Texas Children's	Positive Airway Pressure (PAP) Device Guideline	
Guideline # 6194	***Categories*** Clinical →Utilization Management UM	***This Guideline Applies To:*** Texas Children's Health Plan ***Document Owner*** Bhavana Babber

GUIDELINE STATEMENT:

Texas Children's Health Plan (TCHP) performs authorization of all Positive Airway Pressure devices, including Continuous Positive Airway Pressure (CPAP) and Bi-level Positive Airway Pressure (BIPAP) devices.

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. To request prior authorization for a Positive Airway Pressure device, clinical documentation to support the medical necessity for the selected positive airway pressure device system must be provided.
3. Requests will be approved initially for a trial rental for 3 months.
4. Following the initial 3 month trial period, the device may be considered for continued rental with recertification (for up to 9 additional months) or purchased based on effectiveness, compliance and medical necessity.

    4.1. To establish medical necessity for purchase or continued rental – the following documentation must be provided:

        4.1.1. The client's 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 for adults 19 and older during a consecutive 30 day period.

            4.1.1.1. This can be met by downloads of adherence documentation – provided by DME provider.

            4.1.1.2. If usage is not meeting this goal, clinician will send documentation of compelling clinical importance of continued rental of the equipment for 3 month period and measures implemented to improve adherence.

                4.1.1.2.1. Compelling Clinical conditions may include:

                    4.1.1.2.1.1. Severe neuromuscular disease including but not limited to

4.1.1.2.1.1.1. Muscular dystrophies and myopathies

4.1.1.2.1.1.2. Spinal muscular atrophy

4.1.1.2.1.2. Severe cerebral palsy

4.1.1.2.1.3. Down Syndrome

4.1.1.2.1.4. Achondroplasia

4.1.1.2.1.5. Severe restrictive lung disease (FVC< 50% or <1L)

4.1.1.2.1.6. Severe sleep disordered breathing as documented on polysomnogram (sleep study)

4.1.1.2.1.7. Psychiatric illness such as (but not limited to) depression, bipolar disorder, and schizophrenia.

4.1.2. The client's symptoms as documented by the treating physician are improved with use of the equipment

5. A CPAP device or a Respiratory Assistance Device (such as BiPAP S) 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.

5.1. 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:

5.1.1. The provider was in-network at the time of initial rental request

5.1.2. The member received the requested services through a prior authorization from either another Managed Care Organization (MCO) or Fee for Service (FFS) provider

6. A Respiratory Assistance Device with a set backup respiratory rate (such as BiPAP S/T) may be considered for an initial 3 month rental period with prior authorization and will be considered for rental only on an ongoing basis.

6.1. Continued rental requests from an out of network provider may be approved for up to 90 days if any of the following apply:

6.1.1. The provider was in-network at the time of initial rental request

6.1.2. The member received the requested services through a prior authorization from either another Managed Care Organization (MCO) or Fee for Service (FFS) provider

7. Establishing Medical Necessity for Positive Airway Pressure Devices:

7.1. Continuous Positive Airway Pressure (CPAP) System require that the member has had a sleep study lasting a minimum of 2 hours that documents medical necessity, including the following findings:

7.1.1. Adult CPAP (18 years of age and older) may be approved if one of the following conditions are met:

7.1.1.1. A Sleep Study Respiratory Disturbance Index (RDI) or Apnea/Hypopnea Index (AHI) greater than or equal to 15 per hour

7.1.1.2. A Sleep Study RDI or AHI greater than 5 per hour and at least one of the following:

7.1.1.2.1. Excessive daytime sleepiness (documented by either Epworth greater than 10 or multiple sleep latency test (MSLT) less than 6

