# Vagus and External Trigeminal Nerve Stimulation (for Kansas Only)

**Policy Number**: CS129KS.02
**Effective Date**: December 1, 2025

➲ Instructions for Use

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## Application

This Medical Policy only applies to the state of Kansas.

## Coverage Rationale

For medical necessity clinical coverage criteria for vagus and external trigeminal nerve stimulation, refer to the Kansas Medical Assistance Program, Professional Fee-for-Service Provider Manual.

**Due to insufficient evidence of efficacy, external or transcutaneous (non-implantable) trigeminal nerve stimulation devices (e.g., Monarch® eTNS System, Cefaly®) are unproven and not medically necessary for preventing or treating all conditions, including but not limited to:**

- Attention deficit hyperactivity disorder (ADHD)
- Depression
- Epilepsy
- Headache

**Note**: For vagus nerve blocking for the treatment of obesity, refer to the Medical Policy titled Bariatric Surgery (for Kansas Only).

## Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the services requested.

The patient's medical record must contain documentation that fully supports the medical necessity for the requested services. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures. Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request.

# Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| CPT Code | Description |
|---|---|
| 61885 | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array |
| 61886 | Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to 2 or more electrode arrays |
| 64553 | Percutaneous implantation of neurostimulator electrode array; cranial nerve |
| 64568 | Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator |
| 64570 | Removal of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator |



| HCPCS Code | Description |
|---|---|
| A4541 | Monthly supplies for use of device coded at E0733 |
| E0733 | Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve |
| E0735 | Noninvasive vagus nerve stimulator |
| E0770 | Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified |
| E1399 | Durable medical equipment, miscellaneous |
| L8679 | Implantable neurostimulator, pulse generator, any type |
| L8680 | Implantable neurostimulator electrode, each |
| L8682 | Implantable neurostimulator radiofrequency receiver |
| L8683 | Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver |
| L8685 | Implantable neurostimulator pulse generator, single array, rechargeable, includes extension |
| L8686 | Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension |
| L8687 | Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension |
| L8688 | Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension |

# Description of Services

External or transcutaneous trigeminal nerve stimulation (TNS) is a non-invasive therapy that delivers signals to the brain via the trigeminal nerve. TNS is commonly delivered by applying stimulating electrodes on the skin of the forehead. The Monarch external Trigeminal Nerve Stimulation (eTNS) System is being developed to treat several conditions including attention deficit hyperactivity disorder (ADHD), epilepsy, and depression. The Cefaly device is being developed to treat headaches by transcutaneously stimulating the supraorbital and/or infraorbital branches of the trigeminal nerve.

# Clinical Evidence

## External or Transcutaneous Trigeminal Nerve Stimulation

There is insufficient evidence to support the use of external or transcutaneous trigeminal nerve stimulation due to study limitations. Larger studies are needed to establish safety, efficacy, and long-term outcomes.

Jalal et al. (2025) conducted a systematic review that evaluated the effectiveness of trigeminal nerve stimulation (TNS) as a treatment for drug-resistant epilepsy (DRE). The review included seven studies with a total of 148 individuals, all of whom had persistent seizures despite medication. The findings showed that TNS significantly reduced seizure frequency

across all studies, although the duration of follow-up varied. The therapy was generally well-tolerated, with the most common side effects being skin irritation (12%) and headache (11%). Importantly, no serious or life-threatening adverse events were reported. Additionally, several studies noted improvements in mood and quality of life, as measured by tools like the Beck Depression Inventory (BDI) and Quality of Life in Epilepsy (QOLIE). The review concluded that TNS is a promising and safe neuromodulatory option for DRE, though larger, comparative studies are needed to better define its role in treatment. This study had several limitations. The small number of eligible studies limited the available data, and significant differences in study design, patient characteristics, and outcome measures introduced a moderate to high risk of bias. Inconsistent reporting of key variables—such as seizure localization, epilepsy cause, and prior medication use which further hindered the analysis. Variability in follow-up duration and stimulation protocols also made comparisons difficult and prevented meta-analysis. Additionally, all studies experienced patient attrition, and not all used intention-to-treat analysis, raising concerns about potential bias. Despite these limitations, this review provides a valuable overview of TNS in drug-resistant epilepsy and highlights areas for future research.

