Paediatric Nocturnal Ventilation (Bilevel) Funding Criteria

The funding criteria for adult nocturnal ventilation (bilevel) have been developed in consultation with expert clinicians and align with evidence-based clinical guidelines available at the time of development. The funding criteria provide a basis for consistent and transparent decision making, and assist with safe and appropriate distribution of equipment. The funding criteria do not replace the need for local clinical service guidelines or prescriber clinical reasoning, and recognise that not all items that are clinically recommended will meet the criteria for funding through EnableNSW.

Part A: NOCTURNAL VENTILATION (BILEVEL) CLINICAL FUNDING CRITERIA

This funding criteria refers to infants, children and young people up to 18 years of age, with a demonstrated need for long term nocturnal ventilation in the community.

Eligible Prescribers	Inclusions	Exclusions
Paediatric Respiratory Physician Paediatric Sleep Physician	- Nocturnal ventilation equipment incorporating spontaneous or spontaneous-time mode, adaptive servo-ventilation or volume targeted pressure support, as prescribed - Integrated humidification *EnableNSW is required to purchase the most suitable and cost effective nocturnal ventilation (bilevel) devices from the NSW Government Contract HC18_1802*	- Circuit/tubing/connectors - Masks/interfaces & chinstraps - Filters (including bacterial/viral filters) - Batteries, battery chargers and associated cables/adaptors - Power generators or backup batteries (including unstable or inadequate mains power) - Ventilator car chargers/adaptors - Ventilators solely for transport - Phrenic nerve stimulation products - Nebulisers and associated consumables - External monitoring systems (e.g. pulse oximeters, CO_2 monitoring etc.)

For children who are approaching ventilation usage of 16 hrs per day with significant periods of awake time on ventilation, clinicians should consider a trial of continuous life support ventilation equipment. If meeting the funding criteria for continuous ventilation, the child will be eligible for provision of two identical TGA-approved life support ventilators with batteries (refer to criteria for inclusions).

Diagnostic Group Criteria
An application can be made using one (only) of the following diagnostic group criteria. Specific diagnostic and treatment information is required for each group, as outlined in **Part A**: **A1.** General criteria **A2.** Neuromuscular/ neurodegenerative disease In addition, a nocturnal ventilation titration/treatment study (**A3.**) and, compliance download and clinical letter (**A4.**) will be required for all applications Additional clinical information and details of requirements are outlined in **Part B**
All diagnostic and treatment components must be assessed during a period of clinical stability i.e. not during or immediately recovering from an acute illness.

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A1. GENERAL CRITERIA	
A1.1. Diagnosis Prescriber must submit ONE of the following (1-3): **AND**	1. Arterial carbon dioxide ($PaCO_2$) ≥ 45 mmHg on blood gas (capillary/arterial) or venous PCO_2 ≥ 50mmHg confirming sleep hypoventilation **OR** 2. Evidence of sleep hypoventilation on a diagnostic polysomnogram (PSG) or nocturnal respiratory monitoring (with sufficient sleep achieved) including SpO_2 and CO_2, meeting *one* of the following criteria (a, b or c): a. Transcutaneous CO_2 ($TcCO_2$) > 50mmHg for 25% of the sleep study OR b. $TcCO_2$ ≥ 8mmHg from baseline OR c. $PaCO_2$ ≥ 8mmHg from paired evening-morning blood gas **OR** 3. A diagnosis with predisposition to impaired central control of breathing AND Diagnostic PSG or nocturnal respiratory monitoring demonstrating a. AND b.: a. central apnoea index ≥ 5/hr AND b. significant oxygen desaturation: minimum SpO_2 85% OR repetitive desaturation to less than 90%
A1.2. For children with OSA/OHS only:	Prescriber must confirm on the Equipment request Form that CPAP has been considered or trialled, but is not an appropriate long-term treatment for the child

