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POLICY:

It is the policy of the Sleep Medicine Program to perform a therapeutic trial of nasal CPAP/BiPAP/ASV-ADAPT for patients with Obstructive Sleep Apnea (OSA), Obesity/Central Alveolar Hypoventilation Syndrome, Central Sleep Apnea/CSR and requiring assisted nocturnal ventilation.

DEFINITION:

Continuous Positive Airway Pressure (CPAP) is designed to open the obstructed airway and increase the functional residual capacity in patients by continuously exerting a greater than atmospheric pressure on the airway.

Bilevel PAP serves to accomplish similar results as CPAP, but is also used to increase blood oxygen levels, decrease or increase blood Carbon Dioxide levels, decrease or eliminate oral leaks and provide nocturnal ventilatory assistance to patients suffering from neuromuscular or COPD disease. Based on 2 separate pressure settings; Bilevel is comprised of an expiratory pressure (EPAP) and a higher inspiratory pressure (IPAP). This serves to:

- A. Provide an extended range of pressures if still exhibiting obstructive symptoms at the high limit CPAP expiratory pressure of 16-20cm.
- B. Provide ventilatory assistance.
- C. Provide an alternative to patients having recorded failure to tolerate CPAP or patients in whom CPAP is contraindicated.

VPAP ADAPT (ASV) PAP is a special type of Bilevel PAP designed to correct obstructive as well as central apnea including Cheyne-Stokes Respiration through the application of an End Expiratory Pressure and a varying level of Pressure Support calculated on a breath by breath basis. Once all obstructive symptoms are prevented by determining an effective EEP, the varying degree of Pressure Support serves to directly counteract CSR/Central Apnea by under or over-ventilating until respiration becomes regular. Target ventilation is only 90% of full ventilation thus raising the average CO2 level. This mode must not be used and is not cleared for use by FDA in patients at risk of hypoventilation such as neuromuscular, etc.

BPAP autoSV is a similar type of Bilevel PAP designed to correct obstructive as well as central apnea including Cheyne-Stokes Respiration through the application of an Expiratory Pressure and a varying level of Pressure Support calculated by flow volume. Once all obstructive symptoms are prevented by determining an effective EPAP, the varying degree of Pressure Support serves to directly counteract CSR/Central Apnea by under or over-ventilating until respiration becomes regular. Target ventilation is 100% of

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full ventilation so this mode should be used in patients at risk of hypoventilation such as neuromuscular, etc.

GOALS of TITRATION:

Ultimate success and compliance with CPAP/Bilevel/ASV-ADAPT depends upon adequate titration.

Definition of "ideal" titration: At least 30 minutes of recording at the lowest "optimum pressure or pressure(s)" in [REM for CPAP/Bilevel] and [NREM for ASV-ADAPT] with no more than 2 pillows beneath the head while flat supine (head of bed is not raised) without exhibiting the following symptoms:

- 1. Respiratory Events
- 2. Snoring
- 3. Paradoxing
- 4. Desaturating less than 90%
- 5. Arousing
- 6. Severe Oral or Interface Leaks

EQUIPMENT NECESSARY:

- 1. VPAP generator with humidifier, O2 supply, small and large bore tubing.
- 2. Previously fitted nasal or full face interface (FFM always used as last resort unless using ADAPT).

PAP INITIATION:

- Carefully re-read physician's orders.
- 2. Ensure the patient has checked and signed the Therapeutic Intervention Informed Consent Form to allow the initiation of Positive Airway Pressure and Supplemental O2 and that the PAP Patient Orientation and Biocalibration protocols have been Completed and the NPSG Procedure is being followed.

RETITRATION:

A. Have patient hookup own PAP equipment and hold interface up to nose while technologist tests pressure through "pickoff port" on interface. This should be done with a digital manometer while patient holds breath. Check

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with records and patient to determine if the measured pressure matches the prescribed pressure. Ask patient if a chinstrap and humidifier are used at home. Does the patient experience a dry mouth or oral leaks when sleeping? Is the patient pulling off the interface during sleep? If using Bilevel, listen for appropriate cycling with breaths. Document information.

