

	<p>Positive Airway Pressure (PAP) Device Guideline</p>	
<p>Guideline # 6194</p>	<p>Categories Clinical → Care Coordination – Utilization management</p>	<p>This Guideline Applies To: Texas Children's Health Plan</p>
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GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of all Positive Airway Pressure devices, including Continuous Positive Airway Pressure (CPAP), Bi-level Positive Airway Pressure (BiPAP) devices and Non-Invasive Ventilator (respiratory assist devices or RAD).

PRIOR AUTHORIZATION GUIDELINE

1. All requests for prior authorization for Positive Airway Pressure devices are received via online submission, fax, phone or mail by the Utilization Management Department and processed during normal business hours.
2. Clinical documentation to support the medical necessity for the requested positive airway pressure device system must be provided.
3. A CPAP (E0601) or RAD (including BiPAP) without a set backup rate (E0470) may be considered for an initial three month rental period with prior authorization.
4. When clinical documentation indicates CPAP or RAD (including BIPAP) **without a set backup rate** is effective, they may be considered for purchase OR continued rental with renewal at 6 month intervals up to 12 months.
 - 4.1. A CPAP or BIPAP device without a set backup rate will be considered purchased after 12 months of rental through the same provider and a request for purchase or further rental will not be considered.
 - 4.2. Continued rental requests from an out of network provider may be approved through the 12-month rent-to-purchase period if any of the following apply:
 - The provider was in-network at the time of initial rental request
 - The member received the requested services through a prior authorization from either another Managed Care Organization (MCO) or Fee for Service FFS) provider.
5. A RAD (BiPAP) **with a set backup rate** (E0471 and E0472) may be considered for an initial 3 month rental period with prior authorization and will be considered for **rental only**.
 - 5.1. Continued rental after 3 month trial requires documentation of the following:
 - Symptoms are improved with the usage of the device

- Compliance with device usage
6. Humidification devices (heated or non-heated) for use with a CPAP or RAD device may be a benefit with prior authorization when medically necessary. Documentation submitted must support why humidification is medically necessary for use with positive pressure ventilation. Heated humidifiers (procedure code E0562) are used for members with bypassed upper airways, members receiving mechanical ventilator support, and members with high flow positive airway pressure devices.
- 6.1. Documentation submitted must support why heated humidification is medically necessary. Clinical signs and symptoms that may be an indication for heated humidification include (but are not limited to) the following:
- Dry, nonproductive cough
 - Increased airway resistance
 - Increased incidence of infection
 - Increased work of breathing
 - Complaint of substernal pain and/or airway dryness
 - Thick, dehydrated secretions
 - History of recurrent epistaxis (nosebleeds)
 - History of deviated nasal septum
7. Initial Requests for a Continuous Positive Airway Pressure (CPAP) or auto-titrating CPAP System
- 7.1. A CPAP device may be considered for an initial three-month rental period based on documentation supporting the medical necessity and appropriateness of the device.
- Documentation must include that the member has had a sleep study, lasting minimum of two hours, and at least one of the following criteria:
- For members 17 years of age and younger, polysomnography results documenting an apnea-hypopnea index (AHI) greater than one event per hour
 - For members 18 years of age and older, polysomnography results documenting an AHI or a respiratory disturbance index (RDI) greater than or equal to 15 events per hour
 - For members 18 years of age and older, an AHI or RDI greater than five events per hour with documentation of at least one of the following:
 - Excessive daytime sleepiness assessed by either the Epworth Sleepiness Scale (ESS) with a result greater than 10 or the Multiple Sleep Latency Test (MSLT) with a result less than 6
 - Symptoms of impaired cognition, mood disorders, or insomnia
 - Hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure greater than 90 mm Hg)
 - Ischemic heart disease or previous myocardial infarction

- History of stroke
- Greater than 20 episodes of oxygen desaturation to less than 85 percent during a full night sleep study
- Any one episode of oxygen desaturation of less than 70 percent
- Pulmonary hypertension

7.2 A **CPAP or auto-titrating CPAP System** that is used during a recent hospitalization requires written clinical documentation of observed severe obstructive sleep apnea by a nurse, respiratory therapist, or physician **AND** oxygen desaturation of 90% or lower for more than 5 minutes without other etiology during sleep.

- Auto-titrating CPAP may be considered if medical necessity criteria for CPAP are met but an optimal level of CPAP was not determined.

