Health Technology Review - Appeal Request	
Technology Ref:	HTA19013
Technology Name:	NeuRx DPS® - Diaphragm Pacing System
Reason for Appeal:	New evidence and explanations were provided.
Previous DOH Decision:	Disapprove
Approvals by International Bodies:	Device has FDA HDE approval
Company name:	Reyada Home Health Care Services
Agent in UAE:	Dr. Atef Elshaer
Email:	a.elshaer@reyadamgmt.com

Short Description of the Technology:	The NeuRx Diaphragm Pacing System (DPS) ® is a device that is meant for patients who have both ALS and diagnosed breathing problems. For the NeuRx DPS® to work, the breathing muscle (diaphragm) must be able to respond to stimulation. This can be shown before surgery by a diaphragm movement test or by a breathing nerve test. Patient must be able to exhale at least 45% of the air that a typical healthy person could (in an "FVC" test). Diaphragm Pacing is used to replace, delay and reduce use of invasive mechanical ventilation in indicated patients. It is used to recondition the diaphragm muscles through applying electrical impulses that are transmitted to the diaphragm through intramuscular implanted electrodes. The electrodes are implanted through a minimally invasive abdominal laparoscopic surgery.

Health Technology Assessment Team Recommendation on Appeal:	**Disapproved**

Summary of Review:

Both the Health Technology Assessment team and the sought experts in the Department of Health have reviewed the provided evidence and found out that the shared evidence was part of the initial review of this technology and it poses concerns regarding this technology such as serious adverse events, mortality and quality of life.

With reference to Prof. Ray Onders – please note that conflict of interests were declared in the Onders studies as the primary author has intellectual property right involved with the device and equity in the company.

After carefully considering the appeal, the HTA team stands by the latest guidance issued by the National Institute for Health and Care Excellence (NICE) in 2017 which states:
"Current evidence on intramuscular diaphragm stimulation for ventilator-dependent chronic respiratory failure caused by motor neurone disease suggests that there are serious long-term safety concerns. Evidence on efficacy is limited and therefore, this procedure should not be used to treat this condition"

Based on this, the HTA team agreed to **Not Recommend** this technology.

Technology Image