

Corporate Medical Policy

Cough Stimulating Device

File Name:	cough_stimulating_device
Origination:	7/2006
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Description of Procedure or Service

Normal clearance of the airway rests on 3 basic components: a patent airway, mucociliary clearance, and an adequate cough. Members with spinal cord injuries or a variety of neuromuscular diseases or chest wall deformities may have impaired cough responses, which may lead to respiratory failure during respiratory tract infections due to the inability to clear the profuse respiratory secretions. Chest wall deformities may include kyphosis, scoliosis, or lordosis, while neuromuscular diseases include muscular dystrophy, poliomyelitis, spinal muscle atrophy, myasthenia gravis, amyotrophic lateral sclerosis, or cerebral palsy. The great majority of neuromuscular disease morbidity and mortality is related to respiratory muscle weakness, and the vast majority of episodes of respiratory failure occur during otherwise benign episodes of respiratory tract infections. Chest infections may result in repeated episodes of pneumonia, repeated hospitalization, and finally, in tracheostomy with mechanical ventilation.

The normal cough consists of 4 stages: 1. a precough inspiration to about 85% of total lung capacity; 2. followed by closure of the glottis; 3. development of thoracoabdominal pressure sufficient to generate an explosive decompression of the chest at glottic opening; and 4. opening of the glottis with exsufflation. The peak cough expiratory force typically exceeds 5L/sec, with total expiratory volume of about 2.3L. A variety of techniques have been developed to enhance each of these stages. For example, manually assisted coughing is designed to enhance exsufflation and consists of abdominal pressure delivered by a caregiver timed with the glottic opening. Manual assisted coughing may be offered to patients with a peak cough expiratory flow of less than 5L/sec, but is less effective in the presence of scoliosis or obesity or after meals. Glossopharyngeal breathing is a technique to increase inspiratory flow and is commonly used in patients with a decreased vital capacity due to inspiratory muscle paralysis. This breathing technique involves the use of the tongue and pharyngeal muscles to add to an inspiratory effort by projecting (gulping) boluses of air past the glottis. Mechanical insufflation-exsufflation is designed to deliver alternative cycles of positive and negative pressure. The positive pressure causes air to enter the lungs, followed by a rapid drop in pressure that causes exsufflation. One such device, the CofFlator was first marketed during the 1950s but fell into disuse with the popularity of tracheostomy and suctioning as a technique of ventilatory support. Subsequently, the concept for the device was reactivated and the device redesigned, resulting in 1993 U.S. Food and Drug Administration (FDA) approval of the In-Exsufflator. (JH Emerson Co, Cambridge, Mass.). The device, which may also be referred to as a "coughalator," is designed to deliver insufflation-to-exsufflation pressure of about +40 to -40 cm H₂O, which in turn simulates a powerful cough by creating an expiratory flow of 10L/sec. Cycling between insufflation and exsufflation can either be performed manually or automatically. Five or more treatments are generally given in 1 session until no further secretions are expelled, and hemoglobin desaturations related to mucous plugging are resolved.

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A cough stimulating device, also known as a mechanical insufflator-exsufflator, is a portable electric device intended to help pediatric or adult patients with respiratory insufficiency (i.e., those with ineffective cough) clear retained bronchopulmonary secretions. This noninvasive device uses a blower and a valve to alternately apply a positive pressure and then an abrupt negative pressure to the patient's airway. This rapid shift in pressure produces a high expiratory flow rate from the lungs, simulating a natural cough. Air moves to and from the patient via a breathing circuit consisting of a flexible tube, a bacterial filter, and either a facemask, a mouthpiece, or an adapter to a tracheostomy or endotracheal tube.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

The use of a cough stimulating device (mechanical insufflation-exsufflation) may be considered medically necessary in members with neuromuscular disease or spinal cord injury, impaired ability to cough and who require ventilatory assistance.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

DME Supplier must meet eligibility and/or credentialing requirements as defined by the Plan in order to be eligible for reimbursement.

