Adult 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

Eligible Prescribers	Inclusions	Exclusions
Respiratory Physician 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, end tidal CO_2 system etc.)

For people who are approaching ventilation usage of 16 hrs per day, clinicians should consider a trial of continuous life support ventilation equipment. If meeting the funding criteria for continuous ventilation, the person 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.** Obesity hypoventilation syndrome (OHS) **A2.** Neuromuscular/ neurodegenerative disease **A3.** Chronic obstructive pulmonary disease (COPD) **A4.** Other hypercapnic groups not listed above (General criteria)- e.g. non-COPD lung diseases, chest wall disorders, kyphoscoliosis or mixed diagnoses e.g. overlap syndrome **A5.** Non-hypercapnic central sleep apnoea (adaptive servo ventilation) In addition, compliance download and clinical letter will be required for all applications (**A6.**) 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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<table>
<tr><th colspan="4">A1. DISEASE-SPECIFIC CRITERIA- OBESITY HYPOVENTILATION SYNDROME</th></tr>
<tr><td>A1.1. Diagnosis
Prescriber must submit:
AND</td><td colspan="3">BMI ≥ 30 kg/m^2 (must provide BMI)
AND
Copy of an arterial blood gas (ABG) taken during a period of clinical stability demonstrating awake $PaCO_2$ ≥ 46 mmHg and pH ≥ 7.35</td></tr>
<tr><td rowspan="3">A1.2. Treatment pathway

AND</td><td colspan="2">If stable $PaCO_2$ 46- 51 mmHg:
Diagnostic polysomnogram (PSG) OR level 2 home sleep study OR diagnostic oximetry must be performed</td><td>If stable $PaCO_2$ ≥ 52 mmHg:</td></tr>
<tr><td>If AHI ≥ 30/hr or ODI ≥ 30/hr:
Confirmation that in-lab CPAP titration has been performed
AND
Downloaded compliance report from a 4 week trial of CPAP</td><td rowspan="2">If AHI/ODI < 30/hr:
→ Can proceed to in-lab NIV titration PSG (if clinician decides initial trial of CPAP is not suitable)</td><td rowspan="2">→ Can proceed to in-lab NIV titration PSG (if clinician decides initial trial of CPAP is not suitable)</td></tr>
<tr><td>If clinician decides CPAP treatment is adequate:
→ You may apply for CPAP via Adult CPAP funding criteria

If clinician decides CPAP treatment is inadequate at the end of the four-week CPAP trial, we will accept the following as evidence of CPAP inadequacy:
ABG demonstrating $PaCO_2$ ≥ 46 mmHg after 4 week CPAP trial
OR
Technical and physician report demonstrating ≥ 8mmHg rise in transcutaneous CO_2 from baseline despite optimal CPAP
OR
Sustained oxygen desaturation (SpO_2 ≤ 88% for ≥ 10 minutes) on CPAP in the absence of obstructive events
→ Proceed to in-lab NIV titration PSG</td></tr>
<tr><td>A1.3. NIV treatment study</td><td colspan="3">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)</td></tr>
</table>

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A2. DISEASE-SPECIFIC CRITERIA: NEURODEGENERATIVE AND NEUROMUSCULAR DISORDERS	
A2.1. Diagnosis Prescriber must submit ONE of the following **AND**	Letter documenting an acute event with respiratory de-compensation requiring hospitalisation where complete weaning was not possible **OR** Vital Capacity (VC) ≤ 50% or maximal inspiratory pressure (MIP) ≤ 40 cmH_2O or sniff nasal inspiratory pressure (SNIP) ≤ 40 cmH_2O **OR** Diagnostic PSG or nocturnal respiratory monitoring demonstrating a fall in SpO_2 below 90% for more than 2% of total sleep time OR $TcCO_2$ ≥ 8 mmHg from baseline **OR** Paired evening-morning ABGs demonstrating a $PaCO_2$ rise ≥ 8mmHg **OR** ABG or capillary blood gases demonstrating awake PCO_2 ≥ 46 mmHg **OR (additional options for patients with motor neurone disease or rapidly progressive disease who do not meet the criteria above)** VC ≤ 70% predicted **OR** MIP ≤ 60cmH_2O **OR** SNIP ≤ 60cmH_2O **OR** Clinical letter documenting significant orthopnoea and daytime somnolence
A2.2. Treatment Prescriber must submit ONE of the following:	Overnight oximetry + detailed polygraphic data demonstrating adequate control of gas exchange on prescribed bilevel mode and settings (both technical and physician report required) **OR** 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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A3. DISEASE-SPECIFIC CRITERIA: CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)	
A3.1. Diagnosis Prescriber must submit ONE of the following: **AND**	ABG or capillary blood gases demonstrating awake PCO_2 ≥ 52mmHg and pH ≥ 7.35 taken during a period of clinical stability, ≥ 2 weeks following an acute exacerbation **OR** Provide a clinical letter plus any supportive evidence (e.g. serial ABGs) outlining the requirement for home ventilation in either of the following situations: - During an acute hospital admission, non-invasive ventilation could not be withdrawn without the person developing acute respiratory acidosis, at a time close to discharge and despite resolution of acute issues **OR** - Readmission to hospital with acute hypercapnic respiratory failure/ respiratory acidosis within four weeks of withdrawing NIV during the previous admission to hospital
A3.2. Treatment Prescriber must submit ONE of the following:	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) **OR** Reduction on $PaCO_2$ of ≥ 4mmHg from stable baseline, after 2-4 weeks of treatment with prescribed home bilevel mode and settings **PLUS** Detailed polygraphic data download demonstrating optimisation on prescribed bilevel mode and settings (e.g. in terms of respiratory events, adequacy/stability of tidal volumes/minute ventilation)

