, leads to activation of deeper brain areas associated with concentration and impulse control. It has been suggested that treatment takes at least one month to deliver a noticeable effect and caregivers should consult their providers to reassess the treatment after this period (FDA, 2019).

Regulatory Status

The FDA granted marketing authorization on April 19, 2019 for the Monarch eTNS system via its "de novo" premarket review pathway (utilized for new low- to moderate-risk devices with no existing market equivalent). Monarch eTNS System and substantially equivalent devices of this generic type are classified into Class II with product code QGL and the generic name transcutaneous electrical nerve stimulator for ADHD, a device that stimulates transcutaneously or percutaneously through electrodes placed on the forehead. The Monarch eTNS System, a prescription-only device, is indicated for treatment of pediatric ADHD as a monotherapy in patients ages 7 through 12 years old who are not currently taking prescription ADHD medications. The device is intended for use in the home under the supervision of a caregiver during periods of sleep.

Currently, no other eTNS systems have received FDA approval for the treatment of ADHD.

COVERAGE POLICY

Monarch Trigeminal Nerve Stimulation (eTNS) System **is considered experimental, investigational, or unproven** for ADHD or for any indication.

SUMMARY OF MEDICAL EVIDENCE

Current evidence supporting the use of eTNS for the treatment of ADHD is limited by the lack of high-quality randomized trials, small sample sizes, short-term duration, and the absence of comparative efficacy and safety of pharmacological and non-pharmacological treatments in head-to-head trials. The safety and effectiveness eTNS therapy beyond 4 weeks have not been evaluated. Studies on long-term effects and potential harms are needed, including adverse tissue reaction from electrical stimulation, nerve damage, or other implications from device failure or misuse. There is insufficient evidence to determine the impact of this technology on health outcomes.

The Monarch eTNS System for ADHD based primarily on results of a small, week study that found active eTNS significantly more effective than sham eTNS for improving ADHD symptoms (FDA, 2019). This study represents the best available published evidence to date on eTNS for ADHD (McGough et al., 2019). Larger and longer randomized sham-controlled studies are needed to confirm these results.

Evidence of efficacy for an eTNS System for ADHD is limited to one small four week clinical trial of 62 patients (n=62) randomized to receive active or sham TNS nightly (McGough et al., 2019). The patients were medication-free for at least 1 month prior to the trial and remained medication-free throughout the trial. The primary efficacy outcome measure was the clinician-completed ADHD-RS total score completed at baseline and over subsequent weeks. The group using eTNS device had a statistically significant improvement in ADHD symptoms versus the placebo group. At the end of week four, the average ADHD-RS score in eTNS decreased from 34.1 to 23.4 points, versus decrease from 33.7 to 27.5 points in placebo. Compared with the placebo group, children who used the eTNS device showed statistically significant improvements in ADHD symptoms, with average ADHD-RS scores dropping about 31%. An average decrease of about 18% was seen in children in the placebo group. Slightly over half of participants in the intervention group showed improvement that was clinically meaningful, defined as a score of "much improved" or "very much improved" on the CGI Improvement scale. No serious adverse events in either treatment group or withdrawal from the study due to adverse events were reported. The most common side effects with eTNS were drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache, and fatigue. In conclusion, TNS efficacy for ADHD was shown in this blinded sham-controlled trial however, additional research is recommended to assess treatment response durability and potential impact on brain development with sustained use.

McGough et al. (2015) conducted the first study using TNS in children and adolescents in an 8-week open trial examining the potential feasibility and utility of eTNS for ADHD in a small group of 24 participants ages 7 to 14 years. TNS was well-tolerated with no clinically meaningful adverse events. Subjective improvements on rating scales and laboratory measures of cognition suggest that TNS therapy for youth with ADHD appears to be both feasible and without significant risk. It was concluded that future research in anticipation of designing definitive controlled efficacy trials should evaluate time to onset of TNS response and durability of treatment effects following TNS discontinuation, as well as validate an effective active sham comparator suitable for blinded studies.

Krull et al. (2022), in an evidence-based peer review, TNS is not recommended as a treatment option for ADHD due to the limited clinical experience. The authors stated that additional research is necessary to establish efficacy and safety, as well as to determine which patient with ADHD are most likely to benefit and the appropriate treatment regimen.

National and Specialty Organizations

The **American Academy of Pediatrics (AAP)** published practice guidelines for the diagnosis, evaluation, and treatment of ADHD in children and adolescents. In a 2019 update, the AAP stated that evidence is lacking regarding the benefit of some non-medication treatments including mindfulness, cognitive training, diet modification, EEG biofeedback, and supportive counseling. The guidelines did not call out eTNS in particular; while eTNS is FDA approved, a recommendation was not given as evidence is lacking. One available study was based on one 5-week randomized controlled trial with only 30 participants (McGough et al. 2019).

