Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

***Current Policy Effective Date: 7/1/25**
(See policy history boxes for previous effective dates)

Title: TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION FOR THE MANAGEMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER

Description/Background

The Monarch® external trigeminal nerve stimulation (eTNS) system is a non-invasive nerve stimulation device indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children aged 7 to 12 years who are not currently taking prescription ADHD medications. Monarch® eTNS System is based on a purported mechanism of action that the trigeminal nerve stimulates brain areas thought to be involved in ADHD. Although the exact mechanism of action is not known, neuroimaging studies have shown that eTNS increases activity in the brain regions that are known to be important in regulating attention, emotion, and behavior. The eTNS system consists of a rechargeable, battery-operated external pulse generator which is connected to a single-use, self-adhesive conductive patch which is applied to the forehead just above the eyebrow. Bilateral high frequency nerve stimulation is delivered to the V1 branch of the trigeminal nerve. The V1 branch of the trigeminal nerve carries sensory nerves from the skin of the forehead to the brain. The device was designed to be used in the home at night while the child is sleeping, allowing the supervising caregiver to adjust the level of stimulation delivered by the external pulse generator. The most common side effects of eTNS use includes drowsiness or trouble sleeping, increase in appetite, teeth clenching, headache, and fatigue.

Regulatory Status

NeuroSigma, Inc., Los Angeles, CA, was granted FDA De Novo approval (2019) for the Monarch eTNS System. The external trigeminal nerve stimulation system is indicated “for treatment of pediatric attention deficit hyperactivity disorder as a monotherapy in patients ages

7 through 12 years old who are not currently taking prescription ADHD medications. The device is used by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep." The device generates a low-level electrical pulse and connects via a wire to a small patch that adheres to an individual's forehead, just above the eyebrow. The approval summary states that the long-term effects of the device are unknown and that the device is contraindicated in individuals with an implanted cardiac and/or neurostimulation system or implanted metallic or electronic device in their head.

FDA product code: QGL

Medical Policy Statement

External trigeminal nerve stimulation (eTNS) for the management of attention deficit hyperactivity disorder is considered investigational (e.g., Monarch® eTNS System). There is insufficient evidence in the peer-reviewed medical literature to determine the effects of the technology on health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

A4541 E0733

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Attention-deficit/hyperactivity disorder (ADHD) is one of the most common childhood-onset neurobehavioral psychiatric disorders, according to the Centers for Disease Control and Prevention (CDC). National survey data from 2022 indicate that 11.4% of children, 3-17 years of age, living in the U.S. have been diagnosed with ADHD. According to a national 2022 parent survey, nearly 78% of children with ADHD had at least 1 other co-occurring condition (e.g., depression, autism spectrum disorder, Tourette syndrome, behavioral or conduct problems, anxiety, learning disabilities, developmental delays, speech/language disorder, intellectual disabilities). Current care options for ADHD include behavior therapy and medication or a

combination the modalities. Visser (2014) indicates that pharmacological treatment for ADHD is the single most effective treatment for reducing symptoms of ADHD.

Trigeminal nerve stimulation was approved for ADHD in 2019 by the U.S. Food & Drug administration based on a small proof of concept randomised controlled trial in 62 children with moderate to severe ADHD who showed improvement of ADHD symptoms after 4 weeks of nightly real versus sham eTNS with minimal side effects. The trial's primary endpoint was improvement on a clinician-administered ADHD Rating Scale (RS), ADHD-RS. A higher score is indicative of worsening symptoms. The ADHD-RS used questions about the childs behavior, such as whether they had difficulty paying attention or regularly interrupted others. At the end of week 4, the average ADHD-RS score in the active group decreased from 34.1 points at baseline to 23.4 points, versus a decrease from 33.7 to 27.5 points in the placebo group.

