Titration protocol reference guide

PHILIPS

RESPIRONICS

sense and simplicity

Titration protocol reference guide

IMPORTANT: The suggested guidelines are intended to serve only as a reference. They should be used only in conjunction with the instructions and/or protocol(s) set forth by the physician and institution in which the assist device is being used. The guidelines are not intended to supersede established medical protocols.

These protocols are recommended for adult patients only.

Titration protocol goals

Titration goals

1. Keep the upper airway open (airway management).
2. Stabilize breathing patterns by monitoring the patient's response to therapy.
3. Adjust user-set parameters as needed for optimal therapy efficacy and adherence.

The goals should be individualized to meet the needs of each patient.

Note

All protocols listed in this reference guide are consistent with AASM clinical guidelines.[1,2,3,4]

[1] Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patients with Obstructive Sleep Apnea; J. Clin. Sleep Med 2008, 4(2)157-171

[2] Clinical Guideline for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults; J. Clin. Sleep Med 2009, 5(3)263-276

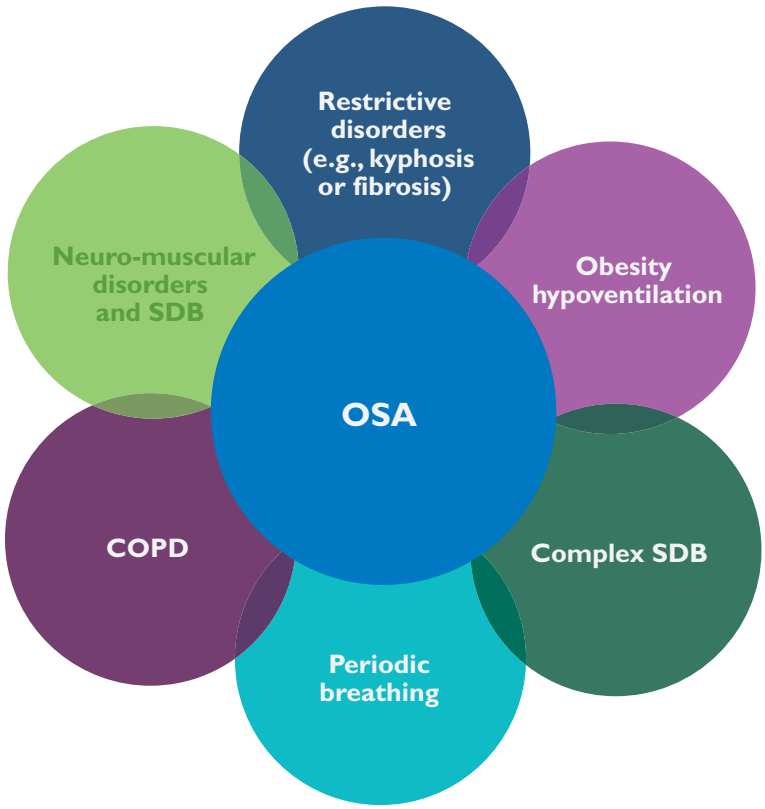
[3] Best Clinical Practices for the Sleep Center Adjustment of Noninvasive Positive Pressure Ventilation (NPPV) in Stable Chronic Alveolar Hypoventilation Syndromes, Accepted for publication J.Clin.Sleep Med Aug. 19, 2010

[4] Device specific validation studies

CPAP

CPAP protocol

Patient types



- CPAP is the gold standard for patients with OSA.
- CPAP provides one constant pressure to the patient's upper airway to prevent airway collapse while the patient sleeps.
- CPAP is the most recommended starting therapy for a variety of patients with sleep-disordered breathing.
- CPAP may be a requirement prior to the initiation of some forms of bi-level therapy (RAD devices).
- Reimbursement criteria for patients who need CPAP therapy:
  - RDI or AHI ≥ 15 events per hour; or
  - RDI or AHI ≥ 5 and ≤ 14 events per hour with:
    - Documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia; or
    - Documented history of hypertension, ischemic heart disease or history of stroke

