



**Kaiser Foundation Health Plan  
of Washington**

**Clinical Review Criteria  
External Trigeminal Nerve Stimulation (eTNS) for ADHD**

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**Criteria  
For Medicare Members**

Source )	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, " <b>External Trigeminal Nerve Stimulation (eTNS) for ADHD</b> " for medical necessity determinations. Use the Non-Medicare criteria below.

**For Non-Medicare Members**

Kaiser Permanente has elected to use the Trigeminal Nerve Stimulation, Transcutaneous: Behavioral Health Care (B-820-T) MCG\* for medical necessity determinations. This service is not covered per MCG guidelines. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

**\*MCG manuals are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

**If requesting review for this service, please send the following documentation:**

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

**Background**

Attention-deficit/hyperactivity disorder (ADHD) is the most common behavioral disorder in childhood. It is defined in the DSM-5 as a "*Persistent pattern of inattention and/or hyperactivity-impulsivity that interferes with functioning or development and negatively impacts directly on social and academic/occupational activities*". The reported prevalence of ADHD in children varies from 2 to 18 percent depending upon the diagnostic criteria and the population

studied. The etiology of the disorder is not fully known, but according to the experts, a combination of genetic, neurological, and environmental factors contributes to its pathogenesis and heterogeneous phenotypes (Felt 2014, Polanczyk 2015, Belanger 2018).

There are three sub-types of ADHD: 1. Predominantly inattentive type (including poor concentration, difficulty completing tasks, ease of distraction, and disorganization); 2. Predominantly hyperactive -impulsive type (e.g. restlessness, persistent fidgeting, impatience, excessive talking, difficulty waiting for turn); and 3. The combined type. Diagnosing a child with ADHD can be challenging due to the lack of specific tests, biomarkers, or symptoms in addition to the common presence of other comorbidities that may affect symptom presentation, increase the severity of the disorder and/ or lead to greater functional impairment. The DSM-5 requires the presence of a sufficient number of core symptoms and functional impairment to diagnose an individual with ADHD. This requires extensive evaluation by a health care professional and involves obtaining information from multiple sources primarily from parents or guardians, teachers, and other school and mental health clinicians involved in the child's care; comprehensive evaluation of the child's symptoms which should include the assessment for other conditions that might coexist with ADHD such as emotional or behavioral disorders (e.g., anxiety, depressive oppositional defiant, and conduct disorders), developmental (e.g. learning and language disorders), and physical conditions (e.g. tics, and sleep apnea) (AAP Guidelines 2011, Felt 2014, Akutagava-Martin 2016, Bélanger 2018).

Treatment of ADHD varies depending on the age of the patient and the presence of comorbidities. It needs to be individualized and is often multimodal requiring the use of both behavioral and pharmacological therapies. The American Academy of Pediatrics guideline recommends behavioral therapy as a first line treatment of preschool aged children (4-5 years of age); FDA- approved medications for ADHD and/or parent- and/or teacher administered behavior therapy as a first line treatment for elementary school-aged children (6–11 years of age); and FDA-approved medications as the first line treatment for adolescents (12-18 years of age). Psychostimulants, are most effective for the treatment of core ADHD symptoms, have generally acceptable adverse effect profiles and may be considered for children aged 6 years and older. Effective behavioral therapies include parent training, classroom management, and peer interventions. Other nonpharmacological interventions such as social, organizational skills, and cognitive training; diet; and exercise should be considered for children with ADHD and other psychiatric and developmental comorbidities (Felt 2014. Feldman 2018).

It is reported that around 70% of patients with ADHD using stimulant medications respond to therapy. In some cases, however, the response may be suboptimal and requires the use of more than one drug. This, in addition to the stigma of using stimulants, its side effects, intolerance, and lack compliance among some children, have led to the investigation of and/or development of alternative non-pharmacological therapies for the potential treatment of ADHD. Among these approaches are EEG-based neurofeedback, computer-based working memory training, and neuromodulation therapy (Grigolon 2019).

Neuromodulation therapy is an evolving therapy that has been, and/or being investigated for the potential treatment of different chronic conditions including pain, spinal cord injuries, epilepsy, movement disorders, and others. It is defined as the "alteration of nerve activity through targeted delivery of a stimulus, such as electrical stimulation or chemical agents, to specific neurological sites in the body". Existing and emerging neuromodulation treatments range from non-invasive techniques such as transcranial magnetic stimulation (TMS) to techniques involving the surgical implantation of devices to alter activity in discrete areas of the nervous system. Among these therapies are deep brain stimulation, hypoglossal nerve stimulation, spinal cord stimulation, vagus nerve stimulation, occipital nerve stimulation and trigeminal nerve stimulation (TNS) (International Neuromodulation Society website).

TNS is a non-invasive neuromodulation technique that has been recently developed for neurological and psychiatric disorders based on the hypothesis that electrical stimulation of the supraorbital branch of the trigeminal nerve modulates cortical and subcortical areas related to neuropsychiatric disorders. The trigeminal nerve carries sensory information from the skin, muscles, and skull to extensive important structures in the brain, including the nucleus solitarius, the locus coeruleus, the vagus nerve and the cerebral cortex. The nerve also sends signals to the anterior cingulate cortex, which is believed to be involved in mood, attention and decision-making (Grigolon 2019, NeuroSigma website, International Neuromodulation Society website).