When Cough Stimulating Device is covered

Cough Stimulating Devices may be considered medically necessary when **ALL** the following criteria are met:

- the member has a neuromuscular disease or high spinal cord injury that is causing a significant impairment of chest wall and/or diaphragmatic movement **AND**
- for whom standard treatments (inhalers, IPPB, incentive spirometry, PEP devices, flutter valve devices and manual techniques such as chest percussion and postural drainage, under the guidance of a skilled professional practitioner) have not been successful in adequately mobilizing retained secretions **AND**
- has a peak cough expiratory flow of less than 2-3L per second **AND**
- is motivated to use the device as prescribed or has able caregivers who can be trained to use the device effectively.

When Cough Stimulating Device is not covered

The use of a cough stimulating device is considered not medically necessary when the criteria above are not met.

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Policy Guidelines

Cough Stimulating Devices may be offered on a temporary basis in members with noninvasive intermittent positive pressure ventilation (IPPV) who are suffering from a respiratory tract illness, or may be used on a more chronic basis in an attempt to avoid the option of tracheostomy and suctioning.

In members with a tracheostomy, a Cough Stimulating Device may be offered in lieu of suctioning.

In general, an impaired ability to cough has been defined as a peak cough expiratory flow of less than 2–3L per second.

Chronic obstructive pulmonary disease, bullous emphysema, known susceptibility to pneumothorax or pneumomediastinum, or exposure to recent barotrauma are considered relative contraindications to cough stimulating devices.

The published data suggest that Cough Stimulating Devices can improve the intermediate outcome of peak cough expiratory flow. While controlled trials would ideally further delineate who is most likely to benefit from the use of a Cough Stimulating Device, particularly those who would benefit from having such a device in the home, such trials are logistically difficult. The heterogeneous nature of the patients, even among those with similar diseases, almost mandates a case by case approach for these patients. For example, the clinical utility of the device would not only depend on the physiologic parameters of lung function, but also on the tempo of the disease course, the availability of home caregivers, and patient preference and motivation. The medical necessity status for the device is based on these considerations.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: A7020, E0482

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.21, 11/09/04

Miller RG, Rosenberg JA, Gelinas DF, Mitsumoto H, Newman D, Sufit R, et al. Practice parameter: the care of the patient with amyotrophic lateral sclerosis (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology: ALS Practice Parameters Task Force. *Neurology* 1999;52(7):1311-23.

ECRI Target Report #837 (March 2003). Mechanical insufflation-exsufflation for respiratory insufficiency. Retrieved May 23, 2006 from http://www.target.ecri.org/summary/detail.aspx?doc_id=1748.

Irwin RS, Bouliet L, Cloutier MM, Gold PM, Ing AJ, O'Byrne P, et al. Managing cough as a

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defense mechanism and as a symptom: a consensus panel report of the American College of Chest Physicians (ACCP). Chest. 1998 Aug;114(Suppl)(2):133S-81S.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.21, 7/8/10.

Specialty Matched Consultant Advisory Panel review- 3/2012

Policy Implementation/Update Information

- 7/24/06 Notification of new policy titled "Cough Stimulating Device." The use of a cough stimulating device (mechanical insufflation-exsufflation) may be considered medically necessary in members with neuromuscular disease or spinal cord injury and impaired ability to cough and who require ventilatory assistance. Notification date 7/24/06. Effective date 10/2/06. (adn)
- 7/2/07 Specialty Matched Consultant Advisory Panel review meeting 5/25/07. No changes to policy coverage criteria. (adn)
- 6/8/09 Specialty Matched Consultant Advisory Panel review meeting 5/13/09. No change to policy coverage criteria.
- 6/22/10 Policy Number(s) removed (amw)
- 1/4/11 Added new HCPCS code A7020 to Billing/Coding section. (lpr)
- 3/29/11 Policy status changed to "Active policy, no longer scheduled for routine literature review." References updated. (mco)
- 3/30/12 Specialty Matched Consultant Advisory Panel review 3/21/2012. Extensively revised the description section and policy guidelines section. Active archive policy converted back to active policy. No change to policy statement. (lpr)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.