



**Kaiser Foundation Health Plan of Washington**

**Clinical Review Criteria**  
**Diaphragmatic/Phrenic Pacing**

- Mark IV™ Breathing Pacemaker System
- NeuRx DPS RA/4 Respiratory Stimulation System

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**Criteria**  
**For Medicare Members**

Source	Policy
CMS Coverage Manuals	<a href="#">Phrenic Nerve Stimulator NCD 160.19</a>
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None

**For Non-Medicare Members**

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

**If requesting this service, please send the following documentation to support medical necessity:**

- Last 3 months of clinical notes from requesting provider &/or consult notes from the 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**

The diaphragm is a musculotendinous sheet separating the thoracic and abdominal cavities. Supplied by the phrenic nerve from the neck, it contracts rhythmically during respiration and is essential for adequate ventilation (Marieb, Mallatt et al. 2005). Interruptions to the diaphragms physiology from spinal cord injuries (SCI) or amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease) can be devastating leading to chronic hypoventilation. In many cases, mechanical ventilation has been used to generate a controlled flow of gas into a patient's airways which often times, adds a degree of complexity to care due to associations with a number of undesirable side effects such as infection and increased need for assistance. In addition, mechanical ventilation inhibits mobility and speech and can be expensive. Unfortunately, many patients cannot be weaned, and consequently, will require chronic mechanical ventilation.

Diaphragm pacing (DP; Synapse Biomedical, Oberlin, OH) was developed to reduce or eliminate the use of a mechanical ventilator allowing patients to breathe and speak more naturally. In addition, DPS also decreases the risk of complications associated with mechanical respirators such as infection. To a certain degree, DPS allows for an improved quality of life as the device does not inhibit the sense of smell and taste, reduces the reliance on external power source and allows the patient increased mobility making everyday activities such as bathing easier.

The diaphragm pacing system (DPS) requires a minimally invasive procedure to implant four electrodes on the diaphragm where the phrenic nerves connect and an additional electrode just below the skin. The electrodes are then connected to an external battery powered system that provides ongoing electrical stimulation causing the diaphragm to contract and assist with breathing. With the overall goal to produce a training effect by repeated stimulation the DPS is advertised to have the potential of preventing progression of respiratory dysfunction.

The NeuRx DPS™ is manufactured by Synapse Biomedical, Inc. and received approval from the U.S. Food and Drug Administration (FDA) under the humanitarian device exemption in 2008 for treatment of respiratory insufficiency in high-level SCIs. More recently (2011), the indications for the device have been expanded for use in patients with ALS.

## Medical Technology Assessment Committee (MTAC)

### Diaphragmatic/Phrenic Pacing

#### 04/21/2014: MTAC REVIEW

**Evidence Conclusion:** In 2008, Alshekhlee and colleagues evaluated 36 SCI patients who had chronic ventilation for more than a year. Prior to surgical implantation of the device, phrenic nerve conduction studies were conducted to confirm nerve viability. While successful implantation of DPS occurred years after injury, 96% of patients were able to pace and tolerate being off the ventilator for more than four hours per day. Fourteen of the patients (56%) were able to pace full time (24 hours/day) and six were able to pace part-time (12-24 hours/day). The remaining 5 patients (20%) were still in the conditioning phase (4+ hours/day) and had only been implanted within 2-5 months of final analysis. Only, one patient was unable to initiate conditioning due to muscle cramps. The authors concluded that DPS can help patients with cervical SPI to breathe unassisted by a ventilator. (Alshekhlee, Onders et al. 2008). [\[Evidence Table 1\]](#). Most recently, Onders and colleagues published a final analysis of the pilot trial of diaphragm pacing in patients with ALS. Aimed to assess the safety and effectiveness of DPS in ALS patients the prospective open-label evaluation provided long-term analysis of DP in ALS patients. In this study, patients were their own controls with outcome measures being obtained at several visits before and after implantation. While not statistically significant, the efficacy endpoint of respiratory decline was promising with a  $-2.38 \pm 2.84\%$  per month slope for decline pre-implant and a  $-1.34 \pm 1.49\%$  per month slope following implant. In the same way, diaphragm thickness following surgery was greater than the thickness measured prior to implantation. The investigators concluded that long-term use of DP had no safety issues and can positively influence diaphragm physiology and survival (Onders, M et al. 2014). [\[Evidence Table 2\]](#). Thus far, the body of evidence has flawed that complicate interpretation. All reports include small sample sizes and are not randomized. Given that the intervention involves surgery, selection bias may play a role with overall healthier patients referred for intervention limiting the generalizability of the results. Furthermore, methodological details on how some of the outcomes were measured and validated have not been well described. Lack of a comparator group is also a limiting factor in these studies. In terms of safety, while there were no reports of serious adverse effects attributable to the device, DPS relies on surgical implantation exposing patients to any risks associated with surgery including. Finally, it should be noted that Raymond Onders, MD, one of the primary investigators of both selected studies, is the developer of the DPS device. Conclusions: There is insufficient evidence to support the safety of DPS in carefully selected patients with SCI and ALS.

**Articles:** The search revealed numerous case reports and retrospective case series. The majority of the evidence focused on the use of DPS in patients with SCI or ALS. No randomized trials were identified. The initial FDA trial that led to the approval under the humanitarian device exemption was selected as well as the pivotal trial that led to the FDA approval of DP as a therapeutic option in ALS patients. The following studies were selected for review:

Alshekhlee A, Onders RP, Syed TU et al. Phrenic nerve conduction studies in spinal cord injury: applications for diaphragmatic pacing. *Muscle & Nerve*. 2008; 38:1546-1552. [\[Evidence Table 1\]](#). Onders RP, Elmo M, Kaplan C et al. Final analysis of the pilot trial of diaphragm pacing in amyotrophic lateral sclerosis with long-term follow-up: diaphragm pacing positively affects diaphragm respiration. *The American Journal of Surgery*. 2014; 207:393-397. [\[Evidence Table 2\]](#).

The use of diaphragmatic/phrenic pacing does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## Applicable Codes

**Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

**Non-Medicare – Considered Not Medically Necessary:**

HCPC Codes	Description
L8696	Antenna (external) for use with implantable diaphragmatic/phrenic nerve stimulation device, replacement, each

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

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05/06/2014	05/06/2014 <sup>MPC</sup> , 03/03/2015 <sup>MPC</sup> , 01/05/2016 <sup>MPC</sup> , 11/01/2016 <sup>MPC</sup> , 09/05/2017 <sup>MPC</sup> , 07/10/2018 <sup>MPC</sup> , 07/09/2019 <sup>MPC</sup> , 07/07/2020 <sup>MPC</sup> , 07/06/2021 <sup>MPC</sup> , 07/05/2022 <sup>MPC</sup>	05/06/2014

<sup>MPC</sup> Medical Policy Committee

Revision History	Description of Change