A 2023 ECRI Clinical Evidence Assessment for external trigeminal nerve stimulation for treating migraine headache indicates that the external trigeminal nerve stimulation (eTNS) reduces pain and improves quality of life compared with sham stimulation or in combination with migraine medication, based on evidence from a systematic review and meta-analysis. Whether these benefits are maintained and which treatment protocols and treatment frequency yield these benefits is uncertain from available evidence. Based on the low-quality evidence, the use of eTNS cannot be determined.

Stanak et al. (2020) performed a systematic review to analyze the effectiveness and safety of eTNS for the prevention and acute treatment of migraine attacks in episodic and chronic migraine individuals. The literature search from four databases that yielded 433 citations and additional seven citations were found via hand-search. Two randomized placebo-controlled trials and five prospective case series were included in the analysis. Results concerning prevention, statistically significant differences were found with respect to reduction of migraine attacks (0.67 less migraine attacks per month), migraine days (1.74 less migraine days per month), headache days (2.28 less headache days per month), and acute antimigraine drug intake (4.24 less instances of acute drug intake per month). Concerning acute treatment, statistically significant differences were found with respect to pain reduction on a visual analogue scale at 1/2/24 h post-acute treatment (1.68/1.02/1.08 improvement, respectively). No serious adverse events happened in any of the studies. E-TNS has the potential to improve migraine symptoms, but the quality of evidence is low. High quality comparative data, studies with larger sample sizes, and studies with standard and relevant primary outcome parameters are needed.

Gil-López et al. (2020) conducted a randomized controlled trial to determine the long-term efficacy and tolerability of external trigeminal nerve stimulation (ETNS) in individuals with focal drug-resistant epilepsy (DRE). Also, to explore whether its efficacy depends on the epileptogenic zone (frontal or temporal), and its impact on mood, cognitive function, quality of life, and trigeminal nerve excitability. Forty consecutive individuals with frontal or temporal DRE, unsuitable for surgery, were randomized to ETNS or usual medical treatment. Participants were evaluated at 3, 6 and 12 months for efficacy, side effects, mood scales, neuropsychological tests, and trigeminal nerve excitability. Subjects had a median of 15 seizures per month and had tried a median of 12.5 antiepileptic drugs. At 12 months, the percentage of responders was 50% in ETNS group and 0% in control group. Seizure frequency in ETNS group decreased by -43.5% from baseline. Temporal epilepsy subgroup responded better than frontal epilepsy subgroup (55.56% vs. 45.45%, respectively). Median stimulation intensity was 6.2 mA. ETNS improved quality of life, but not anxiety or depression. Long-term ETNS affected neither neuropsychological function, but not trigeminal nerve excitability. No serious side effects were observed. According to the authors, ETNS is an effective and well-tolerated therapy for focal DRE. Individuals with temporal epilepsy responded better than those with frontal epilepsy. Future studies with larger populations are needed to define its role compared to other neurostimulation techniques.

In a systematic review of clinical trials, Reuter et al. (2019) assessed the scientific rigor and clinical relevance of the available data to inform clinical decisions about non-invasive neuromodulation. This analysis compared study designs using recommendations of the International Headache Society for pharmacological clinical trials, the only available guidelines for migraine and cluster headache. Pivotal studies were identified for the three non-invasive neuromodulation therapies with regulatory clearance for migraine and/or cluster headache [i.e., non-invasive vagus nerve stimulation (nVNS), single-transcranial magnetic stimulation (sTMS), and external trigeminal nerve stimulation (e-TNS)]. Therapeutic effects on the pain-free response rate at 2 hours were comparable among the three pivotal studies of acute treatment, with significance (vs sham) demonstrated for sTMS (active, 39%; sham, 22%; p = 0.0179) but not for nVNS (active, 30.4%; sham, 19.7%; p = 0.067) or e-TNS (active, 19%; sham, 8%; p = 0.136). Non-invasive vagus nerve stimulation studies demonstrated the most consistent adherence to available guidelines. The scope of this systematic review was limited by the heterogeneity among the clinical trials analyzed and the unavailability of many of the study results, which precluded a formal systematic meta-analysis of all identified studies. This heterogeneity in the pivotal studies of nVNS, e-TNS, and sTMS makes the comparison of these devices and their efficacy outcomes difficult.