- B. **If using CPAP** begin titration using the lab PAP equipment set at whatever pressure was recorded by the digital manometer when testing the patient's equipment. Record 2 hours at this "baseline" pressure, hopefully capturing REM supine. Go to section D.
- C. If using Bilevel begin titration using the patient's own equipment and PAP machine. Leave the digital manometer hooked up to the interface pickoff port to verify pressure readings at least every 30 minutes. Make frequent leak rate and cycle sensitivity observations at bedside. The point is to ensure the patient's home PAP machine is cycling appropriately with each breath. Record 2 hours at these "baseline" pressures, hopefully capturing REM supine. Go to section D.
- D. After running 2 hours at baseline (home) PAP pressure, switch over to the lab titration equipment (if not already using it) and if:
 - 1. No obstructive symptoms were present, titrate downward by 1cm/10 minutes until obstructive symptoms are apparent. Delicately titrate up from the level of obstructive symptom appearance. If obstructive symptoms do not appear at even the lowest pressures (3-4cm) then remove CPAP and run one entire sleep cycle (capturing REM supine) or 1 hour, whichever comes first. If still no obstructive symptoms, run the rest of the study without PAP. However, if obstructive symptoms finally appear, reapply PAP and titrate upwards.
 - Obstructive symptoms were/are present, follow titration rules.

SPLIT NIGHT or INITIAL CPAP STUDY:

A. Ensure patient has satisfied the Split Night Criteria or has a valid order for CPAP.

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- B. Apply pre-fitted PAP interface. Note pressure type and levels that patient was found to tolerate (if different than the standard beginning pressure) during PAP Patient Orientation. Keep this in mind.
- C. Begin at 4cm regardless if patient tolerated the pressure during Orientation. The point is to document patient intolerance, if present, while recording. Ask the patient "Are you having difficulty exhaling against this pressure?" If no problems, continue recording and follow Titration Rules. If the patient is having problems tolerating nasal CPAP pressure, try to record at least two minutes per PAP pressure/Interface combination until arriving at whatever the patient tolerated. Then follow Titration Rules.

INITIAL BILEVEL PAP TITRATION or switch from CPAP:

- A. Ensure patient has a valid order for Bilevel PAP or has satisfied criteria for switching from CPAP.
- B. Apply pre-fitted PAP interface. Note pressure type and levels that patient was found to tolerate (if different than the standard beginning pressure) during PAP Patient Orientation. Keep this in mind.
- C. If initial Bilevel titration begin with one of the following pressures:
 - 1. **Neuromuscular patients:** Start at 7/3cm. Increase per bilevel rules.
 - 2. Hypoventilation patients: Start at 10/5cm. Increase per bilevel rules.
 - 3. COPD patients: Start at 10/5cm. Check to see if MD has ordered titration to begin with supplemental O2. Follow order. Patient may need to sleep with head of bed raised significantly to avoid chest pain. Increase as per bilevel titration rules.
- D. If switching from CPAP to Bilevel due to obstructing at high (16cm small to medium sized patients, 20cm for large patients) E pressure: Do not change E pressure. Start I pressure 4cm above E pressure. Increase I and E per Bilevel rules.
- E. If switching from CPAP to Bilevel due to oxygen desaturations after proving CPAP cannot maintain sats ≥ 90% (large patients can be taken to 20cm): If <88% SaO2 reduce the Expiratory pressure to 2cm below and the Inspiratory pressure to 5cm above the otherwise therapeutic CPAP pressure for a 7cm

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spread. If 88-90% SaO2 reduce the Expiratory pressure to 2cm below and the Inspiratory pressure 3cm above the otherwise therapeutic CPAP pressure for a 5cm spread. Increase as per Bilevel titration rules

F. If switching from CPAP to Bilevel due to patient intolerance: Reduce the Expiratory pressure to 3cm below and the inspiratory pressure to 1cm above the last CPAP pressure for a 4cm spread. Follow Bilevel titration rules.

Initial ResMed VPAP ADAPT (ASV) qualification and setup:

- A. Patient must fit into one of these scenarios:
 - 1. Baseline NPSG documented need for PAP therapy.
 - 2. A full night CPAP titration failed to prevent Central Apneas.
 - 3. You must perform a full night ASV (ADAPT) titration.

- 1. A prior split night having no less than 3 hours of CPAP (not bilevel) titration documented failure to prevent Central Apneas.
- 2. You must perform a full night ASV (ADAPT) titration.