Suggested titration protocol for CPAP

GOAL: Adjust user-set parameters for optimal efficacy and adherence

Acclimation zone

Set mode to CPAP

- Establish initial settings as indicated below or as ordered by physician
- Ensure proper mask fit to enhance comfort and acceptance, and to minimize leaks
- Have patient lie down and breathe on CPAP device at basic settings below
- Recheck mask fit, assure patient comfort and acceptance
- May adjust CPAP and C-Flex or C-Flex+ to patient comfort

CPAP	4 cm H_2O
C-Flex or C-Flex+	To patient comfort

Titration zone

★ Monitor patient PSG

Wait.... Watch.... Observe.... Think

Patience is the key to successful titration

At lights out observe for patient's inability to maintain sleep due to obstructive apneas — If yes → **For patient comfort and to allow sleep onset** increase CPAP to open the airway → Return to ★

and

At lights out observe for indications of therapy intolerance — If yes → **For patient comfort and to allow sleep onset** adjust C-Flex or C-flex+ → Return to ★

If no

Observe for obstructive apneas — If yes → Raise CPAP by 1 cm H_2O → Return to ★

If no

Observe for partial airway obstruction — If yes → Raise CPAP by 1 cm H_2O → Return to ★

If no

Observe for central apneas/ hypopneas — If yes → Decrease CPAP by 1 cm H_2O; wait 20 min.; repeat if necessary → Return to ★

If central apneas/ hypopneas persist, consider retitration with BiPAP autoSV Advanced

if

Patient cannot tolerate pressure increase, or if pressure threshold of 15* cm H_2O is reached, switch to BiPAP S protocol

* based on AASM titration protocol criteria (see page 4)

Prescription zone

CPAP prescription

CPAP = _____ cm H_2O

C-Flex or C-Flex+ = _____

Interface: _____

CPAP reimbursement criteria

CPAP coverage for adults requires a positive OSA diagnosis using a clinical evaluation and one of the following diagnostic sleep tests:

a. Polysomnography performed in a sleep laboratory; or
b. Unattended home sleep monitoring device of Type II; or
c. Unattended home sleep monitoring device of Type III; or
d. Unattended home sleep monitoring device or Type IV, measuring at least three channels

A positive test for OSA is established if either of the following criteria are met using the AHI (Apnea Hypopnea Index) or RDI (Respiratory Distress Index):

a. AHI or RDI greater than or equal to 15 events per hour; or
b. AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia or documented hypertension, ischemic heart disease or history of stroke.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study.

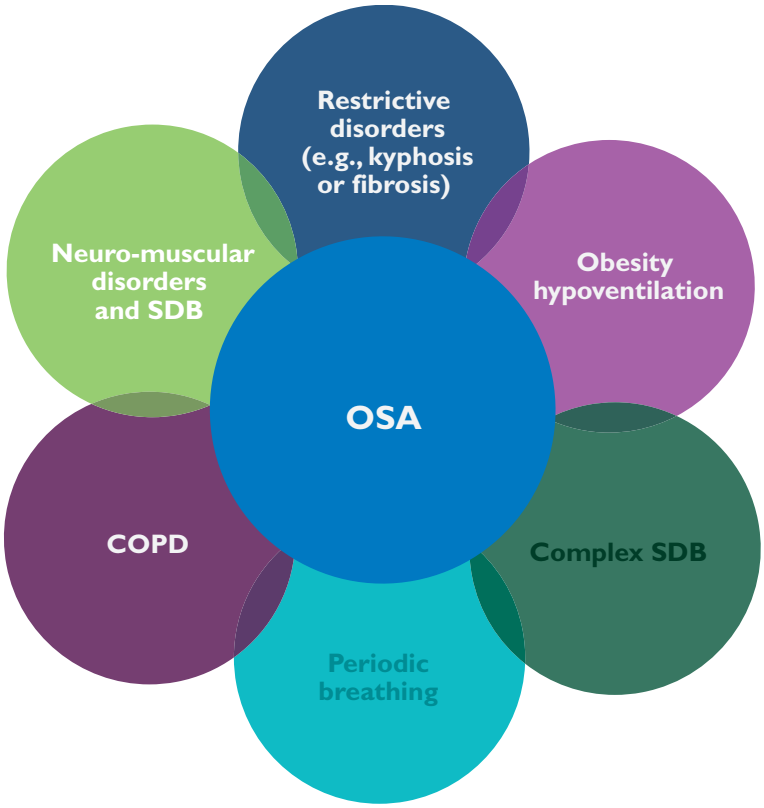
The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the RDI. The RDI is reported in Type III, Type IV, and other home sleep studies.

