Vagus and External Trigeminal Nerve Stimulation (for Indiana Only)

Policy Number: CS129IN.01
Effective Date: April 1, 2021

Instructions for Use

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Related Policies

- Bariatric Surgery
- Deep Brain and Cortical Stimulation
- Implanted Electrical Stimulator for Spinal Cord
- Transcranial Magnetic Stimulation

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

For medical necessity clinical coverage criteria, refer to the Indiana Surgical Services Provider Reference Module.

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
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Incision for 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
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
E1399	Durable medical equipment, miscellaneous

HCPCS Code	Description
K1016	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve
K1017	Monthly supplies for use of device coded at K1016
K1020	Noninvasive vagus nerve stimulator
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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

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 approved the NeuroCybernetic Prosthesis (NCP)® System (Cyberonics, Inc.) in July 1997 (P970003) for use as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years of age with medically refractory, partial-onset seizures. In 2017, this approval was extended for use in patients 4 years of age and older. See the following websites for more information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970003S207
- http://www.accessdata.fda.gov/cdrh_docs/pdf/p970003.pdf

(Accessed June 5, 2019)

In July 2005, the VNS Therapy™ System (Cyberonics, Inc.) was approved for marketing by the FDA for the adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments (PMA Supplement 50). Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970003S050.
(Accessed June 5, 2019)

The VNS Therapy System (Cyberonics now known as LivaNova) received initial FDA Premarket Approval (PMA 970003) on July 16, 1997. The original FDA PMA was granted for VNS Therapy system as an adjunctive therapy in reducing the frequency of seizures in adults and adolescents over 12 years old. Many supplemental approvals have been issued for this system since the original approval. On June 23, 2017, LivaNova received FDA approval (P970003/S207) of its VNS Therapy system for use as an adjunctive therapy in reducing the frequency of seizures in persons four years of age and older with partial onset seizures that are refractory to antiepileptic medications. See the following websites for more information:

- https://www.accessdata.fda.gov/cdrh_docs/pdf/p970003.pdf
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970003

(Accessed June 5, 2019)

The AspireSR Model 106 generator received FDA premarket approval in May 2015 (PMA P970003). The AspireSR is part of Cyberonics's (now known as LivaNova) VNS Therapy System. The AspireSR Model 106 has an additional, optional mode called AutoStim Mode or Automatic Stimulation. This mode monitors and detects tachycardia heart rates, which may be associated with an impending seizure, and automatically delivers stimulation to the vagus nerve. See the following websites for more information:

- http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm?id=P970003S173
- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=353134

(Accessed June 5, 2019)

The Sentiva Model 1000 generator received FDA premarket approval in October 2017 (PMA P970003). The Sentiva is part of LivaNova's VNS Therapy System. The Sentiva Model 1000 has an additional mode called AutoStim Mode or Automatic Stimulation. SenTiva with AutoStim responds to heart rate increases that may be associated with seizures. -See the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970003S210. (Accessed June 26, 2019)

Transcutaneous (Nonimplantable) Vagus Nerve Stimulation Devices

The FDA has cleared gammaCore for the following 3 indications:

- On April 14, 2017, the FDA granted a de novo request that allows the gammaCore® device to be marketed in the U.S. for the treatment of acute pain associated with episodic cluster headache in adults. According to the FDA, the gammaCore Non-invasive Vagus Nerve Stimulator is intended to provide noninvasive vagus nerve stimulation (nVNS) on the side of the neck. The FDA determined that this device should be classified into class II. See the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf15/den150048.pdf.
- On January 23, 2018, the FDA expanded indications for the gammaCore (electroCore LLC) noninvasive vagus nerve stimulator to include the acute treatment of pain associated with migraine headaches in adults. See the following website for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173442.pdf.
- On November 28, 2018, electroCore Inc. received 510(k) clearance from the FDA for an expanded label for gammaCore (non-invasive vagus nerve stimulator) therapy for adjunctive use for the preventive treatment of cluster headache in adult patients. See the following website for more information: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K182369.

(Accessed June 5, 2019)

External or Transcutaneous Trigeminal Nerve Stimulation

The FDA granted a de novo classification for the Monarch external Trigeminal Nerve Stimulation (eTNS) System on April 19, 2019. According to the FDA, this device is indicated to treat attention deficit hyperactivity disorder (ADHD) in patients aged 7 to 12 years who are not currently taking prescription ADHD medication. The device is used for patient treatment by prescription only and is intended to be used in the home under the supervision of a caregiver during periods of sleep. See the following for more information: https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180041.pdf. (Accessed June 5, 2019)

The FDA cleared Cefaly for marketing under the 510(k) de novo process in March 2014. According to the FDA, the Cefaly device is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older. On September 15, 2017, the FDA cleared the Cefaly Acute device as substantially equivalent to the predicate device (Cefaly) for use during an acute migraine attack with or without aura. See the following for more information:

- https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN120019
- https://www.accessdata.fda.gov/cdrh_docs/pdf12/K122566.pdf
- https://www.accessdata.fda.gov/cdrh_docs/reviews/K122566.pdf
- https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171446.pdf

(Accessed June 5, 2019)

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.

Policy History/Revision Information

Date	Summary of Changes
04/01/2021	• New Medical Policy

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 may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. 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.