



BlueCross BlueShield of Louisiana

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Electrophrenic Pacemaker Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00032
Original Effective Date: 06/28/2004
Archived Date: 05/16/2012

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of electrophrenic pacemakers to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for electrophrenic pacemakers will be considered when all of the following criteria are met:

- Permanent, severe hypoventilation caused by brain or high cervical cord lesions; and
- One of the following conditions:
 - Quadriplegia (high C3 or above); or
 - Central alveolar hypoventilation syndrome.

Note: Electrophrenic pacemakers are contraindicated in the following situations:

- Pre-operative screening tests do not demonstrate that phrenic nerves, lungs and diaphragm can sustain ventilation by electrical stimulation;
- Patient has another serious disorder that might affect nerve conduction (e.g., tumors, vascular disease, diabetes, multiple sclerosis, etc.).

When Services Are Considered Not Medically Necessary

The use of electrophrenic pacemakers is considered to be **not medically necessary**** for any of the following conditions:

- Patient can subsist independently of a mechanical respirator;
- Respiratory insufficiency is temporary.

When Services Are Considered Investigational

Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.



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Based on review of available data, the Company considers use of an electrophrenic pacemaker for the following indications to be **investigational***:

- Chronic obstructive pulmonary disease;
- Young children and infants;
- Treatment of hiccups.

Background/Overview

The electrophrenic pacemaker is an implanted electrode and receiver with a pocket or table-top size external transmitter. The device electrically stimulates the phrenic nerves to contract the diaphragm rhythmically, which causes breathing. Diaphragmatic/Phrenic (D/P) nerve stimulation is intended as an alternative to mechanical ventilation in selected patients with ventilatory insufficiency or failure that have retained adequate function in their phrenic nerves and diaphragm. The D/P nerve stimulator is an implanted device that acts as a pacemaker by providing regular electrical pulses to the phrenic nerves. Stimulation of the nerves then causes the diaphragm to contract, which produces negative pressure in the chest, allowing air to enter the lungs. The equipment needed to receive D/P nerve stimulation treatment is small enough to be worn in a pocketed belt or vest, and allows considerable freedom for patients who may be ambulatory or use a wheelchair. It also allows patients to speak and enhances their social integration.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Electrophrenic Pacemaker", 7.01.37, 1:2006.

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines (BCBSLAMPCG) are obtained from Current Procedural Terminology (CPT®)†, copyright 2012 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	64575,64577, 64585, 64590, 64595, 95972
HCPCS	C1816, C1883, L8680, L8681
ICD-9 Diagnosis	All diagnoses
ICD-9 Procedure	34.85

Policy History

Original Effective Date: 06/28/2004

05/07/2004 Medical Director review

05/18/2004 Medical Policy Committee review

06/28/2004 Managed Care Advisory Council approval

03/01/2005 Medical Director review

03/15/2005 Medical Policy Committee review

04/04/2005 Managed Care Advisory Council approval

03/14/2007 Medical Director review

03/21/2007 Medical Policy Committee approval. Coverage eligibility unchanged.

03/12/2008 Medical Director review

03/19/2008 Medical Policy Committee approval. No change to coverage eligibility.

03/04/2009 Medical Director review

03/18/2009 Medical Policy Committee approval. No change to coverage eligibility.

06/03/2010 Medical Policy Committee review

06/16/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.

05/05/2011 Medical Policy Committee review

05/18/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.

05/03/2012 Medical Policy Committee review. Recommend archiving policy.

05/16/2012 Medical Policy Implementation Committee approval. Archived medical policy.

02/19/2013 Coding revised

Next Scheduled Review Date: Archived medical policy.

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. in accordance with nationally accepted standards of medical practice;
- B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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