For example:

- The actual number of AHI episodes recorded is 30 or more in less than two hours, recorded by the polysomnography using actual recorded hours of sleep. The AHI may not be extrapolated or projected.

BiPAP S

Patient types



- Bi-level therapy provides two independently set pressures to maintain airway stability and support ventilation requirements while the patient sleeps:
  - Inspiratory Positive Airway Pressure (IPAP) is the higher pressure. This pressure is applied during inspiration and can augment the patient's tidal volume.
  - Expiratory Positive Airway Pressure (EPAP) is the lower pressure. This pressure is applied during exhalation. It can provide upper airway stability or increase the patient's Functional Residual Capacity (FRC).
- Reimbursement criteria:
  - The beneficiary tried but was unsuccessful with attempts to use the E0601 device; and,
  - Multiple interface options have been tried and the current interface is most comfortable to the beneficiary; and,
  - The work of exhalation with the current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy; and,
  - Lower pressure settings of the E0601 fail to adequately control the symptoms of OSA or reduce the AHI/RDI to acceptable levels.

Suggested titration protocol for BiPAP S mode

GOAL: Adjust user-set parameters for optimal efficacy and adherence

Acclimation zone

Switch mode to BiPAP S

- Establish initial settings as indicated or as ordered by physician
- Ensure proper mask fit to enhance patient comfort and acceptance, and to minimize leaks
- Have patient breathe on BiPAP device at basic settings to the right
- Recheck mask fit, assure patient comfort and acceptance
- May adjust IPAP, EPAP and Bi-Flex to patient comfort

* For patients who could not fall asleep on CPAP, increase IPAP to 8 cm H_2O and maintain EPAP at 4 cm H_2O[1]

* For patients who cannot tolerate pressure increases or who reach a predetermined pressure threshold on CPAP, place the IPAP pressure at their current CPAP setting and set EPAP pressure 4 cm H_2O or more below the IPAP to create a starting pressure support level (IPAP/EPAP pressure difference)[1]

IPAP	See above*
EPAP	See above*
Bi-Flex	To patient comfort

[1] J. Clin. Sleep Med. 2008; 4(2):151-171

Titration zone

★ Monitor patient PSG

Wait.... Watch.... Observe.... Think

Patience is the key to successful titration

At lights out observe for patient's inability to maintain sleep due to obstructive apneas — If yes → **For patient comfort and to allow sleep onset** increase EPAP to open the airway and increase IPAP to maintain current pressure support level (IPAP/EPAP difference) → Return to ★

and

At lights out observe for indications of therapy intolerance — If yes → **For patient comfort and to allow sleep onset** adjust Bi-Flex → Return to ★

If no

Observe for obstructive apneas — If yes → Raise EPAP and IPAP by 1 cm H_2O to maintain current pressure support level (IPAP/EPAP difference) → Return to ★

If no

Observe for partial obstructive airway events — If yes → 1. Check for mask leak 2. Raise IPAP by 1 cm H_2O → Return to ★