7.3 Request for purchase or continued rental of a CPAP device is considered medically necessary if the following documentation is provided:

- Symptoms and/or findings of sleep disordered breathing, as documented by the treating physician, are improved with use of the CPAP.
- Continuous use of the equipment for minimum of four hours per 24 hour period for more than 50% of nights during a consecutive 30 day period for children 18 and under and 70% of nights during a consecutive 30 day period for adults.
- If usage is not meeting this goal, the treating physician must submit documentation of compelling clinical importance of continued rental of the equipment for an additional 1 to 3 month period, the counseling, and the measures implemented to improve adherence.

7.4 Conditions where use of CPAP is of compelling clinical importance include (but are not limited to):

- Down Syndrome
- Achondroplasia
- Severe obstructive sleep apnea
- Psychiatric illness Autism

8. Members with sleep disordered breathing may qualify for a **BiPAP device WITHOUT a backup rate** if member has a diagnosis of:

8.1 Obstructive sleep apnea (OSA) **AND**

- Meets the criteria for CPAP in section 7 **AND**
- CPAP failed to be effective in treating the member's OSA or is considered contraindicated due to other medical conditions (such as severe neuromuscular disease or heart failure).

8.2. Restrictive thoracic disorders (neuromuscular diseases or severe thoracic cage abnormalities including but not limited to muscular dystrophies, spinal muscular atrophy,

Charcot Marie Tooth, amyotrophic lateral sclerosis, spinal cord injury, severe scoliosis, severe chest wall deformities) **AND** significant respiratory insufficiency is documented by one of the following:

- An arterial blood gas (ABG) PaCO₂ greater than or equal to 45 mm Hg, obtained while awake and breathing the member's routinely prescribed fraction of inspired oxygen concentration (FiO₂)
- Sleep oximetry demonstrates oxygen saturation less than or equal to 88 percent for 5 minutes or longer of continuous nocturnal recording time (minimum recording time of 2 hours), obtained while member is breathing his or her routinely prescribed FiO₂
- TcCO₂ value of 50 or more for ≥ 25% of the total sleep time
- Maximal inspiratory pressure less than 60 cm H₂O
- Forced vital capacity less than 50 percent of predicted volume
- Sleep study documents obstructive sleep apnea and CPAP is considered contraindicated due to the member's weakness and/or pulmonary restriction.

8.3 Severe Chronic Obstructive Pulmonary Disease (COPD) **AND**

- An arterial blood gas PaCO₂ less than 52 mm Hg, obtained while awake and when the member is either using 2 LPM of oxygen or the member's prescribed FIO₂, whichever is higher
- Sleep oximetry demonstrates oxygen saturation less than or equal to 88 percent for 5 minutes or longer of continuous nocturnal recording time (minimum recording time of 2 hours), obtained while breathing oxygen at 2 LPM or the member's prescribed FIO₂ (whichever is higher)
- Documentation of rationale for why CPAP alone would not be effective.

8.4 Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA)

- Condition characterized by the development of central apneas or central hypopneas during pressure titrations performed in a sleep lab titration study for CPAP or BiPAP without a backup rate.
- BiPAP without a backup rate will be considered with prior authorization for the treatment of CSA or CompSA when a facility based polysomnogram is performed and supports all of the following:
 - The member has a diagnosis of CSA or CompSA
 - The sleep study documents one of the following:
 - The sum total of central hypopneas plus central apneas is greater than 50 percent of the total apneas and hypopneas rate; **Or**
 - A central hypopnea/apnea rate index greater than 5 events per hour; and significant improvement of the sleep-associated hypoventilation while breathing the members prescribed FiO₂
 - Documentation ruling out CPAP as effective therapy if either OSA or CSA is a component of the initially observed sleep associated hypoventilation

8.5 Hypoventilation Syndrome

- BIPAP without a backup rate may be considered for treatment of hypoventilation syndrome with prior authorization when **ALL** of the following criteria are met:
 - An initial arterial blood gas PaCO₂, obtained while awake with the member breathing their prescribed FIO₂, greater than or equal to 45 mm Hg
 - Spirometry shows a forced expired volume in 1 sec (FEV₁) or the forced vital capacity (FVC) greater than or equal to 70 percent
 - A facility-based polysomnogram demonstrates oxygen saturation less than or equal to 88 percent for 5 minutes or longer of continuous nocturnal recording time (minimum recording time of 2 hours) not caused by obstructive upper airway events
 - TcCO₂ or EtCO₂ of 50 or more for ≥ 25% of the total sleep time.