7.1.1.2.2. Documented symptoms of impaired cognition, mood disorders, or insomnia

7.1.1.2.3. Documented hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure greater than 90 mm Hg)

7.1.1.2.4. Documented ischemic heart disease

7.1.1.2.5. Documented history of stroke

7.1.1.2.6. Greater than 20 episodes of oxygen desaturation less than 85 percent during a full night sleep study

7.1.1.2.7. Any one episode of oxygen desaturation less than 70 percent

7.1.1.2.8. Pulmonary hypertension

7.1.1.2.9. Obesity hypoventilation syndrome

7.1.1.2.10. Congestive heart failure

7.1.1.3. Pediatric CPAP (17 years of age and younger) may be approved if any of the following conditions are met:

7.1.1.3.1. Sleep study documents Apnea Hypopnea Index (AHI) greater than 1 or hypoventilation (25% of the total sleep time with CO2 levels greater than 50 mmHg with a clinical symptom of obstructive sleep apnea such as snoring, paradoxical breathing, or daytime symptoms of hyperactivity, behavioral problems, or learning problems

7.1.1.3.2. Adenoidectomy or tonsillectomy has been unsuccessful in relieving symptoms of obstructive sleep apnea

7.1.1.3.3. Observation during sleep study documents presence of severe obstructive sleep apnea as described by clinical observation by nurse, respiratory therapist, or physician AND oxygen desaturation with sleep to 90% or lower for more than 5 minutes without other etiology.

7.2. Bi-level Positive Airway Pressure devices (BIPAP)

7.2.1. Members with Obstructive Sleep Apnea may qualify for a BIPAP device if:

7.2.1.1. The client meets the criteria for CPAP above AND one of the following is documented:

7.2.1.1.1. Member was intolerant of CPAP

7.2.1.1.2. A CPAP device was found to be ineffective during the initial facility based or sleep laboratory titration trial testing

7.2.1.1.3. CPAP is contraindicated due to neuromuscular disease, weakness, restrictive lung disease, heart failure, hypoventilation or other clearly documented medical necessity justification.

7.2.1.1.4. ***If a CPAP device is tried and found ineffective during the initial facility-based titration or home trial, substitution of a BIPAP device does not require a new face-to face clinical evaluation or a new sleep test.

7.2.1.2. Members with documented Restrictive Thoracic disorders and obstructive sleep apnea may qualify for BIPAP device for Sleep Disordered Breathing including the following:

7.2.1.2.1. The member has a neuromuscular disorder with severe weakness (e.g., muscular dystrophy, Spinal Muscular Atrophy, Amyotrophic lateral sclerosis (ALS), spinal cord injuries, severe cerebral palsy) or the member has a diagnosis of a severe thoracic cage abnormality (e.g., severe chest wall deformities, severe scoliosis,)

7.2.1.2.2. Member has severe restrictive lung disease (FVC < 50% or < 1L)

7.2.1.2.3. Member has diaphragm paralysis or diaphragm paresis

7.2.1.3. Members with Severe Chronic Obstructive Pulmonary Disease (COPD)

7.2.1.3.1. A BIPAP device without a backup rate may be considered for the treatment of severe COPD, when all of the following criteria are met:

7.2.1.3.1.1. An arterial blood gas or arterialized capillary blood gas PaCO2 greater than 52 mm Hg, obtained while awake and when the member is either using 2 LPM of oxygen or the client's prescribed FIO2 (the blood gas should be drawn while the client is using whichever concentration of oxygen is the higher of the two).

7.2.1.3.1.2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% 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 client's prescribed FIO2 (whichever is higher).

7.2.1.3.1.3. Prior to initiating therapy, documentation of sleep apnea and that treatment with CPAP has been considered with an explanation of why it was ruled out.

7.2.1.3.1.3.1. Unless there is sufficient information in the medical record submitted with the request to demonstrate that the client does not suffer from some form of sleep apnea (obstructive sleep apnea (obstructive sleep apnea), CSA or complex sleep apnea) as the predominant cause of awake hypercapnia or nocturnal arterial oxygen desaturation).