If no

Observe for central apneas/ hypopneas — If yes → Decrease pressure(s) to prior setting and wait 20 min.; repeat if necessary. → If central apneas/ hypopneas persist, consider retitration with BiPAP autoSV Advanced

If no

if → Patient cannot tolerate pressure, try different Bi-Flex settings

Prescription zone

BiPAP S prescription

IPAP = _____ cm H_2O

EPAP = _____ cm H_2O

Bi-Flex = _____

Interface: _____

BiPAP S reimbursement criteria

Obstructive Sleep Apnea

Criterion A

A positive test for OSA is established if either of the following criteria are met using the AHI (Apnea Hypopnea Index) or RDI (Respiratory Distress Index):

a. AHI or RDI greater than or equal to 15 events per hour; or
b. AHI or RDI greater than or equal to 5 and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia or documented hypertension, ischemic heart disease or history of stroke.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study.

The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the RDI. The RDI is reported in Type III, Type IV, and other home sleep studies.

The AHI or RDI is calculated on the average number of events per hour. If the AHI or RDI is calculated based on less than two hours of continuous recorded sleep, the number of recorded events to calculate AHI or RDI during sleep testing must be at minimum the number of events that would have been required in a two-hour period. For example, the actual number of AHI episodes recorded is 30 or more in less than two hours, recorded by the polysomnography using actual recorded hours of sleep. The AHI may not be extrapolated or projected.

and

Criterion B

A single level positive airway pressure device has been tried and proven ineffective based on a therapeutic trail conducted in either a facility or in a home setting.

If a CPAP device is tried and found ineffective during the initial three-month home trial, substitution of a RAD device does not require a new initial face-to-face evaluation or a new sleep test.

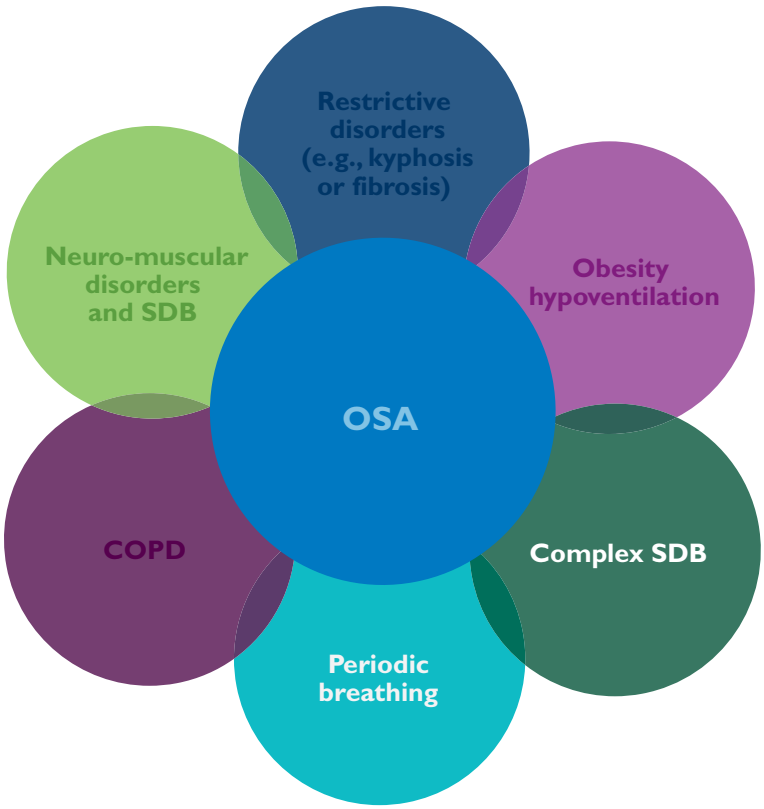
If a CPAP device has been used for more than three months and the patient is switched to a RAD device, a new initial face-to-face evaluation is required but a new sleep study is not required. A new 90-day trial will be required on the RAD device.

For more information regarding CMS PAP policy, please refer to the Helpful Hints for Filing Positive Airway Pressure (PAP) and Related Accessories (ask your sales associate).