A2. DISEASE-SPECIFIC CRITERIA: NEURODEGENERATIVE AND NEUROMUSCULAR DISORDERS	
Diagnosis Prescriber must submit ONE of the following (1-3):	1. Documentation of repeated respiratory admissions (e.g. two or more respiratory related admissions per year) or recurrent respiratory illnesses consistent with a decline in respiratory function, outlined in a letter from the physician **OR** 2. An acute event with respiratory decompensation requiring hospitalisation where complete weaning off ventilatory support has not been possible **OR** 3. Diagnostic PSG or nocturnal respiratory monitoring demonstrating $TcCO_2$ rise > 4mmHg during REM sleep

A3. REQUIRED FOR ALL NOCTURNAL VENTILATION REQUESTS (in addition to criteria above):	
Nocturnal ventilation treatment study Prescriber must submit:	Recent nocturnal ventilation titration PSG demonstrating adequate control of sleep disordered breathing and gas exchange on the prescribed mode and settings (both technical and physician report required)

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A4. REQUIRED FOR ALL NOCTURNAL VENTILATION REQUESTS (in addition to criteria above):	
A4.1. Home trial & compliance download Prescriber must submit: **AND**	Downloaded compliance report from a trial of nocturnal bilevel ventilation at home for at least two (2) consecutive weeks within in the previous four (4) months, demonstrating consistent usage of ≥ 4 hours per night for ≥ 70% of nights
A4.2. Clinical letter Prescriber must submit:	Recent letter from Paediatric Respiratory/Sleep Physician confirming that the child is clinically stable on long-term nocturnal ventilation, and who will be responsible for ongoing clinical review of the child.

PART B: ADDITIONAL CLINICAL INFORMATION AND REQUIREMENTS	
B1. Information and requirements for all PSG and limited channel studies	• Full technical reports **AND** physician reports must be submitted for all PSG and limited channel studies **Limited channel and home-based diagnostic studies:** • Recognising that in-lab PSG studies are the gold standard for diagnosing sleep-breathing disorders and hypoventilation in children, EnableNSW will accept limited channel and home-based studies performed at the physician's discretion. • As a minimum, limited channel diagnostic studies submitted to EnableNSW for bilevel requests must include SpO_2, $TcCO_2$ and respiratory band (plethysmography) measurements • Where possible, efforts should be made to measure airflow • As above, the full technical and Paediatric Sleep/Respiratory Physician reports must be submitted
B2. Requirement for recent treatment and follow-up information	• Only treatment PSG studies and documents ≤ 2 years old may be evaluated for eligibility. • For children and young people previously established on nocturnal ventilation (bilevel) therapy more than 2 years ago: - Repeat diagnostic sleep studies are not required unless there has been a change in the child's respiratory/sleep condition since original establishment onto nocturnal ventilation (bilevel) (e.g. adenoidectomy/tonsillectomy) or if clinically indicated - Treatment, Compliance and Follow up documentation must be recent as per the above criteria
B3. Requirements for blood gases	• Full blood gas results/printouts must be provided. • Blood gases must be taken during a period of clinical stability. • If there are any anomalies or confounders, please indicate this in a clinical letter.
B4. Age and weight considerations for bilevel device selection	• The technical working group of expert clinicians acknowledged that small infants and children can be managed safely at home on standard bilevel machines even if they are not within the manufacturer's intended use for the child's weight and age.

