Paediatric Nocturnal 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

- Nocturnal ventilation equipment incorporating spontaneous, spontaneous-time mode or volume targeted pressure support, as prescribed
- Integrated humidification

Exclusions

- Circuit/tubing
- External monitoring systems (e.g. pulse oximeters, end tidal CO₂ system etc.)
- Masks/interface (e.g. Nasal, full face, nasal pillows, chin straps)
- Ventilators solely for transport
- Power generators
- Ventilator car chargers/adaptors
- Filters (such as bacterial/viral filters)
- Masks, mouthpiece for non-invasive support
- Phrenic nerve stimulation products
- Nebulisers and associated consumables
- Filters (including bacterial/viral filters)
- Second ventilator and/or battery back-up except where prescribed as life support equipment (i.e. complex ventilator for a child who cannot spontaneously breathe during sleep)

Contracts

- 956 Electro-medical
- 1002444 SOA for Ventilator equipment 2012 – 2016 (NSW Government contract for complex ventilators)

Please contact EnableNSW for information on the contract.

Ineligible Groups

Children and young 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
- Lifetime Care and Support Authority
- Third party/Worker’s Compensation/other compensation related to the injury/disease
- Children in hospital whose respiratory condition has not stabilised and/or require the equipment for discharge

Eligible Prescribers

The primary prescribing team may include: Paediatric specialist physician in respiratory medicine, sleep medicine, spinal cord injury or intensive care in consultation with the multidisciplinary care team (e.g. nurse practitioners, clinical nurse consultant, clinical nurse specialist, biomedical engineer).

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

Recommended Review Timeline

It is recommended that the prescribing physician/team perform a clinical review within 3 months to assess initial compliance, then annually or as indicated by the requirements of the prescribing physician.

Other Considerations

- If the child is prescribed interface and circuits (dry or wet) for invasive support a separate equipment request will need to be made for those products as per the Paediatric Suction Units, Electrical Humidification and Respiratory Consumables Clinical Criteria
- If integrated humidification for use with invasive support is being requested, justification will be required.
- If the child is prescribed oxygen, a separate equipment request will need to be made for this equipment as per the Paediatric Home Oxygen Clinical Criteria.

Transition to adult services

Equipment requests for a person older than 16 should apply for equipment through the Adult Nocturnal Ventilation - Clinical Criteria. In circumstances where a young person is aged between 16-18 and their respiratory/sleep care is managed by a paediatric service, requests will be assessed against paediatric Clinical Criteria where requested by the prescriber.
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EQUIPMENT ELIGIBILITY

This Clinical Criteria refers to children/young people ≤ 16 years of age, with a demonstrated need for long term (≥ 12 months) nocturnal ventilation therapy. Please refer to the Paediatric Continuous Ventilation - Clinical Criteria for children/young people requiring ventilation equipment for ≥ 16hrs/day usage.

To be assessed for eligibility, all technical reports of sleep studies, follow-up report recommending therapy and authorised prescription settings submitted to EnableNSW must be reported and documented by a qualified respiratory/sleep physician.

Nocturnal ventilation equipment may be provided on the treating physician’s request for a child diagnosed with hypoventilation who meets the relevant General Criteria. Some children, i.e. those with neuromuscular disorders, due to the nature of their disease may not be initiated onto nocturnal ventilatory support through the General Criteria pathway. Alternative criterion for children/young people with neuromuscular disorders is listed under Disease Specific Criteria.

GENERAL CRITERIA

Equipment for nocturnal ventilatory support may be provided on the treating physician’s request for a child or young person who meets the following criteria 1 – 5:

**Diagnosis**

1. \( \text{PaCO}_2 \geq 45 \text{mmHg} \) on blood gas (capillary or arterial) or \( \geq 50 \text{mmHg} \) on venous blood gas confirming sleep hypoventilation OR
2. Evidence of sleep hypoventilation on a full attended diagnostic sleep study or nocturnal respiratory monitoring with sufficient sleep achieved including \( \text{SpO}_2 \) and \( \text{CO}_2 \) (this may include mean oxygen saturation level ≤ 93%) AND
   a. \( \text{TcCO}_2 \geq 8 \text{mmHg} \) from baseline OR
   b. \( \text{PaCO}_2 \geq 8 \text{mmHg} \) from paired evening-morning blood gas

**Treatment**

3. A nocturnal ventilation titration sleep study demonstrates improved control of sleep disordered breathing (SDB) and control of blood gas
   a. Please note: In children with Obstructive Sleep Apnea (OSA)/Obesity Hypoventilation Syndrome (OHS), a full technical and physician report of a CPAP titration sleep study will be required; demonstrating that CPAP is insufficient in treating sleep disordered breathing e.g. continued \( \text{CO}_2 \) retention ≥ 8 mmHg from baseline or sustained oxygen desaturation ≤ 85%
   b. The prescriber must specify the cause of hypoventilation if the diagnosis is not OSA/OHS

**Compliance**

4. The downloaded compliance report (preferably statistical and graphical summary) of the most recent 4 consecutive weeks, performed within 12 weeks prior to application lodgement date, which demonstrates usage of nocturnal ventilation ≥ 4 hours per night for ≥ 70% of nights

**Follow up report**

5. Follow-up report from Paediatric Sleep/Respiratory Physician reporting benefits from nocturnal ventilation treatment and the need for long-term nocturnal ventilation therapy

DISEASE SPECIFIC CRITERIA

**Neuromuscular disorders**

Equipment for nocturnal ventilatory support may be provided on the treating physician’s request for a child or young person who meets the following criteria 6 – 9:

**Diagnosis**

6. Documentation of diagnosis of neuromuscular disorder AND
   a. More than 3 hospitalisations for chest infections per year OR
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<td>b.</td>
<td>An acute event with respiratory decompensation requiring hospitalisation where complete weaning off ventilatory support has not been possible</td>
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Treatment
7. Full technical and physician report of a nocturnal ventilation titration sleep study demonstrates improved control of sleep disordered breathing (SDB) and control of blood gases

Compliance
8. The downloaded compliance report (preferably statistical and graphical summary) of the most recent 4 consecutive weeks, performed within 12 weeks prior to application lodgement date, which demonstrates usage of nocturnal ventilation ≥ 4 hours per night for ≥ 70% of nights

Follow up report
9. Follow-up report from Paediatric Sleep/Respiratory Physician reporting benefits from nocturnal ventilation treatment and the need for long-term nocturnal ventilation therapy

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

Social/carer criteria
- The child 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 child will comply with equipment usage as prescribed
- Information is provided to the child and/or relevant users (family/carers) 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 child and/or carer has an emergency plan in the event of respiratory equipment failure outside of business hours
- An electricity rebate application is completed. For more information see: http://www.energy.nsw.gov.au/customers/rebates

Environmental Factors
- The equipment prescribed is compatible with the child’s home environment and is suitable for safe management of the child in the community

The responsibility of EnableNSW is to ensure that:
- Appropriate nocturnal ventilation equipment that meets the child’s clinical and safety needs as per the prescription (e.g. the child’s weight and/or age)
- Delivery of the equipment to the child or Health Service
- The equipment provided complies with the Therapeutic Goods Act (TGA) and has a valid Australian Register of Therapeutic Goods (ARTG) number
- Equipment is arranged for repair/ replacement within business hours. This may include provision of an equivalent loan unit if the equipment is to be removed for repair or testing
- The serial numbers/service history of the equipment is collected