BiPAP autoSV
Advanced

BiPAP autoSV Advanced protocol

Patient types



- BiPAP autoSV Advanced is designed for patients who have mixed apneas, complex apneas, periodic breathing or central apnea.

- BiPAP autoSV Advanced provides three types of support:
  - Auto-titrating CPAP or bi-level PAP to prevent airway collapse during OSA events
  - Automatically calculated back-up rate for central apneas
  - Pressure support ventilation during periods of hypoventilation

- Settings for BiPAP autoSV Advanced:
  - Rate
  - Rise time
  - Inspiratory time
  - $EPAP_{min}$ = minimum expiratory pressure
  - $EPAP_{max}$ = maximum expiratory pressure
  - PS_{min} = minimum pressure support
  - PS_{max} = maximum pressure support
  - Max pressure = maximum pressure level

Suggested titration protocol for BiPAP autoSV Advanced

GOAL: Adjust user-set parameters for optimal efficacy and adherence

Acclimation zone

Set mode to BiPAP autoSV Advanced

- Establish initial settings as indicated below or as ordered by physician
- Ensure proper mask fit to allow algorithm to work effectively
- Have patient breathe on autoSV Advanced at basic settings below
- Adjust $EPAP_{min}$, Bi-Flex and PS_{min} settings to patient comfort

$EPAP_{min}$	4 cm H_2O*	Max pressure	25 cm H_2O
$EPAP_{max}$	15 cm H_2O	Rate	auto
PS_{min}	0 cm H_2O	Bi-Flex	To patient comfort
PS_{max}	20 cm H_2O		

*If patient has known CPAP pressure of < 10 set $EPAP_{min}$ at 4 cm H_2O or patient comfort

*If patient has known CPAP pressure of > 10 set $EPAP_{min}$ at 6-8 cm H_2O or patient comfort

Titration zone

★ Monitor patient PSG

Wait.... Watch.... Observe.... Think

Patience is the key to successful titration

At lights out observe for patient's inability to maintain sleep due to severe obstructive apneas

and

At lights out observe for indications of therapy intolerance

If no

Observe for peak inspiratory pressure being limited by PS_{max}

If no

Observe for inadequate breathing rate

If no

If yes

If yes

If yes

If yes

For patient comfort and to allow sleep onset increase $EPAP_{min}$ to open the airway

For patient comfort and to allow sleep onset adjust Bi-Flex settings or increase PS_{min}

Observe for:
1. Leak: fix mask leak
2. Obstructive events: increase $EPAP_{min}$
3. Central events: increase PS_{max}

Set fixed rate to a minimum 8-10 bpm or 2 below resting respiratory rate including apneas; set I-Time for 1.5 seconds

Return to ★

Return to ★

Return to ★

Return to ★

Wait a minimum of 20 minutes to assess effect before making another change.

Prescription zone

BiPAP autoSV Advanced prescription

$EPAP_{min}$	= _____ cm H_2O	Rate	= Auto or _____ BPM
$EPAP_{max}$	= _____ cm H_2O	I-Time	= _____ sec (with fixed rate only)
PS_{min}	= _____ cm H_2O	Rise time and Bi-Flex	= To patient comfort
PS_{max}	= _____ cm H_2O		
Max pressure	= _____ cm H_2O	Interface: _____	

BiPAP autoSV Advanced reimbursement criteria

Central sleep apnea or complex sleep apnea

Prior to initiating therapy, a complete facility-based, attended PSG must be performed documenting the following criterion:

Criterion A
The diagnosis of central sleep apnea or complex sleep apnea

↓ and

Criterion B
Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the patient's usual FIO_2

↓ and

If all above criteria are met, either an E0470 or E0471 device will be covered for the first three months of therapy.