Two studies by McGough et al (2015 & 2019) assessed the efficacy and safety of trigeminal nerve stimulation (TNS) using the Monarch eTNS System™ . McGough et al (2015) examined participants (n=24) ages 7–14 with ADHD who were enrolled in an 8-week open trial. TNS was administered nightly during sleep, and recipients were assessed weekly with parent- and physician-completed measures of ADHD symptoms and executive functioning as well as measures of treatment compliance, adverse events, and side effects. Computerized tests of cognitive functioning were administered at baseline, 4- and 8 weeks. Authors concluded that TNS for the treatment of ADHD merited further investigation for evaluation of the time to onset for TNS response, durability of treatment effects following TNS discontinuation, and to provide a blind sham treatment comparative study. Some authors noted conflicts of interest with NeuroSigma.

McGough et al 2019 reported on a double-blind, sham-controlled study of pediatric individuals with ADHD. Sixty-two children (8 to 12 years) diagnosed with ADHD with full-scale IQ ≥ 85 and Kiddie Schedule for Affective Disorders and Schizophrenia were randomized to receive either active (n=32) or sham (n=30) TNS, with bilateral stimulation of the V1 branch of the trigeminal nerve for 8 hours per night for 4 weeks, followed by 1-week without intervention. Clinical assessments included weekly clinician-administered ADHD Rating and Clinical Global Impression (CGI) scales, and qEEG at baseline and week 4. The primary outcome measure was the clinician completed ADHD Rating Scale total score. Results revealed that ADHD-Rating Scale totals showed significant group-by-time interactions, demonstrating a differential treatment effect (F=8.12, df=1/228, p=.005). The CGI-Improvement scale favored active treatment over sham (p=.003). Quantitative EEG readings were obtained in both groups but there were no participant specific correlations to other outcomes. No serious adverse events were observed in either group, nor did any individual withdraw from the study due to adverse events. Significant increases in weight and pulse were seen with active TNS over the trial period. No differences were noted between active and sham TNS with regard to blood pressure. Limitations include sample size, short duration of treatment and follow-up, and lack of comparison to standard of care.

Wong et al (2019) investigated the effectiveness of TNS on individuals with ADHD and reported on the 2 studies listed above. Authors concluded that more studies with larger sample sizes to confirm any positive findings are needed, as well to assess the safety and compliance of individuals for this method of treatment.

Summary of Evidence

For individuals with ADHD who receive TNS, the evidence is limited. Relevant outcomes are symptoms, functional outcomes, QOL, and medication use. Results of the RCTs concluded that TNS is an effective and safe treatment option for pediatric individuals with ADHD. However, the studies included small subject samples, was of short duration and did not compare TNS to the current standard of care. Large, long term, blinded studies comparing TNS to the standard therapy for ADHD are needed. There are no guidelines which support the use of TNS for ADHD. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

American Academy of Pediatrics (AAP)
The AAP updated its clinical practice guideline (2019) for the diagnosis, evaluation, and treatment of ADHD in children and adolescents. The revised guideline states that external trigeminal nerve stimulation (eTNS) "cannot be recommended as a treatment for ADHD" because supporting evidence is "sparse and in no way approaches the robust strength of evidence documented for established medication and behavioral treatments for ADHD." The AAP indicates that considerably more extensive studies on the efficacy and safety of eTNS are needed.

Centers for Disease Control and Prevention
The CDC (2024) makes the following recommendation for children with ADHD:

- For children with ADHD younger than 6 years of age, the American Academy of Pediatrics (AAP) recommends parent training in behavior management as the first line of treatment, before medication is tried.
- For children 6 years of age and older, the recommendations include medication and behavior therapy together—parent training in behavior management for children up to age 12 and other types of behavior therapy and training for adolescents. Schools can be part of the treatment as well. Recommendations also include adding behavioral classroom intervention and school supports.

National Institute for Health and Care Excellence
The NICE (2019) published a guideline on the diagnosis and management of ADHD. It includes recommendations for behavioral therapy and pharmacotherapy but does not address eTNS.

Government Regulations

National:
No determination noted for the use of TNS for ADHD.

