MEDICAL POLICY

POLICY TITLE	MECHANICAL INSUFFLATION-EXSUFFLATION DEVICE
POLICY NUMBER	MP 6.022

Effective Date:	1/1/2024

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I. POLICY

Mechanical insufflation-exsufflation (MI-E) may be considered **medically necessary** in individuals with all of the following:

- Impaired ability to cough secondary to neuromuscular disease or spinal cord injury **AND**
- Absence of ALL of the following:
  - Chronic Obstructive Pulmonary Disease (COPD)
  - Bullous emphysema
  - Known susceptibility to pneumothorax or pneumo-mediastinum
  - Exposure to recent barotrauma.

Mechanical insufflation-exsufflation is considered **investigational** in all other situations not listed above. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 6.015 Airway Clearance Devices
MP 6.026 Durable Medical Equipment (DME) and Supplies

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Normal clearance of airways rests on three (3) basic components: a patent airway, mucociliary clearance, and an adequate cough. Patients with spinal cord injuries or a variety of neuromuscular diseases or chest wall deformities may have impaired cough responses. This 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 subsequent respiratory failure occurring during otherwise benign episodes of respiratory tract infections. Chest infections may result in repeated episodes of pneumonia, repeated hospitalizations, 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. In general, an impaired ability to cough has been defined as a peak cough expiratory flow of less than 2-3L per second.

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. One such device, the CoughAssist, is a portable electric device which utilizes a blower and valve to alternately apply a positive and then a negative pressure to a patient's airway in order to assist the patient in clearing retained bronchopulmonary secretions. Air is delivered to and from the patient via a breathing circuit incorporating a flexible tube, a bacterial filter and either a facemask, a mouthpiece or an adapter to a tracheostomy or endotracheal tube. Physicians, respiratory therapists, nurses and trained family members may administer this therapy.

Mechanical in-exsufflation (MI-E) has been used in a variety of patient populations as an adjunct to noninvasive ventilation using intermittent positive pulmonary ventilation (IPPV) (delivered nasally or orally). For example, many patients with neuromuscular disease or chest wall deformities with progressive ventilatory failure will use noninvasive IPPV either nocturnally or throughout the day, depending on such parameters as vital capacity and oxygenation levels. Patients managed at home with noninvasive IPPV may monitor oxygen desaturation levels. A sudden decrease in oxygen desaturation may prompt the use of MI-E to eliminate the presumed offending mucus plug. Advocates of MI-E state that even patients requiring 24 hour IPPV can be managed noninvasively for prolonged periods of time without hospitalization using this technique. In patients with tracheostomies, MI-E has been used as an alternative or complement to suctioning. In addition, it is suggested that MI-E is more comfortable to the patient than suctioning. MI-E may either be offered on a temporary basis in patients with

noninvasive 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 invasive tracheostomy and suctioning.

IV. RATIONALE

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Summary

The published data suggest that MI-E can improve the intermediate outcome of peak cough expiratory flow. In some studies, patients have served as their own control, with a decreased incidence of hospitalization among patients who switch from tracheostomy to a noninvasive approach, which may include MI-E as one component. While controlled trials would ideally further delineate who is most likely to benefit from MI-E, 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 MI-E 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 non-investigational status for the MI-E device is based on these considerations.

V. DEFINITIONS

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EXSUFFLATION is the forceful expulsion of air from a cavity by artificial means, such as the use of a mechanical exsufflator.

GLOSSOPHARYNGEAL refers to the tongue and pharynx.

INSUFFLATION is the act of blowing a gas, vapor, or powder into a cavity, such as the lungs.

INTERMITTENT POSITIVE PRESSURE refers to a mechanical method for assisting pulmonary ventilation employing a device that administers air or oxygen for the inflation of the lungs under positive pressure. Synonym: intermittent positive pressure ventilation (IPPV).

TRACHEOSTOMY refers to an incision of the trachea through the skin and muscles of the neck overlying the trachea.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

HCPCS Code	Description
A4468	Exsufflation belt, includes all supplies and accessories
A7020	Interface for cough stimulating device, includes all components, replacement only
E0482	Cough stimulating device, alternating positive and negative airway pressure

ICD-10-CM Diagnosis Code	Description
B91	Sequelae of poliomyelitis
E74.02	Pompe disease
E74.05	Lysosome-associated membrane protein 2 [LAMP2] deficiency
G12.0	Infantile spinal muscular atrophy, type I [Werdnig-Hoffman]
G12.1	Other inherited spinal muscular atrophy
G12.20	Motor neuron disease, unspecified
G12.21	Amyotrophic lateral sclerosis
G12.22	Progressive bulbar palsy
G12.23	Primary lateral sclerosis
G12.24	Familial motor neuron disease
G12.25	Progressive spinal muscle atrophy
G12.29	Other motor neuron disease