Central sleep apnea is defined as:

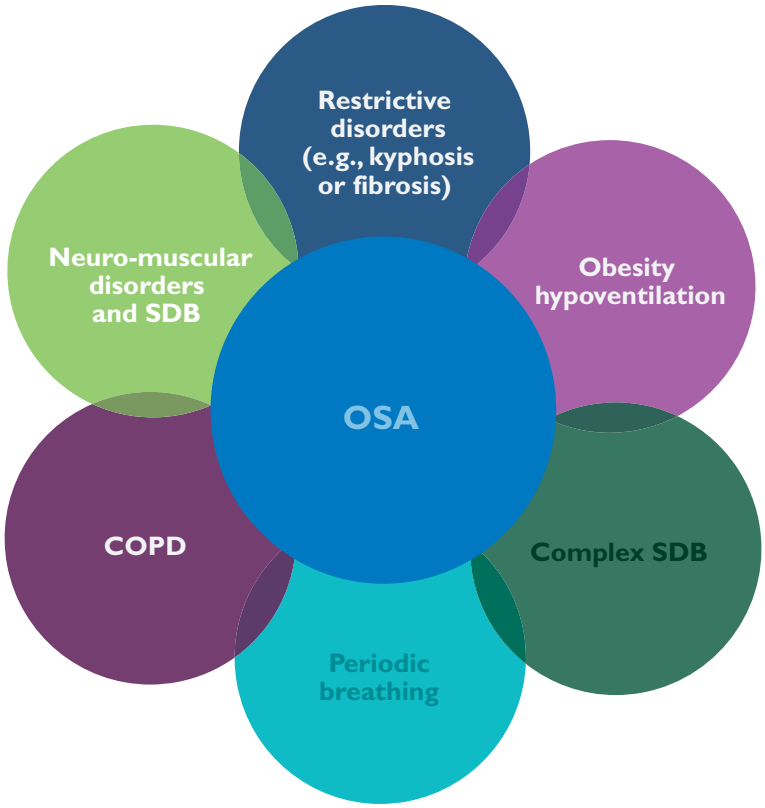
1. An apnea hypopnea index (AHI) greater than 5; and
2. Central apneas/hypopneas greater than 50% of the total apneas/hypopneas; and
3. Central apneas or hypopneas greater than or equal to 5 times per hour; and
4. Symptoms of either excessive sleepiness or disrupted sleep.

Complex sleep apnea is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to 5 times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meet the definition of CSA described previously.

BiPAP AVAPS

BiPAP AVAPS protocol

Patient types



BiPAP AVAPS (average volume assured pressure support) is designed to maintain tidal volumes for patients who have respiratory insufficiency and need noninvasive ventilatory support.

BiPAP AVAPS provides three types of support:

- A back-up rate to assist patients who have difficulty maintaining a consistent respiratory rate
- Pressure support to assist patients who have difficulty maintaining tidal volume
- Expiratory pressure to assist patients who need to increase their FRC or maintain airway stability

Settings for BiPAP AVAPS:

- Rate
- Rise time
- EPAP pressure
- Inspiratory time
- Tidal volume
- $IPAP_{min}$ (minimum inspiratory pressure)
- $IPAP_{max}$ (maximum expiratory pressure)

Reimbursement criteria: noninvasive positive pressure ventilators are generally covered for treatment of respiratory insufficiency associated with neuromuscular diseases, restrictive thoracic disorders, hypoventilation syndrome, chronic obstructive pulmonary disease, and central apnea.