Local:
No determination noted for the use of TNS for ADHD.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

1. Centers for Disease Control and Prevention. Data and Statistics on ADHD. 2024. https://www.cdc.gov/adhd/data/index.html. Accessed December 12, 2024.
2. Centers for Disease Control and Prevention. "Attention Deficit/Hyperactivity Disorder (ADHS): Treatment of ADHD." 2024. https://www.cdc.gov/adhd/treatment/index.html#:~:text=For%20children%206%20years%20of,of%20the%20treatment%20as%20well. Accessed December 12, 2024.
3. Hayes, Inc. Emerging Technology Report. Monarch eTNS for attention-deficit disorder. Lansdale, PA. Hayes, Inc. Dec 17, 2019. Archived Apr 28, 2021. https://evidence.hayesinc.com/report/pg.monarchetns. Accessed December 27, 2023.
4. Hayes, Inc. Evidence analysis Research Brief: External Trigeminal Nerve Stimulation (Monarch eTNS System) for Treatment of Attention Deficit/Hyperactivity Disorder. April 23, 2021. Archived May 23, 2022. https://evidence.hayesinc.com/report/earb.monarch5149. Accessed December 27, 2023.
5. McGough J, Loo S, Sturm A, et al. An Eight-week, Open-trial, Pilot Feasibility Study of Trigeminal Nerve Stimulation in Youth With Attention deficit/Hyperactivity Disorder. *Brain Stimulation* 2015; 8:299-304.
6. 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):403-411.e3. PMID: 30768393.
7. National Institute for Health and Care Excellence. Attention Deficit Hyperactivity Disorder: Diagnosis and Management. 2019. https://www.nice.org.uk/guidance/ng87. Accessed December 12, 2024.
8. NeuroSigma Inc., Monarch eTNS® System. https://www.monarch-etns.com/. Accessed December 12, 2024.
9. U.S. Food and Drug Administration (FDA). "FDA News Release: FDA Permits Marketing of First Medical Device for Treatment of ADHD." 2019. https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-first-medical-device-treatment-adhd. Accessed December 12, 2024.
10. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). De Novo Decision Summary (DEN180041). De Novo Classification request for Monarch eTNS system. (NeuroSigma, Inc., Los Angeles, CA.) 2019. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180041.pdf. Accessed December 12, 2024.
11. Visser, SN., Danielson, ML., Bitsko RH., et al. "Trends in the Parent-report of Health Care Provider Diagnosed and Medicated ADHD: United States, 2003—2011." *J Am Acad Child Adolesc Psychiatry*. 2014 January ; 53(1): 34–46.e2. doi:10.1016/j.jaac.2013.09.001.
12. Wolraich, ML., Hagan, JF., et al. Clinical practice guideline for the diagnosis, evaluation, and treatment of attention deficit/hyperactivity disorder in children and adolescents. *American Academy of Pediatrics* (2019) 144:4

https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/Clinical-Practice-Guideline-for-theDiagnosis?autologincheck=redirected. Accessed December 12, 2024.
13. Wong HC, Zaman R. Neurostimulation in Treating ADHD. *Psychiatr Danub*. 2019 Sep;31(Suppl 3):265-275. PMID: 31488739.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 12/11/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/23	2/21/23		Joint policy established (slp) Vendor managed: N/A
5/1/24	2/20/24		• Routine maintenance (slp) • Vendor managed: Northwood • K1016 and K1017 deleted effective 1/1/23; replaced with A4541 and E0733
5/1/25	2/18/25		• Routine maintenance (slp) • Vendor managed: Northwood
7/1/25	4/15/25		• Policy replaced by new policy, effective 7/1/25: "Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation (e.g., Cefaly®, Cala ONE™, Cala TRIO™, eTNS, Axon)"

Next Review Date: Policy replaced.

See new policy, effective 7/1/25: "Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation (e.g., Cefaly®, Cala ONE™, Cala TRIO™, eTNS, Axon)"

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION FOR THE MANAGEMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.