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 is intended to supplement certain standard WellCare benefit plans. The terms of a member’s particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member’s benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member’s Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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. Note: The lines of business (LOB) are subject to change without notice; consult www.wellcare.com/Providers/CCGs for list of current LOBs.

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. 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
- Medicare – All Markets

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 members with severe, chronic respiratory failure requiring mechanical ventilation caused by brain or high cervical cord lesions; AND,
- Member is at least 18 years of age; AND,
- Member 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 member 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.

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

- The member 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. amyotrophic 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

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 ICD-9-CM Procedure Codes
04.92 Implantation or replacement of peripheral neurostimulator (leads)
34.85 Implantation of diaphragmatic pacemaker

Draft ICD-10-PCS Codes
00HE0MZ Insertion of Neurostimulator Lead into Cranial Nerve, Open Approach
00HE3MZ Insertion of Neurostimulator Lead into Cranial Nerve, Percutaneous Approach
00HE4MZ Insertion of Neurostimulator Lead into Cranial Nerve, Percutaneous Endoscopic 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
0DH60MZ Insertion of Stimulator Lead into Stomach, Open Approach
Insertion of Stimulator Lead into Stomach, Percutaneous Approach
Insertion of Stimulator Lead into Stomach, Percutaneous Endoscopic Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
Removal of Stimulator Lead from Stomach, Percutaneous Endoscopic Approach
Removal of Neurostimulator Lead from Peripheral Nerve, Open Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Open Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
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Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
Insertion of Neurostimulator Lead into Peripheral Nerve, Percutaneous Approach
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Open Approach
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Approach
Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Open Approach
DIAPHRAGMATIC / PHRENIC NERVE STIMULATION
HS-185

0BHS3MZ
Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Approach

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

0JH834Z (GEM Combination 1)
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHR0MZ (GEM Combination 2)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Open Approach

0JH604Z
Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach

0BHR0MZ (GEM Combination 3)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Open Approach

0JH634Z
Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHR0MZ (GEM Combination 4)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Open Approach

0JH804Z
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0BHR0MZ (GEM Combination 5)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Open Approach

0JH634Z
Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHR3MZ (GEM Combination 6)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Approach

0JH834Z
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHR3MZ (GEM Combination 7)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Approach

0JH604Z
Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach

0BHR3MZ (GEM Combination 8)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Approach

0JH804Z
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0BHR3MZ (GEM Combination 9)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Approach

0JH804Z
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0BHR4MZ (GEM Combination 10)
Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Endoscopic Approach

0JH834Z
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia,
Percutaneous Approach

0BHR4MZ (GEM Combination 11) Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Endoscopic Approach

0JH604Z Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach

0BHR4MZ (GEM Combination 12) Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Endoscopic Approach

0JH634Z Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHR4MZ (GEM Combination 13) Insertion of Diaphragmatic Pacemaker Lead into Right Diaphragm, Percutaneous Endoscopic Approach

0JH604Z Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach

0BHS0MZ (GEM Combination 14) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Open Approach

0JH634Z Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHS0MZ (GEM Combination 15) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Open Approach

0JH804Z Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0BHS0MZ (GEM Combination 16) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Open Approach

0JH834Z Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHS0MZ (GEM Combination 17) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Open Approach

0JH634Z Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

0BHS3MZ (GEM Combination 18) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Approach

0JH804Z Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach

0BHS3MZ (GEM Combination 19) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Approach

0JH604Z Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach

0BHS3MZ (GEM Combination 20) Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Approach
Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

Insertion of Diaphragmatic Pacemaker Lead into Left Diaphragm, Percutaneous Approach

Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Open Approach

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

Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Percutaneous Approach

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

Insertion of Pacemaker, Single Chamber into Chest Subcutaneous Tissue and Fascia, Open Approach

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

Insertion of Pacemaker, Single Chamber into Abdomen Subcutaneous Tissue and Fascia, Percutaneous Approach

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

Covered ICD-9-CM Diagnosis Codes

Primary Diagnosis:
518.83 Chronic respiratory failure
518.84 Acute and chronic respiratory failure

Secondary Diagnosis:
327.25 Congenital central alveolar hypoventilation syndrome
335.20 Amyotrophic lateral Sclerosis
335.21 Progressive muscular atrophy
335.22 Progressive bulbar palsy
335.23 Pseudobulbar palsy
335.29 Other
344.01 - 344.09 Quadriplegia
344.89 Other specified paralytic syndrome
786.09 Other dyspnea and respiratory abnormalities
V46.11 Dependence on respiratory status

Draft ICD-10-CM Diagnosis Codes

Primary Diagnosis
J96.10 - J96.12 Chronic respiratory failure, unspecified or with hypoxia or hypercapnia
J96.20 - J96.22 Acute and chronic respiratory failure, unspecified or with hypoxia or hypercapnia

Secondary Diagnosis
G47.35 Congenital central alveolar hypoventilation syndrome
G12.21 Amyotrophic lateral sclerosis
G12.22 Progressive bulbar palsy
DIAPHRAGMATIC / PHRENIC NERVE STIMULATION
HS-185

G12.8 Other spinal muscular atrophies and related syndromes
G12.20 Motor neuron disease, unspecified
G12.29 Other motor neuron disease
G82.50-G82.54 Quadriplegia
G83.81 Brown-Sequard syndrome
G83.82 Anterior cord syndrome
G83.83 Posterior cord syndrome
G83.84 Todd’s paralysis (postepileptic)
G83.89 Other specified paralytic syndromes
R06.00 Dyspnea
R06.09 Other forms of dyspnea
R06.3 Periodic breathing
R06.83 Snoring
R06.89 Other abnormalities of breathing
Z99.11 Dependence on respirator (ventilator) status

Experimental / Investigational / Unproven / Not Covered

Non-Covered ICD-9-CM Diagnosis Codes - This list is not all inclusive
045.00 - 045.93 Acute poliomyelitis
138 Late effects of acute poliomyelitis
335.20 - 335.29 Motor Neuron Disease
359.0 - 359.29 Muscular dystrophies and other myopathies

Draft ICD-10-CM Diagnosis Codes - This list is not all inclusive
A80.30 - A89.39 Acute paralytic poliomyelitis, other and unspecified
B91 Sequelae of poliomyelitis
G14 Post-polio syndrome
G12.20 - G12.29 Motor neuron disease
G71.11 - G71.19 Myotonic disorders
G71.2 Congenital myopathies
G72.0 - G71.19 Other and unspecified myopathies


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>4/2/2015</td>
<td>Approved by MPC. Addition of ICD-10 codes.</td>
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<tr>
<td>5/1/2014, 6/6/2013</td>
<td>Approved by MPC. No changes.</td>
</tr>
<tr>
<td>8/2/2012</td>
<td>Approved by MPC. Added CMS statement; does not change coverage.</td>
</tr>
<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
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<tr>
<td>8/2/2011</td>
<td>Approved by MPC. No changes.</td>
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