McGough et al. (2019) conducted a blinded sham-controlled trial to assess the efficacy and safety of trigeminal nerve stimulation (TNS) for attention-deficit/hyperactivity disorder (ADHD) and potential changes in brain spectral power using resting-state quantitative electroencephalography. Sixty-two children 8 to 12 years old, with full-scale IQ of at least 85 and Schedule for Affective Disorders and Schizophrenia-diagnosed ADHD, were randomized to 4 weeks of nightly treatment with active or sham TNS, followed by 1 week without intervention. Assessments included weekly clinician-administered ADHD Rating Scales (ADHD-RS) and Clinical Global Impression (CGI) scales and quantitative electroencephalography at baseline and week 4. ADHD-RS total scores showed significant group-by-time interactions. CGI-Improvement scores also favored active treatment. Resting-state quantitative electroencephalography showed increased spectral power in the right frontal and frontal midline frequency bands with active TNS. The study found that only slightly more than half of those receiving therapy had clinically meaningful improvement and a virtual lack of clinically meaningful adverse events. The authors concluded that this study demonstrates TNS efficacy for ADHD in a blinded sham-controlled trial, with estimated treatment effect size similar to non-stimulants. According to the authors, additional research should examine treatment response durability and potential impact on brain development with sustained use.

Chou et al. (2019) assessed the safety and efficacy of external trigeminal nerve stimulation for acute pain relief during migraine attacks with or without aura via a sham-controlled trial. This was a double-blind, randomized, sham-controlled study conducted across three headache centers in the United States. Adult individuals who were experiencing an acute migraine attack with or without aura were recruited on site and randomly assigned 1:1 to receive either verum or sham external trigeminal nerve stimulation treatment for 1 hour. Neurostimulation was applied via the e-TNS Cefaly device. Pain intensity was scored using a visual analogue scale (0 = no pain to 10 = maximum pain). The primary outcome measure was the mean change in pain intensity at 1 hour compared to baseline. A total of 106 individuals were randomized and included in the intention-to-treat analysis (verum: n = 52; sham: n = 54). The primary outcome measure was significantly reduced in the verum group than in the sham group. With regards to migraine subgroups, there was a significant difference in pain reduction between verum and sham for ‘migraine without aura’ attacks. For ‘migraine with aura’ attacks, pain reduction was numerically greater for verum versus sham but did not reach significance. No serious adverse events were reported, and five minor adverse events occurred in the verum group. The authors concluded that one-hour treatment with external trigeminal nerve stimulation resulted in significant headache pain relief compared to sham stimulation and was well tolerated, suggesting it may be a safe and effective acute treatment for migraine attacks. According to the authors, study limitations included the following: there was a small sample size and unbalanced baseline characteristics between the verum and sham groups for migraine type, migraine duration, and prior acute medication use. These differences in baseline characteristics were subsequently accounted for in a post hoc ANCOVA analysis, without modifying the significance of the treatment effect defined by the primary outcome.

Generoso et al. (2019) examined the effects of trigeminal nerve stimulation (TNS) in major depressive disorder (MDD) after a 10-day experimental protocol. This was a randomized, double blind, and sham-controlled phase II study with 24 individuals with severe MDD. Individuals underwent a 10-day intervention protocol and were assessed with the 17-item Hamilton Depression Rating Scale (HDRS-17) at following three observation points: baseline (T1), after 10 days (T2), and after one month of the last stimulation session (T3). Main clinical outcome analysis of variance (ANOVA) was performed. Individuals in the active group presented a mean reduction of 36.15% in depressive symptoms after the stimulation protocol. There was a significant interaction between group and time regarding HDRS-17 scores. Post hoc analyses exhibited a statistically significant difference between active and sham group symptoms at T2 and T3, which highlights the sustained amelioration of depressive symptoms. The authors concluded that this study found improvement in depressive symptoms for individuals undergoing a 10-day stimulation protocol of TNS, and this was sustained after one month of follow-up. The authors indicated that the study had several limitations such as a relatively small sample size and no long-term follow-up.