A4. OTHER HYPERCAPNIC GROUPS NOT LISTED ABOVE (GENERAL CRITERIA)- E.G. NON-COPD LUNG DISEASES, CHEST WALL DISORDERS, KYPHOSCOLIOSIS OR MIXED DIAGNOSES E.G. OVERLAP SYNDROME	
A4.1. Diagnosis Prescriber must submit ONE of the following: **AND**	$PaCO_2$ ≥ 46 mmHg **AND** pH ≥ 7.35 on ABG taken during a period of clinical stability (copy of full result required) **OR** $PaCO_2$ rise ≥ 8 mmHg on paired evening-morning ABGs taken during a period of clinical stability (copy of full result required) **OR** $TcCO_2$ rise ≥ 8 mmHg from baseline during diagnostic PSG or nocturnal respiratory monitoring (both technical and physician report required)
A4.2. Treatment	Recent nocturnal ventilation titration sleep study 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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<table>
<tr><th colspan="3">A5. NON-HYPERCAPNIC CENTRAL SLEEP APNOEA (BILEVEL ADAPTIVE SERVO-VENTILATION- ASV)</th></tr>
<tr><td rowspan="3">A5.1. Safety and medical optimisation
Prescriber must provide:

AND</td><td colspan="2">Recent echocardiogram confirming left ventricular ejection fraction (LVEF) > 45% (copy of report required). Physician must be satisfied that the echocardiogram report provided reflects the person’s current ejection fraction.
AND
Confirmation that the medical management of the person’s heart failure has been optimised
AND
Confirmation that the physician has assessed the safety of the prescribed mode and settings for the person</td></tr>
<tr><td>If LVEF > 45%</td><td>If LVEF ≤ 45%</td></tr>
<tr><td>Continue with pathway as below</td><td>EnableNSW does not fund bilevel devices for this group. The prescriber may wish to request funding for CPAP (see EnableNSW Adult CPAP Funding Criteria)</td></tr>
<tr><td>A5.2. Diagnosis
Prescriber must submit ONE of the following:
AND</td><td colspan="2">Recent diagnostic PSG or nocturnal respiratory monitoring demonstrating central sleep apnoea (CSA)/Cheyne-Stokes Respiration (CSR) with AHI ≥ 20/hr in which at least 50% of events are central
OR
Recent CPAP titration sleep study or nocturnal respiratory monitoring on CPAP demonstrating CSA/CSR with ongoing AHI ≥ 20/hr in which at least 50% of events are central</td></tr>
<tr><td>A5.3. Inadequacy of CPAP
Prescriber must provide:
AND</td><td colspan="2">A 2-4 week home trial of CPAP must be performed before proceeding with bilevel ASV treatment.
Provide downloaded compliance report on titrated fixed pressure CPAP demonstrating that CSA/CSR is not resolved AND/OR letter outlining attempts to establish CPAP treatment, but that a 2-week trial was not tolerated</td></tr>
<tr><td>A5.4. Treatment
Prescriber must provide:</td><td colspan="2">Recent ASV titration PSG demonstrating improved control of sleep disordered breathing and gas exchange</td></tr>
</table>

A6. REQUIRED FOR <u>ALL</u> NOCTURNAL VENTILATION/BILEVEL/ASV REQUESTS (in addition to criteria above):	
A6.1. Home trial & compliance download **AND**	Downloaded compliance report from a trial of nocturnal bilevel ventilation/ ASV 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
A6.2. Clinical letter	Recent letter from Respiratory/Sleep Physician confirming that the person is clinically stable on long-term nocturnal ventilation/ASV, and who will be responsible for ongoing clinical review of the person.