Suggested titration protocol for BiPAP AVAPS

GOAL: Adjust user-set parameters for optimal efficacy and adherence

Set mode to S/T with AVAPS

Acclimation zone

- Establish initial basic settings as indicated to the right or as ordered by physician
- Ensure proper mask fit to allow algorithm to work effectively
- Have patient breathe on bi-level device at the basic settings
- May adjust $IPAP_{min}$, Tidal volume, I-Time and Rate to patient comfort

Tidal volume:	See box to the right
EPAP:	4 cm H_2O
$IPAP_{min}$:	8 cm H_2O
$IPAP_{max}$:	25 cm H_2O
Rate:	8-10 bpm or two below patient resting rate
I-Time:	1.5 seconds
Rise time:	2 – 3

3 ways to choose a starting tidal volume with AVAPS:

1. MD suggestion
2. Patient comfort
3. Ideal body weight: 8 ml/kg*

*AVAPS suggested tidal volume settings based on height and ideal weight.

height	59"	61"	63"	65"	67"	69"	71"	73"	75"
ideal weight	52.0 kg	55.5 kg	59.0 kg	62.5 kg	66.5 kg	70.5 kg	74.5 kg	78.5 kg	83.0 kg
8 ml/kg V_T	420 ml	440 ml	470 ml	500 ml	530 ml	560 ml	600 ml	630 ml	660 ml

★ Monitor patient PSG

Wait.... Watch.... Observe.... Think

Patience is the key to successful titration

Titration zone

At lights out observe for patient's inability to maintain sleep due to obstructive apneas — If yes

1. For patient comfort and to allow sleep onset, increase EPAP to open the airway
2. Increase $IPAP_{min}$ to maintain current pressure support level (IPAP/EPAP difference)

Return to ★

and

At lights out observe for indications of therapy intolerance — If yes

1. Check for mask leak
2. Adjust rise time to patient comfort
3. Decrease tidal volume to patient comfort by 10 ml increments

Return to ★

If no

Unable to maintain sleep due to obstructive apneas — If yes

Increase EPAP and $IPAP_{min}$ by same amount to open the airway

Return to ★

If no

Unable to maintain tidal volume with sleep — If yes

1. Check for leaks
2. Increase $IPAP_{max}$ if <25
3. Assess I-Time

Return to ★

If no

Unable to maintain SpO_2 >90% for 5 continuous minutes — If yes

1. Increase tidal volume to patient comfort by 10 ml increments for optimal therapy
2. Assess EPAP, consider increase
3. Assess rate, consider increase
4. Consider adding supplemental O_2

Return to ★

If no

Observe for inadequate back-up rate — If yes

Increase rate by 2 bpm. Assess I-Time and Rise Time for optimal therapy

Return to ★

If no

Prescription zone

BiPAP AVAPS prescription

EPAP	=	_____ cm H_2O	I-Time	=	_____ sec
$IPAP_{min}$	=	_____ cm H_2O	Rise time	=	To patient comfort
$IPAP_{max}$	=	_____ cm H_2O			
Tidal volume	=	_____ ml	Interface: _____		
Rate	=	_____ BPM			

BiPAP AVAPS reimbursement criteria

Restrictive thoracic disorders

Criterion A
There is documentation in the patient's medical record of a neuromuscular disease (e.g., amyotrophic lateral sclerosis) or severe thoracic cage abnormality (e.g., postthoracoplasty for TB).

and

Criterion B1
An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is ≥ 45 mm Hg.

or

Criterion B2
Sleep oximetry demonstrates oxygen saturation ≤ 88% for at least five minutes (minimum recording time of 2 hours), done while breathing patient's prescribed/recommended FIO_2.

or

Criterion B3
For neuromuscular disease (only), maximal inspiratory pressure is <60 cm H_2O or forced vital capacity is <50% predicted.

and

Criterion C
COPD does not contribute significantly to the patient's pulmonary limitation.

If all above criteria are met, either an E0470 or E0471 will be covered for the first three months of therapy.

Severe COPD

Initial coverage criteria (first three months)

Criterion A
An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is ≥ 52 mm Hg.

and

Criterion B
Sleep oximetry demonstrates oxygen saturation is ≤ 88% for at least 5 minutes of nocturnal recording time (minimum recording time of 2 hours) done while breathing oxygen at 2 LPM or the patient's prescribed FIO_2 (whichever is higher).

and

Criterion C
Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.

If all of the above criteria are met, an E0470 will be covered for the first three months of therapy.