Boon et al. (2018) conducted a systematic review on the currently available neurostimulation modalities primarily with regard to effectiveness and safety for drug-resistant epilepsy (DRE). The authors found that there is insufficient data to support the efficacy of trigeminal nerve stimulation (TNS) for DRE. According to the authors, additional data collection on potentially promising noninvasive neurostimulation modalities such as TNS is warranted to evaluate its therapeutic benefit and long-term safety.

## Clinical Practice Guidelines

### *American Academy of Pediatrics*

The American Academy of Pediatrics [based on the above McGough (2019)] updated their clinical practice guideline 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. (Wolraich et al. 2019).

### *National Institute for Health and Care Excellence (NICE)*

The National Institute for Health and Care Excellence (NICE) published guidance on the use of a transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine in 2022. The guidance indicates that the evidence on the safety of transcutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine is adequate and raises no major safety concerns. For efficacy, the evidence for treating an acute migraine attack is adequate but, for treating subsequent attacks, is limited in quality and quantity. So, for treating acute migraine, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. The evidence for preventing migraine is inadequate in quality. So, for preventing migraine, this procedure should only be used in the context of research.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

### Implantable Vagus Nerve Stimulators

The FDA has approved a number of Implantable Vagus Nerve Stimulator devices. Refer to the following website for more information (use product codes LYJ, MUZ, and QPY): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed July 21, 2025)

### Transcutaneous (Non-Implantable) Vagus Nerve Stimulation Devices

The FDA has approved a number of devices used for Transcutaneous (Non-Implantable) Vagus Nerve Stimulation. Refer to the following website for more information (use product codes PKR and QAK) https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed July 21, 2025)

### External or Transcutaneous Trigeminal Nerve Stimulation

The FDA has approved a number of devices used for External or Transcutaneous Trigeminal Nerve Stimulation. Refer to the following website for more information https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm (use product codes PCC and QGL). (Accessed July 21, 2025)

To locate marketing clearance information for a specific device or manufacturer, search the Center for Devices and Radiological Health (CDRH) 510(k) database or the Premarket Approval (PMA) database by product and/or manufacturer name. (Accessed July 21, 2025)

## References


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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.e3.

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Stanak M, Wolf S, Jagoš H, Zebenholzer K. The impact of external trigeminal nerve stimulator (e-TNS) on prevention and acute treatment of episodic and chronic migraine: A systematic review. J Neurol Sci. 2020 May 15;412.

Wolraich ML, Hagan JF Jr, Allan C, et al.; Subcommittee on children and adolescents with attention-deficit/hyperactive disorder. Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents. Pediatrics. 2019 Oct;144(4):e20192528.

# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 03/01/2026 | **Related Policies**<br>• Updated reference link to reflect the current policy title for *Transcranial Magnetic Stimulation for Treating Physical Health Conditions (for Kansas Only)* |
| 02/01/2026 | **Related Policies**<br>• Updated reference link to reflect the current policy title for *Implanted Electrical Stimulator for the Spinal Cord (for Kansas Only)* |
| 12/01/2025 | **Medical Records Documentation Used for Reviews**<br>• Added language to indicate:<br>  ○ Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service<br>  ○ Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested<br>  ○ The patient's medical record must contain documentation that fully supports the medical necessity for the requested services<br>  ○ This documentation includes but is not limited to relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures<br>  ○ Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available upon request<br>**Supporting Information**<br>• Updated *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information<br>• Archived previous policy version CS129KS.01 |

# Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its policies and guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare uses InterQual® for the primary medical/surgical criteria, and the American Society of Addiction Medicine (ASAM) criteria for substance use disorder (SUD) services, in administering health benefits. If InterQual® does not have applicable criteria, UnitedHealthcare may also use UnitedHealthcare Medical Policies that have been approved by the Kansas Department of Health and Environment. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.