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PART B: ADDITIONAL CLINICAL INFORMATION AND REQUIREMENTS	
B1. Information and requirements for PSG and oximetry studies, and polygraphic downloads	The following documentation is required for all PSG studies and non-lab (oximetry + polygraphic) treatment studies: • A physician report and recommendation based on the study **AND** • Full technical report of the study Requirements for non-lab (oximetry + polygraphic) studies: • 1-2 nights of oximetry including continuous overnight SpO_2 trace* +/- transcutaneous CO_2 trace with statistical summary **PLUS** • 1-2 nights of detailed polygraphic data downloaded from the machine (one night per page, breath-by-breath traces optional). As a minimum, detailed flow and pressure data are required, however, tidal volumes, minute ventilation, and other respiratory variables/events may also assist clinical decision making and help provide evidence of adequacy of nocturnal ventilation settings • *Please note that intermittent/serial spot check/low resolution SpO_2 measures or observation chart printouts will not be accepted.
B2. Requirements for blood gases and assessment of hypercapnia	• Either arterial or arterialised capillary PCO_2 will be accepted as valid measures of CO_2. Venous PCO_2 measures will not be accepted. • 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 (e.g. metabolic acidosis), please indicate this in a clinical letter.
B3. Provision of equipment with auto-titrating modes for hypercapnia	• In line with clinical recommendations for patients with nocturnal hypoventilation/ daytime 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. • If a person has been prescribed a mode 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 on optimal pressures is superior to the standard modes is also required.
B4. Fixed pressure bilevel ventilation for non-hypercapnic central sleep apnoea	Enable NSW's funding criteria do not cover the provision of fixed pressure bilevel ventilators for people with non-hypercapnic CSA. As was highlighted in recent expert technical working groups, many clinicians advise against the use of bilevel ASV or fixed pressure bilevel ventilation for non-hypercapnic CSA due to the increased mortality risk reported in people with heart failure-related CSA and ejection fraction ≤ 45%, who were treated with bilevel ASV. It was highlighted that fixed pressure bilevel ventilation may produce similar or exaggerated effects on the cardiovascular system to that of ASV, or induce central apnoeas through over-ventilation, and that there is not adequate data on the safety of fixed pressure bilevel ventilation for people with non-hypercapnic CSA. Requests for fixed pressure bilevel ventilators for NHCSA will only be considered on a discretionary basis and only for people with LVEF >45%, with the following additional information from the prescribing physician: • Justification letter including confirmation that the physician has assessed the potential risks of prescribing fixed pressure bilevel ventilation for your patient, and reasons why this particular treatment modality has been chosen. • Documentation of discussions/ assessment of risk in conjunction with a cardiologist.

B5. Complete settings are required to set up the bilevel machine	Complete settings are required in order to avoid delays in the person'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. Templates are available on our website. Please contact device suppliers for additional technical information and support around required settings and scripts.
B6. Equipment provided for nocturnal tracheal ventilation	People 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 secretion management 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 person. - Provide EnableNSW with updated contact information if there are any changes. • Provide up to date bilevel device settings to EnableNSW Repairs & Maintenance Team on request- these are required for any repairs to be initiated.
C2. It is the responsibility of the prescribing physician/clinical teams to submit/organise and ensure the following:	Training, safety, and repairs: • The person and/or family/carers are trained and are capable of using the equipment safely and appropriately, including basic equipment care and minor troubleshooting. • The person and/or 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 equipment). • The person/primary carer should retain a copy of current bilevel prescription settings. • The person must be willing to comply with device usage as prescribed by their physician and must be informed that therapy compliance data will be recorded by the clinical service. • Provide the person 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 person and/or carer 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 person must have contact details for their clinical team. Any concerns about the person's nocturnal ventilation/ASV management or health condition must be discussed with the clinical team. • If the person is not compliant with nocturnal ventilation/ASV, the physician or clinical service should review and provide assistance to the person. Equipment and environment factors: • Ensure the bilevel equipment prescribed is compatible with the person's home environment and all other equipment or consumables prescribed, and is suitable for safe management of the person in the community. • Ensure that the person'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 persons assessed requirements may be either reallocated or new.
C4. Availability of new bilevel ventilator 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.