Coverage for E0471

An E0471 will be covered for a patient with COPD in either of the two scenarios below, depending on the testing performed to demonstrate the need.

Scenario 1

For patients who qualify for an E0470, an E0471 started any time after a period of initial use of an E0470 is covered if both Criterion A and B are met.

Criterion A
An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, shows that the beneficiary's $PaCO_2$ worsens ≥7 mm Hg compared to the original result from Criterion A (initial coverage criteria).

and

Criterion B
A facility-based PSG demonstrates oxygen saturation ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events.

Scenario 2

For patients who qualified for an E0470, an E0471 will be covered if, at any time no sooner than 61 days after initial issue of the E0470, both Criterion A and B are met.

Criterion A
An arterial blood gas $PaCO_2$, is done while awake and breathing the patient's prescribed FIO_2, still remains ≥ 52 mm Hg.

and

Criterion B
Sleep oximetry while breathing with the E0470 demonstrates oxygen saturation is ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) done while breathing oxygen at 2 LPM or the patient's prescribed FIO_2 (whichever is higher).

Hypoventilation syndrome

An E0470 device will be covered if Criterion A, B and either C or D are met.

Criterion A
An initial arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, is ≥ 45 mm Hg.

and

Criterion B
Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted.

and

Criterion C
An arterial blood gas $PaCO_2$, done during sleep or immediately upon awakening and breathing the patient's prescribed FIO_2, shows the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the original result in Criterion A.

and

Criterion D
A facility-based PSG demonstrates oxygen saturation ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

An E0471 device is covered for a patient with hypoventilation syndrome if Criteria A, B, and either C or D are met.

Criterion A
A covered E0470 device is being used.

and

Criterion B
Spirometry shows an FEV1/FVC ≥ 70% and an FEV1 ≥ 50% of predicted.

and

Criterion C
An arterial blood gas $PaCO_2$, done while awake and breathing the patient's prescribed FIO_2, shows that the beneficiary's $PaCO_2$ worsens ≥ 7 mm Hg compared to the ABG result performed to qualify the patient for the E0470 device.

and

Criterion D
A facility-based PSG demonstrates oxygen saturation ≤ 88% for 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

Continued coverage beyond the first three months of therapy

Patients covered for the first three months of an E0470 or an E0471 must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the patient may certainly need to be evaluated at earlier intervals after therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating physician. Medicare will not continue coverage for the fourth and succeeding months of therapy until this re-evaluation has been completed.

There must be documentation in the patient's medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient to be consistently using the E0470 or E0471 for an average of 4 hours per 24-hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit. This would constitute reason for Medicare to deny continued coverage as not medically necessary.

A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of 4 hours per 24-hour period) and that the patient is benefiting from its use, must be obtained by the supplier of the device for continued coverage beyond three months.

Central sleep apnea or complex sleep apnea

Prior to initiating therapy, a complete facility-based, attended PSG must be performed documenting the following criterion:

Criterion A
The diagnosis of central sleep apnea or complex sleep apnea

↓ and

Criterion B
Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the patient's usual FIO_2

↓ and

If all above criteria are met, either an E0470 or E0471 device will be covered for the first three months of therapy.

Central sleep apnea is defined as:

1. An apnea hypopnea index (AHI) greater than 5; and
2. Central apneas/hypopneas greater than 50% of the total apneas/hypopneas; and
3. Central apneas or hypopneas greater than or equal to 5 times per hour; and
4. Symptoms of either excessive sleepiness or disrupted sleep.

Complex sleep apnea is a form of central apnea specifically identified by the persistence or emergence of central apneas or hypopneas upon exposure to CPAP or an E0470 device when obstructive events have disappeared. These patients have predominately obstructive or mixed apneas during the diagnostic sleep study occurring at greater than or equal to 5 times per hour. With use of a CPAP or E0470, they show a pattern of apneas and hypopneas that meet the definition of CSA described previously.

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