	• If the prescriber is requesting funding for a standard bilevel device outside of the manufacturer's intended use for weight and age, the prescriber must provide a supporting letter acknowledging that they have individually assessed the patient and considered the suitability and safety of a standard bilevel machine, and that this has been discussed with and consented by the child's family/guardian. **OR** A weight and age-appropriate bilevel device (as per manufacturer's intended use) can be requested
B5. Provision of equipment with auto-titrating modes for hypercapnia	• The expectation of the funding criteria is that fixed pressure nocturnal ventilation modes will be adequately trialled first, and auto-titrating modes and features are only considered when fixed pressure titration does not adequately control sleep-disordered breathing. It should be noted that some auto-titrating modes are not recommended for all age and weight ranges. • If a child has been prescribed a mode or setting that is not available on a standard bilevel machine, EnableNSW will require objective evidence that the modes and settings available on standard machines (e.g. fixed pressure S, ST and PC modes) have been trialled and are inadequate in controlling sleep-disordered breathing on optimal pressure during the titration study. Evidence that the prescribed mode/settings are superior to the standard modes is also required.
B6. Complete settings are required to set up the bilevel machine	• Complete settings are required in order to avoid delays in the child's bilevel machine being set up and delivered. • Proforma scripts are encouraged to assist in ensuring all of the required settings for the specific prescribed device are provided initially. Please contact device suppliers for additional technical information and support around required settings and scripts.
B7. Equipment provided for nocturnal tracheal ventilation	• Children requiring nocturnal-only tracheal ventilation will be eligible for one (1) bilevel ventilator that is TGA-approved for invasive ventilation, one (1) standalone electrical humidifier, plus consumables as per Paediatric Suction Units and Respiratory Consumables for Secretion Management funding criteria.

PART C: PRESCRIBER RESPONSIBILITIES, ONGOING REQUIREMENTS	
C1. Ongoing clinical review, ongoing contact requirements, obtaining settings for repairs	• In line with clinical best practice guidelines, EnableNSW expects that people using EnableNSW bilevel devices have ongoing regular review with their respiratory/sleep physician to ensure they continue to be on the optimal treatment • As the prescriber of this equipment, the respiratory/sleep physician agrees to: - Provide current contact details, and alternative contact details for clarification of clinical information or other bilevel equipment updates for the child and their family • Provide up to date bilevel settings to EnableNSW Repairs & Maintenance Team on request, which are required for repairs to be initiated

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C2. It is the responsibility of the prescribing physician/clinical teams to submit/organise and ensure the following:	Training, safety, and repairs: • The child and family/carers are trained and are capable of using the equipment safely and appropriately, including basic equipment care and minor troubleshooting • The child and family/carers are trained how to regularly clean and inspect the bilevel equipment, and safely store and transport the equipment (e.g. empty the humidifier chamber before transporting the machine) • The child/primary carer should retain a copy of current bilevel prescription settings • The child and family/carers should work with the prescribing physician to ensure that they comply with device usage, and must be informed that therapy compliance data will be recorded by the clinical service • If the child is not using the provided bilevel device as prescribed, the physician or clinical service should review and provide assistance to the child and family/carers • Provide the child and family/carers with information about their treatment plan, ongoing clinical review and assessment requirements in relation to their bilevel treatment • EnableNSW can be contacted to coordinate repairs and/or replacement within business hours (9am-5pm, Monday to Friday). EnableNSW and contracted equipment suppliers do not provide a 24 hour equipment support contact line. • The child's family and carers must be aware of the procedure to follow in the event of bilevel equipment failure, and have a plan in place for bilevel equipment failure outside of business hours. The child and family/carers must have contact details for their clinical team. Any concerns about the child's bilevel management or health condition must be discussed with the clinical team. Equipment and environment factors: • Ensure the bilevel equipment prescribed is compatible with the child's home environment and all other equipment or consumables prescribed, and is suitable for safe management of the child in the community • Ensure that the child's place of residence has access to a stable electrical power source that is sufficient for device operation • The clinical team must notify EnableNSW if the equipment is no longer required • A NSW Government Planning & Environment Electricity Rebate Form is completed: https://www.service.nsw.gov.au/transaction/apply-life-support-energy-rebate-retail-customers
C3. Equipment allocation	• Available equipment that meets the child's assessed requirements may be either reallocated or new.
C4. New bilevel models, modes or features	• EnableNSW will not exchange functioning bilevel ventilator or integrated humidifier equipment on the basis of newer device models, modes, or new or updated features becoming available