G12.8	Other spinal muscular atrophies and related syndromes
G12.9	Spinal muscular atrophy, unspecified
G14	Postpolio syndrome
G35	Multiple sclerosis
G70.01	Myasthenia gravis with (acute) exacerbation
G71.00	Muscular dystrophy, unspecified
G71.01	Duchenne or Becker muscular dystrophy
G71.02	Facioscapulohumeral muscular dystrophy
G71.09	Other specified muscular dystrophies
G71.11	Myotonic muscular dystrophy
G71.12	Myotonia congenita
G71.13	Myotonic chondrodystrophy
G71.14	Drug induced myotonia
G71.19	Other specified myotonic disorders
G71.2	Congenital myopathies
G71.20	Congenital myopathies, unspecified
G71.21	Nemaline Myopathy
G71.22	Centronuclear Myopathy
G71.220	X-linked myotubular myopathy
G71.228	Other centronuclear myopathy
G71.29	Other congenital myopathy
G71.3	Mitochondrial myopathy, not elsewhere classified
G71.8	Other primary disorders of muscles
G71.9	Primary disorder of muscle, unspecified
G72.0	Drug-induced myopathy
G72.1	Alcoholic myopathy
G72.2	Myopathy due to other toxic agents
G72.3	Periodic paralysis
G72.41	Inclusion body myositis [IBM]
G72.49	Other inflammatory and immune myopathies, not elsewhere classified
G72.81	Critical illness myopathy
G72.89	Other specified myopathies
G72.9	Myopathy, unspecified
G73.7	Myopathy in diseases classified elsewhere
G82.50	Quadriplegia, unspecified
G82.51	Quadriplegia, C1-C4 complete
G82.52	Quadriplegia, C1-C4 incomplete
G82.53	Quadriplegia, C5-C7 complete

G82.54	Quadriplegia, C5-C7 incomplete

IX. REFERENCES

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Other:
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X. POLICY HISTORY

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MP 6.022	**CAC 12/2/03**
	CAC 5/31/05
	CAC 5/30/06 Consensus
	CAC 1/30/07 Milliman Criteria
	CAC 11/27/07
	CAC 11/25/08
	CAC 9/29/09 Consensus - policy statement unchanged, references updated
	CAC 11/30/10 Consensus
	CAC 11/22/11 Consensus review
	4/08/13- Admin code review.
	7/19/13 Admin coding review complete
	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements.
	CAC 9/30/14 Consensus review. References updated. No changes to the policy statements. Rationale added. Coding reviewed.
	CAC 9/29/15 Consensus review. References reviewed. No change to policy statements. Coding reviewed and unchanged. LCD changed from L12872 to L33795
	7/15/16 Administrative posting. LCD revised to reflect Noridian LCD L33795.

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POLICY NUMBER	MP 6.022

	CAC 9/27/16 Consensus review. No changes to the policy statements**.** Variations reformatted.
	CAC 9/26/17 Consensus review. Policy statement unchanged. References updated. Coding updated. Added new ICD 10 codes effective from 10/1/17.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	6/8/18 Consensus review. No changes to the policy statements. Rationale condensed. References updated**.**
	10/1/18 Admin Update: Removed deleted ICD-10 codes, added new ICD-10 codes effective 10/1/18. **10/29/18** Consensus Coding Review. No Changes.
	4/15/19 Consensus review. No changes to policy statement. References updated.
	4/23/20 Consensus review. No changes to policy statement. Coding reviewed, added diagnosis codes E74.02 and G70.01. References updated.
	9/2/20 Admin update. ICD codes added, G71.20, G71.21, G71.22, G71.220, G71.228, G71.29
	7/26/2021 Consensus review. No change to policy statement. References updated and coding reviewed.
	1/10/2022 Consensus review. No change to policy statement. Product and Benefit Variations updated. Disclaimer updated. References added.
	06/30/2023 Minor review. Removed "who require non-invasive ventilatory assistance" from policy statement. Reworded statement for clarity and to include contraindications. Added policy guidelines. Updated references.
	10/01/2023-Admin Update- New diagnosis code added to policy from new code review.
	12/13/2023 Admin update. New code A4468 added. Effective 1/1/24.

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