### Adult Continuous Ventilation - Clinical Criteria

This criteria has been developed in consultation with expert clinicians and is based on available evidence at the time of development. This document is designed to specify the criteria to access assistance through EnableNSW for this group of assistive technology, and provide a basis for consistent and transparent decision making.

#### Included Equipment
- Prescription under this Clinical Criteria includes 2 complex ventilators (identical) with appropriate alarms and battery back up systems
- In-use carry bag and/or mounting bracket

#### Exclusions
- Cough Assist Devices and associated consumables
- Monitoring systems (e.g. pulse oximeters, end tidal CO₂ system etc.)
- Ventilators solely for transport
- Ventilator car chargers/adaptors
- Filters (such as bacterial/viral filters)
- Power generators
- Masks, mouthpiece for non-invasive support
- Phrenic nerve stimulation products
- Nebulisers and associated consumables

#### Contracts in Place
- 1002444 SOA for Ventilator equipment 2012 - 2016 (NSW Government contract for complex ventilators)
  
  Please contact EnableNSW for information on the contract

#### Ineligible Groups
People who are eligible for services and equipment from any of the following will not be eligible to receive equipment through EnableNSW (see EnableNSW Policy).
- ADHC owned and operated supported accommodation facility or services
- Respite or temporary care facilities
- Transitional Aged Care Package
- Home Care Packages (levels 1-4)
- Lifetime Care and Support Authority
- Dust Disease Board
- Department of Veteran’s Affairs Gold Card holder
- Department of Veteran’s Affairs White Card holder if the requested assistive technology is for an injury/condition developed during/or as a result of time in service
- Third party/Worker’s Compensation/other compensation related to the injury/disease
- People in hospital whose respiratory condition has not stabilised and/or require the equipment for discharge

#### Eligible Prescribers
The primary prescribing team may include: Specialist physician in respiratory medicine, sleep medicine, spinal cord injury or intensive care in consultation with the multidisciplinary care team (e.g. clinical nurse consultant, clinical nurse specialist, occupational therapists, physiotherapist, biomedical engineer, speech pathologists).

It is recommended that a multidisciplinary service advise on the person’s setup and equipment requirements. Centres with limited or no experience with the management of complex, ventilator dependent people should liaise with a recognised tertiary institution to assist in planning home discharge.

#### Recommended Review Timeline
It is recommended that a review is performed every 6-12 months, or as determined by the stability of the underlying clinical condition.

Reviews may be conducted in a variety of settings e.g. Home, clinic or hospital admission.

Respiratory reviews should be conducted by the primary prescribing physician or nominated reviewing clinical team that manages the person’s ventilation requirements in the community.

As a minimum an updated prescription will be required annually as part of the equipment maintenance program.

#### Other Considerations
- If the person is prescribed consumables that interface (e.g. circuits etc.) for invasive support, a separate equipment request will need to be made for those products as per the Adult Suction Units, Electrical Humidification and Respiratory Consumables Clinical Criteria
- If the person is prescribed oxygen, a separate equipment request will need to be made for this equipment as per the Adult Home Oxygen Clinical Criteria
- If there is a requirement for the ventilator to be mounted on a wheelchair, an assessment must be arranged
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with the biomedical engineer, seating service and/or allied health staff as soon as possible to ensure that there is no delay in safely mounting the ventilator onto the wheelchair

**EQUIPMENT ELIGIBILITY**

This Clinical Criteria refers to persons ≥ 16 years of age, with a demonstrated need for long term (≥ 12 months) continuous mechanical ventilation. For the purposes of this document, continuous ventilation is defined as requiring ventilation ≥ 16hrs/day.

To support the request for continuous ventilation equipment, the clinical team must provide a comprehensive report (including evidence e.g. copies of tests and complete prescription settings) detailing EACH of the following categories (1-3): Diagnosis, Stability and Adequacy of Care.

**Diagnosis**
The person is either 1. Dependent on ventilation for life support or 2. Requires ventilation ≥ 16hrs/day;

1. **Dependent on ventilation for life support**
   Evidence (e.g. report) that the person is diagnosed with a chronic congenital, medical or traumatic condition (e.g. a brain stem condition, spinal cord injury SCI, or tetraplegia) with no spontaneous respiratory effort, requiring continuous mechanical ventilation to sustain life. For example:
   - Spinal cord injury at a level consistent with loss of respiratory muscle function OR
   - Inability to spontaneously trigger the ventilator in a consistent manner during wakefulness during weaning trials OR
   - Absent or only weak inspiratory efforts when ventilatory support is withdrawn resulting in a significant fall in tidal volume or minute ventilation OR
   - Development of physiological signs of respiratory distress when removed from ventilatory support such as diaphoresis and tachycardia OR
   - Repeated attempts to reduce the time on ventilatory support have resulted in acute respiratory compromise with falls in oxygen saturation and/or rises in carbon dioxide

