Children's Medical Services Health Plan (CMS Health Plan)

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

Staywell of Florida

WellCare (Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Heritage Health

WellCare Prescription Insurance

Diaphragmatic / Phrenic Nerve Stimulation

Policy Number: HS-185

Original Effective Date: 8/19/2010

Revised Date(s): 8/2/2011; 8/2/2012; 6/6/2013; 5/1/2014; 4/2/2015; 4/7/2016; 4/6/2017; 3/1/2018; 3/28/2019; 4/16/2020

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of an enrollee's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, an enrollee's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the enrollee. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any. All links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change prior to the annual review date. Lines of business (LOB) are subject to change without notice; current LOBs can be found at www.wellcare.com. All guidelines can be found at this site as well by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Diaphragmatic/phrenic nerve stimulator devices are indicated for certain ventilator-dependent individuals who lack voluntary control of their diaphragm muscles to enable independent breathing without the assistance of a mechanical ventilator for at least four continuous hours a day.

New FDA approval for distribution of the NeuRx DPS™ RA/4 Respiratory Stimulation System (Synapse Biomedical, Inc., Oberlin, OH) was granted under a Humanitarian Device Exemption (HDE) on June 17, 2008. The FDA-approved indications are: For use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least 4 continuous hours a day and is *for use only in patients 18 years of age or older.*

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This FDA approval is subject to the manufacturer developing an acceptable method of tracking device implantation to individual patient recipients.[1]

The Avery Breathing Pacemaker System (i.e., the Mark IV™ Avery Biomedical Device, Inc., Commack, NY) is the only other diaphragmatic/phrenic stimulator system approved for use by the FDA in the United States. The pacemaker is classified as a Class III neurologic therapeutic device requiring premarket approval (PMA). The device is approved "For persons who require chronic ventilatory support because of upper motor neuron respiratory muscle paralysis (RMP) or because of central alveolar hypoventilation (CAH) and whose remaining phrenic nerve, lung, and diaphragm function is sufficient to accommodate electrical stimulation". Clinical trials that have studied the efficacy of this device have been very limited and of small numbers of subjects.[2]

The NeuRx DPS™ RA/4 Respiratory Stimulation System is implanted through minimally invasive laparoscopic surgery and provides electrical stimulation to muscles and nerves that run through the diaphragm. This eliminates any direct contact with the phrenic nerve, allows all circuitry and electronics to remain outside the body, and provides direct, selective activation to each hemidiaphragm. According to manufacturer information, when stimulated by the NeuRx DPS, the diaphragm contracts, mimicking natural breathing and allowing air to fill the upper and lower parts of the lungs, rather than forcing air in with a mechanical ventilator. The device uses four electrodes implanted in the muscle of the diaphragm to electronically stimulate contraction; this stimulation allows the patient to inhale. The DPS is lightweight and battery powered, eliminating the need for an external power source.[3]

POSITION STATEMENT

Applicable To:

- ☑ Medicaid – All Markets (excluding KY)
- ☑ Children's Medical Services Health Plan (CHIP)
- ☑ Medicare – All Markets

Exclusions

Diaphragmatic/phrenic nerve stimulation **is not considered medically necessary** when:

- The enrollee can breathe spontaneously for 4 hours or more without the use of a mechanical respirator; **OR,**
- The respiratory insufficiency is temporary; **OR,**
- Motor neuron disease, (i.e. amyotropic lateral sclerosis [ALS]) is present; **OR.**,
- Used in patients whose phrenic nerve, lung, or diaphragm function are not sufficient to achieve adequate diaphragm movement from electrical stimulation.

Diaphragmatic/phrenic nerve stimulation **is considered experimental and investigational** for all other indications not listed above.

Therapy utilizing a phrenic nerve stimulator is covered by Medicare for selected patients with partial or complete respiratory insufficiency caused by a variety of conditions, including respiratory paralysis resulting from lesions of the brain stem and cervical spinal cord, and chronic pulmonary disease with ventilatory insufficiency. It is intended as an alternative for patients with respiratory insufficiency who are dependent upon a mechanical ventilator as well as maintenance of a permanent tracheotomy stoma. The policy notes that phrenic nerve stimulators are not always effective, and that any patient considered for this technology must have an intact phrenic nerve and diaphragm. The policy does not specifically mention ventilatory support using stimulation provided by electrodes implanted into the diaphragm.[4]

Coverage

Diaphragmatic/phrenic nerve stimulation **is considered medically necessary** if **ALL** of the following criteria are met:

- The device is FDA approved (i.e. NeuRx DPS™, Mark IV™); **AND,**
- The stimulation is used as an alternative to invasive mechanical ventilation for enrollees with severe,

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chronic respiratory failure requiring mechanical ventilation caused by brain or high cervical cord lesions; **AND,**
- Enrollee is at least 18 years of age; **AND,**
- Enrollee has ventilatory failure from stable, high spinal cord injuries **OR** central alveolar hypoventilation syndrome.

