Policy for the use of Mechanical Insufflator/Exsufflator (MI-E) - Cough Assist Machines
The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decision are considered within the wider constraints of the CCG’s legally responsibility to remain fiscally responsible.
An effective cough is an essential protective mechanism against respiratory tract infections. Cough can become ineffective due to respiratory muscle weakness in neurological and neuromuscular conditions, prolonged inactivity (e.g. post intubation), nerve injury, tracheostomy and vocal cord pathology.

Patients who have an ineffective/weak cough due to neuromuscular and neurological conditions and cervical cord injury are unable to clear secretions and are therefore susceptible to respiratory tract infections including pneumonia which require antibiotics and hospital admission. Respiratory tract infections caused by respiratory muscle weakness is the most common cause of hospital admission for patients with neuromuscular conditions. These include patients with conditions such as muscular dystrophy, spinal muscular atrophy, motor neurone disease and spinal cord injury.

The mechanical insufflator/exsufflator (MI-E/ Cough Assist machine) assists the clearance of bronchopulmonary secretions in those patients with an ineffective cough by the use of both positive and negative pressure.

The MI-E (Cough Assist Machine) is a non-invasive therapy that safely and consistently removes secretions in patients with an ineffective ability to cough (measured by peak cough flow <270 l/m). The Cough Assist device clears secretions by gradually applying a positive pressure to the airway, then rapidly shifting to negative pressure. The rapid shift in pressure produces a high expiratory flow, creating an effective cough by significantly increasing peak cough flow, which improves airway clearance and removes bronchopulmonary secretions, thereby preventing and reducing respiratory tract infections.

Respiratory function should be assessed in people with more complex care needs by a Specialist Ventilation MDT that includes consultants with a special interest in ventilatory support / weaning, physiotherapists, specialist ventilation nurses. The MDT may include palliative care and speech and language clinicians.

All patients being considered for cough assist device should be discussed with the Local Respiratory Specialist Team, however ONLY the Specialist Ventilation MDT may assess and apply for funding for a cough assist machine for the patient however, once funding has been secured, the local Respiratory Specialist Team may provide assessment, equipment if clinically indicated and on-going monitoring and support to the patient. If annual funding renewal is required, then review with the Specialist Ventilation MDT will be required to ensure that use of the device remains clinically indicated in the patient.

N.B the Specialist Ventilation MDT will need to be ratified by the CCG as an appropriate centre, with an appropriately skilled MDT prior to funding applications being accepted by the CCG.
**Benefits of Cough Assist**

- Removes secretions from the lungs
- Reduces the occurrence of respiratory infections and the ensuing requirement for antibiotics
- Supports a patient to avoid hospitalisation and need for intubation and tracheostomy
- Recruits lung volume and prevents atelectasis
- Decreases the risk of patient mortality
- Safe, non-invasive alternative to suctioning
- Easy for patients and caregivers to operate
- Can be used with a face mask, mouthpiece or with an adapter to a patient’s endotracheal or tracheostomy tube
- Approved for home use in adults and children
- Available in automatic and manual models
- Portable so patients can increase independence and clear secretions in community, thereby improving quality of life

In preparing this policy, an evidence review was commissioned to ascertain the strength of the available clinical evidence to support the use of cough assist machines. Clinical and public engagement was undertaken which highlighted a number of studies and clinical opinion, published since the evidence review was undertaken.

The CCG, noted in particular, the significant amount of clinical opinion, both, local, national and international, which supported the use of cough assist machines in certain clinical circumstances within the community. The support of the use of the device by NHS England within an in-patient setting in certain clinical circumstances was also taken into consideration and the support given to the use of the machines by NICE and the British Thoracic Society, despite the availability of often low quality evidence to support the use of cough assist machines. It was noted by the CCG that it may potentially be difficult for Randomised Control trials to be undertaken in this area due to ethical considerations and that each procedure / treatment which is reviewed in the policy pathway is reviewed in the specific and individual circumstances in which it is presented.
Eligibility Criteria

The patient must be diagnosed with one of the following conditions:

- Motor Neurone Disease
- Spinal Muscular Atrophy
- Muscular Dystrophy
- Myasthenia gravis
- Spinal cord injury
- Multiple Sclerosis
- Guillain-Barre Syndrome
- Post polio syndrome with respiratory impairment
- Kypho-scoliosis
- Syringomyelia
- Other neuromuscular disease which is known to cause respiratory muscle weakness or upper airway functional impairment.

AND

In line with the above diagnosis the patient must also be unable to cough or clear secretions effectively:

- PCF (Peak Cough Flow) less than 160 L/min AND
- VC (vital capacity) below 1.1L in general respiratory muscle weakness, AND
- Reduced Peak Cough Flow (PCF) of 270 l/pm or < 270 l/pm and have clinical symptoms or a weak cough and therefore require intervention necessary to clear bronchial secretions or infection

AND

The patient must be assessed and continue to be monitored by a specialist ventilation team with expert clinical knowledge and experience in the use of Cough Assist machines.

AND

Prior approval for funding must be sought for a cough assist machine to be provided in the community prior to the patient being supplied with a Cough Assist machine. For each patient funded with a Cough Assist Machine the provider should provide a written annual update by the specialist ventilation team to evidence that continuation of treatment is clinically effective before the next year of funding will be continued.
**Contraindications to treatment with a Cough Assist Machine**

The specialist ventilation team will individually assess each patient prior to commencing treatment with a cough assist machine and consider all contraindications before use.

These could include:
- Any patient with a history of bullous emphysema
- Susceptibility to pneumothorax or pneumo-mediastinum

This means *(for patients who DO NOT meet the above criteria)* the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.
Guidance:


35. Chatwin


52. Sivasothy P, Brown L, Smith IE, Shneerson JM. Effect of manually assisted cough and mechanical insufflation on cough flow of normal subjects, patients with chronic obstructive pulmonary disease (COPD), and patients with respiratory muscle weakness. Thorax 2001;56(6):438-44


57. Respiratory Care of the Patient with Duchenne Muscular Dystrophy. ATS Consensus statement Finder JD. American Journal of Respiratory and Critical