The **National Institute for Health and Care Excellence (NICE)** published guidelines on the *Diagnosis and Management of Attention Deficit Hyperactivity Disorder (ADHD)* in children, young adults, and adults (March 2018). The guidelines were updated in September 2019 and included recommendations for pharmacotherapy and non-pharmacological treatment, but do not cover eTNS.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes – N/A

HCPCS Codes

HCPCS	Description
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
K1017	Monthly supplies for use of device coded at K1016

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022	Policy reviewed, no changes to criteria, updated references
12/8/2021	Policy reviewed, no changes to criteria, updated references.
6/8/2021	Coding reviewed; added two HCPCS codes (K1016, K1017) and removed codes for tens units (N/A).
12/9/2020	New policy. IRO Review. Policy reviewed on November 23, 2020 by a practicing, board-certified physician in the areas of Psychiatry, Psychiatry Child and Adolescent.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS. Accessed November 2022.
2. ClinicalTrials.gov. Trigeminal nerve stimulation for ADHD (TNS for ADHD). Available at ClinicalTrials.gov. Updated July 2, 2019. Accessed November 2022.
3. Food and Drug Administration (FDA). Device classification under section 513(f)(2) (De Novo). Available at FDA. Decision Date April 19, 2019. Accessed November 2022.
4. Food and Drug Administration (FDA). News release: FDA permits marketing of first medical device for treatment of ADHD. Available at FDA. Published April 19, 2019. Accessed November 2022.

Evidence Based Reviews and Publications

1. Hayes. Emerging technology report: Monarch eTNS for Attention-Deficit/Hyperactivity Disorder. Available from Hayes. Published December 17, 2019. Archived April 28, 2021. Accessed November 2022.Registration and login required.
2. Krull, KR. Attention deficit hyperactivity disorder in children and adolescents: Overview of treatment and prognosis. Available from UpToDate. Updated June 6, 2022. Accessed November 2022. Registration and login required.

Peer Reviewed Publications

1. Danielson ML, Bitsko RH, Ghandour RM, Holbrook JR, Kogan MD, Blumber SJ. Prevalence of parent-reported ADHD diagnosis and associated treatment among U.S. children and adolescents. J Clin Child Adolesc Psychol. Mar-Apr 2018;47(2):199-212. doi: 10.1080/15374416.2017.1417860.
2. McGough JJ, Loo SK, Sturm A, Cowen J, Leuchter AF, Cook IA. An eight-week, open-trial, pilot feasibility study of trigeminal nerve stimulation in youth with attention-deficit/hyperactivity disorder. Brain Stimul. Mar-Apr 2015;8(2):299-304. doi: 10.1016/j.brs.2014.11.013.
3. McGough JJ, Sturm A, Cowen J, Tung K, Salgari GC, Leuchter AF, et al. Double-blind, sham-controlled, pilot study of trigeminal nerve stimulation for attention-deficit/hyperactivity disorder. J Am Acad Child Adolesc Psychiatry. 2019 Apr;58(4):403-411.e3. doi: 10.1016/j.jaac.2018.11.013.
4. Moffitt TE, Houts R, Asherson P, Belsky DW, Corcoran DL, Hammerle M, et al. Is adult ADHD a childhood-onset neurodevelopmental disorder? Evidence from a four-decade longitudinal cohort study. Am J Psychiatry. 2015 Oct;172(10):967-77. doi: 10.1176/appi.ajp.2015.14101266.

National and Specialty Organizations

1. American Psychiatric Association (APA). Diagnostic and statistical manual of mental disorders: DSM-5. 5th ed. Published 2013.
2. National Institute for Health and Care Excellence (NICE). Attention deficit hyperactivity disorder: diagnosis and management [NG87]. Published March 14, 2018. Updated September 13, 2019. Available from NICE. Accessed November 2022.
3. Wolraich ML, Hagan JF, Allan C, Subcommittee on Children and Adolescents with Attention-Deficit/Hyperactive Disorder et al. Clinical practice guideline for the diagnosis, evaluation, and treatment of Attention-Deficit/Hyperactivity Disorder in children and adolescents. Pediatrics (2020) 145 (3): e20193997. doi: 10.1542/peds.2019-3997. Erratum for: Pediatrics. 2019 Oct;144(4): PMID: 32111626.. Accessed November 2022.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*