_____ 1. Baseline NPSG documented need for PAP therapy with definite Central and

- possibly Mixed/Obstructive events present.
- 2. You must start PAP titration in CPAP mode and only switch to ASV (ADAPT) after a 3 hour CPAP titration documents failure to prevent Cental apneas. Titrate ASV (ADAPT) for at least 3 more hours.
- B. Ensure patient does not have any of the following disease states*:
 - 1. Chronic, prolonged or profound hypoventilation.
 - 2. Moderate to severe Chronic Obstructive Pulmonary Disease (Chronically elevated PCO2 on ABG >45mmHG.)
 - 3. Restrictive thoracic or neuromuscular disease
- *If any disease state listed in [B] is present, discontinue ASV-ADAPT titration protocol and attempt treatment with BiPAP Auto SV.
- C. Perform ADAPT checklist to:
 - 1. Erase previous data.
 - 2. Reset factory defaults via selecting "default" option in clinical menu. Default settings are: EEP = 5cm, Min PS = 3cm, Max PS = 10cm.
 - 3. Program interface type being used Actual Interface exhalation port leak must be equal to the known leak of the programmed interface.

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- 4. Perform initial "Learn Circuit" calibration. Learn circuit calibration must be reperformed every time the circuit configuration is altered in any way, such as an interface, humidifier or tubing change.
- D. Perform supine BP check*. If Systolic is 80 or greater, proceed with protocol. Each subsequent check should be done by the same person/same automatic BP device.
- *If Systolic is < 80 mmHG at any time, discontinue ADAPT titration protocol and attempt treatment with BiPAP Auto SVt.
- E. Fit patient with a ResMed Full Face or nasal mask.
- F. Start therapy at default settings of 10/5. Keep patient awake.
- G. After 5 minutes of therapy, take BP again. If Systolic is >79 continue with therapy.
- H. After 20 minutes of therapy, take BP again. If Systolic is >79 continue protocol.
- I. Stop Therapy. Wait 5 minutes and take BP again. Compare BP post therapy to during therapy. If BP increases by 15 after ADAPT was stopped, the patient should be monitored closely throughout titration. This indicates ADAPT therapy was lowering BP. This guideline is dependent upon the original BP. A lower Systolic reading cannot tolerate as much change.

TITRATION RULES SECTION

1. CPAP TITRATION RULES

- A. **If mild obstructive symptoms are present**: increase by 1cm/10 minutes until:
- B. If moderate obstructive symptoms are present: increase by 1cm/5 minutes until:
- C. If severe obstructive symptoms are present: increase by 2cm/5 minutes to a maximum of 10cm, then increase by 1cm/5 minutes until:
 - 1. All respiratory events, flow limitation, snoring, paradoxing, desaturating <90% and arousals have ceased. -or-

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- 2. A maximum expiratory pressure of 16cm (small to medium sized patients) or 20cm (large patients) has been reached and symptoms have not ceased, at which time follow Bilevel titration protocol. -or-
- 3. Oral leaks and/or arousals become uncontrollable. A pressure reduction or position change may be necessary to find the best compromise between pressure, arousals, obstructive symptoms and oral leak. If oral leaks/arousals are still uncontrollable follow Bilevel titration protocol. -or-
- 4. Central apneas or slowing respiratory rate begin. If this happens reduce pressure until centrals cease and/or RR increases back to normal. -or-
- 5. Patient cannot tolerate expiratory pressure after making sure the problem is not oral leak/dryness, nasal congestion, interface trouble or claustrophobia.
 - A. If at beginning pressures of 4-5cm, decrease to 3cm. If still cannot tolerate, roll patient to side and retry 3-5cm. If still cannot tolerate, then increase to 6-7cm. If still cannot tolerate, follow bilevel titration rules.
 - B. If below optimum pressure but above beginning pressures and still having significant OSA symptoms, reduce pressure and let patient fall back asleep. Patient may need to roll to side at this time. After asleep, continue increasing PAP as close as possible to optimum pressure then roll supine to fine tune pressure. Many patients cannot tolerate sub-optimal expiratory pressures. If still cannot tolerate expiratory pressure follow Bilevel titration rules.
 - C. If at or below optimum pressure but above beginning pressures and only having insignificant OSA symptoms (mild snoring, mild paradoxing, and/or mild desats in REM) reduce pressure 1-2cm and continue titration. If patient complains again about exhalation pressure, reduce by another 1-2 cm or until significant OSA symptoms return (moderate snoring, hypopneas, arousals, moderate paradoxing, or desaturations below 90%). Patient may need to roll to side if remaining titration time will allow. After moderate OSA symptoms have returned, increase PAP again until patient displays mild OSA symptoms and hold at that pressure. If patient still cannot tolerate expiratory pressure, follow Bilevel titration rules.