AND,

When all of the following criteria are met for direct or phrenic nerve stimulation:

- Diaphragm movement with stimulation is visible under fluoroscopy; **AND,**
- Stimulation of the diaphragm either directly or through the phrenic nerve results in sufficient muscle activity to accommodate independent breathing without the support of a ventilator; **AND,**
- The enrollee has normal chest anatomy, a normal level of consciousness, and has the ability to participate in and complete the training and rehabilitation associated with the use of the device.

NOTE: If phrenic nerve stimulation is used, acceptable nerve function must be demonstrated with EMG recordings and nerve conduction times.

CODING

Covered CPT®* Codes

64575	Incision for implantation of neurostimulator electrode array; peripheral nerve, (excludes sacral nerve)
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

Covered HCPCS Codes

C1778	Lead, neurostimulator (implantable)
C1816	Receiver and/or transmitter, neurostimulator (implantable)

Covered 2017 ICD-10-PCS Codes
Please reference ICD-10 PCS for the complete code description for Insertion of Neurostimulator)

01HY0MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
0DP64MZ	Removal of Stimulator Lead from Stomach, Percutaneous Endoscopic Approach
01PY0MZ	Removal of Neurostimulator Lead from Peripheral Nerve, Open Approach
01HY0MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
01HY3MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
01HY4MZ	Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Endoscopic Approach
0DH64MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Endoscopic Approach
0DH60MZ	Insertion of Stimulator Lead into Stomach, Open Approach
0DH63MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Approach
0DH60MZ	Insertion of Stimulator Lead into Stomach, Open Approach
0DH64MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Endoscopic Approach
0DH60MZ	Insertion of Stimulator Lead into Stomach, Open Approach
0DH63MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Approach
0DH64MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Endoscopic Approach
0DH63MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Approach
0DH60MZ	Insertion of Stimulator Lead into Stomach, Open Approach
0DH63MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Approach
0DH64MZ	Insertion of Stimulator Lead into Stomach, Percutaneous Endoscopic Approach
0BHR0MZ	Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Open Approach
0BHR3MZ	Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Approach
0BHR4MZ	Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Endoscopic Approach
0BHS0MZ	Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Open Approach
0BHS3MZ	Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Approach

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0BHS4MZ Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Endoscopic Approach

Covered ICD-10-CM Diagnosis Codes
Additional Diagnoses

Experimental / Investigational / Unproven / Not Covered
ICD-10-CM Diagnosis Codes - *This list is not all inclusive*
A80.30 - A80.39 Acute paralytic poliomyelitis, unspecified (A80.30)
B91 Sequelae of poliomyelitis
G14 Postpolio syndrome
G12.20 - G12.29 Motor neuron disease, unspecified (G12.20)
G71.11 - G71.19 Myotonic muscular dystrophy (G71.11)
G71.2 Congenital myopathies
G72.9 – G71.19 Unspecified myopathies
J96.10 - J96.12 Chronic respiratory failure, unspecified or with hypoxia or hypercapnia (J96.10)
J96.20 – J96.22 Acute and chronic respiratory failure, unspecified or with hypoxia or hypercapnia (J96.20)

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply enrollee coverage or provider reimbursement. Consult the enrollee's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. 510(k) premarket notification database: NeuRx DPS™ RA/4 respiratory stimulation system - summary of safety and probable benefit. U.S. Food and Drug Administration Center for Devices and Radiological Health Web site. https://www.accessdata.fda.gov/cdrh_docs/pdf7/H070003b.pdf. Published June 17, 2008. Accessed March 10, 2020.
2. Premarket Approvals for the Avery Breathing Pacemaker System Mark IV™ (Avery Biomedical Device, Inc., Commack, NY). Summary of Safety and Effectiveness. No. P860026. U.S. Food and Drug Administration Center for Devices and Radiological Health Web site. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma_template.cfm?id=p860026. Published 2003. Accessed March 10, 2020.
3. Diaphragmatic / phrenic nerve stimulation. Hayes Directory Web site. http://www.hayesinc.com. Published August 11, 2011 (Archived September 11, 2016). Accessed March 10, 2020.
4. National coverage determination for phrenic nerve stimulator (160.19). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Accessed March 10, 2020.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
4/16/2020, 3/28/2019, 3/1/2018, 4/6/2017, 4/7/2016	• Approved by MPC. No changes.
4/2/2015	• Approved by MPC. Addition of ICD-10 codes.
5/1/2014, 6/6/2013	• Approved by MPC. No changes.
8/2/2012	• Approved by MPC. Added CMS statement; does not change coverage.
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.

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