In April 19, 2019, the FDA granted marketing approval, through a de novo premarket review pathway\*, of the Monarch eTNS System (NeuroSigma) to be used as a non-drug option for the treatment of attention deficit hyperactivity disorder (ADHD) in children 7 to 12 years of age who are not currently taking prescription ADHD medication (FDA website accessed May 9, 2019).

The Monarch eTNS System™ (NeuroSigma, Inc., Los Angeles CA) is a small device, the size of a cell phone, powered by a 9-volt battery. It is connected through a thin wire to a small electrode patch that adheres to a patient's forehead during sleep. The system delivers mild electrical stimulation to the branches of the trigeminal nerve, which sends therapeutic signals to the parts of the brain assumed to be involved with concentration and impulse control. The child wears the patch for an average of eight hours at night and removes it in the morning. The electrical stimulation feels like a tingling sensation on the skin, and the device should be used in the home under the supervision of a caregiver during periods of sleep. The exact mechanism of eTNS is not yet known, but according to some investigators, neuroimaging studies showed that eTNS increases activity in the brain regions that are believed to be important in regulating attention, emotion and behavior. It is reported that the response to eTNS may take up to 4 weeks to become evident, and patients should consult with their health care professional after four weeks of use to assess treatment effects (FDA website).

According to the FDA, “the Monarch eTNS System should not be used in children under seven years of age, in patients with an active implantable pacemaker, with active implantable neurostimulators, or in patients with body-worn devices such as insulin pumps. The eTNS System should also not be used in the presence of radio frequency energy such as magnetic resonance imaging (MRI) as it has not been tested in an MRI machine, or cell phones, because the phone's low levels of electromagnetic energy may interrupt the therapy. The most common side effects observed with eTNS use are drowsiness, an increase in appetite, trouble sleeping, teeth clenching, headache and fatigue. No serious adverse events were associated with use of the device” (FDA website).

## Medical Technology Assessment Committee (MTAC)

### *External Trigeminal Nerve Stimulation (eTNS) for ADHD*

07/08/2019: MTAC REVIEW

#### **Evidence Conclusion:**

- There is insufficient published evidence to determine the comparative safety and effectiveness eTNS to stimulants and /or behavioral therapies currently used for the treatment of ADHD in children.
- There is low-moderate quality evidence from one relatively small sham-controlled randomized pilot trial that eTNS has more than a placebo short-term effect in improving the severity and frequency of ADHD symptoms examined by ADHD-RS and CGI-I in around 50% of selected children 8-12 years of age during 4 weeks of therapy.
- There is insufficient evidence to determine the sustainability of the observed effect of eTNS after discontinuation of the treatment.
- There is insufficient evidence to determine the long-term safety and efficacy of TNS in the treatment of children with ADHD.
- There is insufficient evidence to determine the optimal duration of TNS therapy i.e. whether it should be used only for 4 weeks, long-term, or periodically applied to the child.
- eTNS therapy is not without side effects; it was associated with an increase in appetite, weight gain, fatigue, headache, drowsiness and other adverse events. The authors noted that the adverse effects were not clinically significant leading to discontinuation of the treatment.
- Long-term RCTs comparing the effectiveness of eTNS to other therapies is needed to determine the equivalence or superiority of TNS to standard therapies, optimal duration of treatment, durability of the observed effect, and whether TNS would have a potential impact on child's brain development.

**Articles:** The literature search only identified the published pivotal randomized, sham-controlled pilot study on trigeminal nerve stimulation for ADHD (McGough, 2019) and an earlier small observational feasibility study of trigeminal nerve stimulation in youths ADHD (McGough, 2015). Both studies were conducted by the same group of principal investigators who had financial ties with the industry.

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 Apr; 58(4): 403-411.

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 Mar-Apr; 8(2):299-304. See [Evidence Table](#)

The use of External Trigeminal Nerve Stimulation (eTNS) for ADHD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

### Considered Not Medically Necessary:

CPT® /HCPC Codes	Description
<b>K1016</b>	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
Dx Codes	Description
<b>F90.0-F90.9</b>	Attention-deficit hyperactivity disorder

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
08/06/2019	08/06/2019 <sup>MPC</sup> , 08/04/2020 <sup>MPC</sup> , 08/03/2021 <sup>MPC</sup> , 08/02/2022 <sup>MPC</sup>	08/03/2021

<sup>MPC</sup> Medical Policy Committee

Revision History	Description
08/06/2019	MPC approved to adopt non-coverage policy
08/03/2021	Added HCPC code K1016 and Dx codes F90.0-F90.9. MPC approved to adopt MCG Care Guideline B-820-T Trigeminal Nerve Stimulation, Transcutaneous: Behavioral Health Care for medical necessity reviews. Requires 60-day notice, effective date January 1, 2022.