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2. BILEVEL PAP TITRATION RULES

- A. If mild to moderate obstructive symptoms (hypopneas, snoring, paradoxing, arousing) are present: Increase Inspiratory pressure by 1cm every 5 minutes.
- B. If severe obstructive symptoms (apneas) are present: Increase Expiratory pressure by 1cm every 5 minutes.
- C. If desaturating below 90% after obstructive symptoms have been fixed: Increase the Inspiratory pressure by 1cm/5 minutes until the Inspiratory pressure has reached maximum but do not exceed a spread of 10cm. If still desaturating, increase the Inspiratory and Expiratory pressures by 1cm/10 minutes to a maximum of 4cm over prior levels. If still desaturating, reduce Expiratory pressure to prior level and set Inspiratory pressure not more than 8cm above the Expiratory pressure. Add Supplemental O2 via protocol.
- **D. Maintain a minimum 4-5cm between Inspiratory and Expiratory pressures**, even if that means having to raise the Inspiratory pressure to keep ahead of the Expiratory pressure.
- E. Obesity Hypoventilation and COPD patients need a wide spread (8-10cm not uncommon) to blow off CO2 and take up O2 to maintain an SpO2 of 90%. If possible, a higher flow exhaust port such as a Respironics "Plateau" exhalation valve or interface with higher exhaust flow and lower deadspace should be used. Extreme care should be taken if adding supplemental O2 to a COPD patient due to the possibility of decreasing or eliminating the hypoxic stimuli to breathe. It is advisable to ascertain individual supplemental O2 Liters/min. high and low limits from the Medical Director prior to patient intake. Use of a "backup rate" should be considered in these patients.
- F. Neuromuscular patients need Expiratory pressures as low as possible (generally <7cm.) Begin titrating with 3cm Expiratory pressure and 7cm Inspiratory pressure. Attempt to manipulate all obstructive symptoms except apneas with Inspiratory pressure, although increases in Expiratory pressure may be necessary. Watch for central apneas when increasing E pressure. Back down if necessary. Use of a "backup rate" should be considered in these patients.
- G. Only use Supplemental O2 when: 1. Desaturations cannot be corrected with Bilevel alone 2. A physician has ordered its use with Bilevel PAP.

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H. If patient cannot tolerate Bilevel then switch back to CPAP. Use O2 if necessary.

3. ASV-ADAPT TITRATION RULES

- A. Start at default settings. Make no changes for 20 minutes [40 for CHF pts.]
- B. If patient is having obstructive events: Increase EEP by 1-2 cm every 20 minutes until events are gone.
- C. After obstructive events have ceased, observe patient 10 minutes before making further changes.
- D. If patient is still having Central events/CSR during Non-REM Sleep: Increase Maximum Pressure Support (beyond default 10cm) by 1cm every 10 minutes to allow device to meet target ventilation.
- E. If patient is still having exclusively Central events at the highest Maximum Pressure Support value (beyond default 10cm) and EEP is >5: Decrease EEP by 1cm every 5 minutes until clear obstructive symptoms are seen. Document EEP level. Do not decrease EEP below 5cm. Then raise EEP by 1cm every 5 minutes until the clear obstructive symptoms are abolished. Do not chase solitary PAP Flow Limitation in this scenario. If the EEP was found to be unnecessarily high, consider lowering the MAX PS range by the same amount, not to go lower than the default range of 10cm Max PS. Resume titration.
- F. Do Not increase Maximum Pressure Support for Centrals occurring during REM. If excessive centrals are present in REM, the default backup rate (15 breaths/min) will fire.
- G. The leak must remain less than: FFM = 24 L/Min. Nasal Mask = 12 L/Min.

BIPAP AUTO SV TITRATION RULES - under construction