9. Members with sleep disordered breathing may qualify for a **BiPAP device WITH a backup rate** if the member meets criteria for BIPAP without a backup rate **AND**:

- The desired therapeutic respiratory response was not achieved with BiPAP without a set backup rate, or there is medical justification clearly describing why the desired therapeutic respiratory response could not be achieved by BiPAP without a set backup rate.

10. Mechanical Ventilation

10.1 Invasive and noninvasive ventilators (E0465, E0466, and E0467) are considered for rental only with prior authorization and documentation of medical necessity indicating a clinical need for mechanical ventilation.

- Mechanical ventilation may be considered for the treatment of, but not limited to:
 - Neuromuscular or musculoskeletal diseases and conditions affecting the respiratory muscles
 - Thoracic restrictive diseases
 - Chronic respiratory failure

10.2 Back-Up Mechanical Ventilator

- A back-up ventilator is defined as an identical or similar device used to meet the same medical needs as the primary ventilator for the member, but provided in the home as a precaution in case of malfunction of the primary ventilator.
- Requests for a back-up ventilator in the home must meet **both** the following criteria to be considered medically necessary:
 - The member cannot maintain spontaneous ventilations for four or more consecutive hours.
 - The member lives in an area where a replacement ventilator cannot be provided within two hours.
- Prior authorization requests for a back-up ventilator must include **ALL** of the following documentation:

- The amount of time the member is able to maintain spontaneous ventilation.
- The distance and/or delivery time of a replacement ventilator to the member's home
- All requests for a back-up ventilator in the home require medical director review.

11. Requests that do not meet the criteria established by this guideline will be referred to a TCHP Medical Director/ Physician Reviewer for review.

12. Preauthorization is based on medical necessity and not a guarantee of benefits or eligibility. Even if preauthorization is approved for treatment or a particular service, that authorization applies only to the medical necessity of treatment or service. All services are subject to benefit limitations and exclusions. Providers are subject to State and Federal Regulatory compliance and failure to comply may result in retrospective audit and potential financial recoupment.

REFERENCES:

Government Agency, Medical Society, and Other Publications:

Texas Medicaid Provider Procedure Manual, Durable Medical Equipment, Medical Supplies, and Nutritional Products Handbook, Accessed February 23, 2023 [2_DME_and_Supplies.fm \(tmhp.com\)](https://www.tmhpa.com/2-DME-and-Supplies.fm)

Peer Reviewed Publications

Finder JD, Birnkrant D, Carl J, Farber HJ, Gozal D, Iannaccone ST, Kovesi T, Kravitz RM, Panitch H, Schramm C, Schroth M, Sharma G, Sievers L, Silvestri JM, Sterni L; American Thoracic Society. Respiratory care of the patient with Duchenne muscular dystrophy: ATS consensus statement. *Am J Respir Crit Care Med*. 2004 Aug 15;170(4):456-65.

Marcus CL, Brooks LJ, Draper KA, Gozal D, Halbower AC, Jones J, Schechter MS, Ward SD, Sheldon SH, Shiffman RN, Lehmann C, Spruyt K; American Academy of Pediatrics. Diagnosis and management of childhood obstructive sleep apnea syndrome. *Pediatrics*. 2012 Sep;130(3):e714-55.

Hull J, Aniapravan R, Chan E, et al British Thoracic Society guideline for respiratory management of children with neuromuscular weakness *Thorax* 2012;67:i1-i40

Jardine E, Wallis C Core guidelines for the discharge home of the child on long term assisted ventilation in the United Kingdom *Thorax* 1998;53:762–767

Marcus C, Brooks LJ, Draper K, Gozal D, et al Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome *Pediatrics* 2012;130:576–584

AARC Clinical Practice Guideline Long-Term Invasive Mechanical Ventilation in the Home —2007 Revision & Update; *Respiratory Care* 2007; 52: 1056-1062

Wang CH, Finkel RS, Bertini ES, et al Consensus Statement for Standard of Care in Spinal Muscular Atrophy J Child Neurol 2007 22: 1027-1049

Hoover-Fong J, Scott CI, Jones MC; COMMITTEE ON GENETICS. Health Supervision for People With Achondroplasia. Pediatrics. 2020 Jun;145(6):e20201010

Bull MJ; Committee on Genetics. Health supervision for children with Down syndrome. Pediatrics. 2011 Aug;128(2):393-406.

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