2. **Ventilator use required ≥ 16hrs/day**
The person has respiratory decompensation which has resulted in the need for respiratory support of ≥ 16 hours per day where complete weaning off ventilatory support is not possible. This can be evidenced by technical and physician reports of tests performed prior to and after cessation of ventilatory support, which shows either of the following:
   - 2.1. A fall in SpO\(_2\) to ≤ 92% whilst awake (in the absence of lung disease) OR
   - 2.2. Rise in CO\(_2\) (≥ 8mmHg from baseline on paired arterial, end-tidal or transcutaneous monitoring) when off ventilatory support OR
   - 2.3. Documentation of signs of hypoventilation or respiratory distress relieved by ventilatory support OR
   - 2.4. For people with progressive disorders and already established on bilevel ventilation; the download of nocturnal ventilation therapy compliance data demonstrating usage of equipment ≥ 16hrs/day

**Stability**
The long term ventilation prescription has been monitored over a trial period of at least 1 week following commencement of ventilation on the device proposed for long term home use (on the community appropriate ventilator) and the person has demonstrated tolerance of associated electro-medical devices and respiratory consumables as evidenced by:

3. Download of compliance data from the 1 week trial on the community appropriate ventilator demonstrating usage of equipment ≥ 16hrs/day AND
4. Complete prescription settings including (but not limited to): day/night time settings, invasive/non-invasive delivery, mode, alarms etc. AND
5. The person is medically stable on the current community appropriate ventilator settings and no longer requires major alterations to meet their long term need (as evidenced on downloaded technical report of oximetry or CO\(_2\) trend)
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**Adequacy of current care**
- 6. An individual plan that has been communicated to all members of the team (the person, clinical team, community carers etc.) which meets age and disability-appropriate and physical, emotional and social goals
- 7. That a risk assessment in the community has been conducted and documented and the person can be safely managed on the prescribed equipment in the community
- 8. That the person and the family/primary carer have acknowledged the risks and responsibility for safely managing the person and the equipment in the community
- 9. A plan has been communicated to the person and their family/primary carer to manage clinical and equipment emergencies

**The responsibility of the Prescribing/clinical team is to ensure that:**

**Social/carer criteria**
- The person and/or relevant users (family/primary carer) have been trained by the clinical team and are capable of using the equipment safely and appropriately, including basic equipment care and trouble shooting.
- The person will comply with device usage as prescribed
- Information is provided to the person about their ongoing treatment plan, clinical review and assessment requirements in relation to mechanical ventilation. This may include information about regular follow-up as per the Recommended Review Timeline

**Equipment factors**
- Any change to the prescription is to be communicated to all relevant parties including EnableNSW
- EnableNSW is contacted if the equipment is no longer required. EnableNSW can be contacted to coordinate repairs and/or replacement within business hours (9am-5pm, Monday-Friday)
  - NB: EnableNSW and contracted equipment suppliers do not provide a 24 hour equipment support contact line
- The person and/or carer has an emergency plan in the event of respiratory equipment failure outside of business hours. Emergency procedures may include utilisation of the second ventilator or presentation to hospital and that the appropriate local community services have been notified of the person’s needs

**Environmental Factors**
- Consideration of the environment where the equipment will be used e.g. school, work, mounting on a wheelchair etc.
- The equipment prescribed is compatible with the person’s home environment and is suitable for safe management of the person in the community
- As part of the home assessment, a competent person has assessed the electrical appropriateness of the accommodation to ensure that it meets or has been modified to meet the requirements of the equipment to be used and the person. As a recommendation:
  - There should be a dedicated and clearly identified power point (i.e. marked as red) on a separate circuit for the ventilator with an appropriate safety switch which may be easily reset by the person or carer from inside the room while being ventilated. Multiple outlets may be present if the person requires ventilation at different locations. Where ever possible a dedicated circuit for each outlet must be used
  - There should be sufficient additional power capacity and power outlets to run the remainder of the electro-medical equipment e.g. battery charger, suction machine, electric bed
  - There should be a separate General Purpose Outlet for each piece of equipment that needs to be plugged into mains power. Extension boards, extension leads and double adaptors are not to be used except in an emergency

**The responsibility of EnableNSW is to ensure that:**

The equipment supplier arrangements include:
- Appropriate ventilator equipment that meets the person’s clinical needs as per the prescription, and facilitates access to the community
- Delivery of the device/s to the person or Health Service
- The provision of equipment that complies with the Therapeutic Goods Act (TGA) and has a valid Australian Register of Therapeutic Goods (ARTG) number
- A contractual service and preventative maintenance agreement as per manufacturer’s recommendations including provision of an identical loan unit if equipment is to be removed for repair, maintenance or testing
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- The collection of serial numbers and service history of the device with reports being provided to EnableNSW

Bibliography