7.2.1.4. Members with Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA)

7.2.1.4.1. BIPAP device without or with a backup rate will be considered for the treatment of central sleep apnea or CompSA when a facility based sleep study is performed and supports all of the following:

7.2.1.4.1.1. The client has a diagnosis of central sleep apnea or CompSA

7.2.1.4.1.2. The sleep study documents a central hypopnea/apnea rate index greater than 5 events per hour; and significant improvement of the sleep-associated hypoventilation while breathing the member's prescribed FiO2.

7.2.1.5. Members with Hypoventilation Syndrome

7.2.1.5.1. A BIPAP device may be considered for treatment of hypoventilation syndrome when all of the following criteria are met:

7.2.1.5.1.1. An initial arterial blood gas or arterialized capillary blood gas PaCO2, obtained while awake with the client breathing their prescribed FIO2, greater than or equal to 45 mm Hg.

7.2.1.5.1.2. A facility-based sleep study demonstrates oxygen saturation less than or equal to 88% for 5 minutes or longer of continuous nocturnal recording time or pCO2 over 50 for 25% or more of recording time (minimum recording time of 2 hours) not caused by obstructive upper airway events.

7.2.1.5.1.3. A genetic test documents the presence of Congenital Central Hypoventilation Syndrome with a disease causing mutation documented in the PHOX2B gene. (Note: A patient with Congenital Central Hypoventilation syndrome will usually require a portable ventilator rather than a Bi-level Positive Airway Pressure device).

7.2.2. Members may qualify for a Bi-level Positive Airway Pressure System With Backup Rate (B-PAP ST) if:

7.2.2.1. A diagnosis of central sleep apnea or a neuromuscular disease producing respiratory insufficiency, AND

7.2.2.1.1. Sleep study records central apnea greater than 5 central apneas per hour

7.2.2.1.2. For members who are 18 years of age and younger with:

7.2.2.1.2.1. Central apneas greater than 20 seconds regardless of bradycardia

7.2.2.1.2.2. Desaturation or central apneas of less than 20 seconds with desaturation greater than 4 percent

7.2.2.1.2.3. Bradycardia

7.2.2.1.3. The member has an arterial PO2 at or above 50 mm Hg , or an arterial oxygen saturation at or below 89 percent by transcutaneous oximetry associated with a diagnosis of neuromuscular respiratory insufficiency or failure (not COPD).

7.2.2.2. Hypoventilation Syndromes including:

7.2.2.2.1. Medication or substance use (central or obstructive sleep apnea may be present but are not the primary cause of the hypoventilation)

7.2.2.2.2. Obesity hypoventilation

7.2.2.2.3. Congenital central alveolar hypoventilation

7.2.2.2.4. Late-onset central hypoventilation with hypothalamic dysfunction

7.2.2.2.5. Idiopathic central alveolar hypoventilation

7.2.2.2.6. Hypoventilation due to a medical disorder (central or obstructive sleep apnea may be present but are not the primary cause of the hypoventilation)

7.2.2.2.7. Cheyne – Stokes respiration due to congestive heart failure.

7.2.2.3. An arterial blood gas or arterialized capillary blood gas PaCO2 greater than or equal to 45 mm Hg, obtained while awake and breathing the client's routinely prescribed FIO2

7.2.2.4. Chronic increased work of breathing

7.2.2.4.1. Presence of tachypnea or retractions when patient is at rest and NOT with inter-current illness.

7.2.2.5. Documentation of significant sleep disordered breathing (as per CPAP criteria above) PLUS reduced respiratory muscle strength or severe pulmonary restriction:

7.2.2.5.1. Maximal inspiratory pressure or Maximal expiratory force less than 10 cm H20, or

7.2.2.5.2. Forced vital capacity less than 50% of predicted

7.2.2.5.3. More than 20% decrease in supine vital capacity compared to seated or standing vital capacity

7.2.2.6. Members with Severe Chronic Obstructive Pulmonary Disease (COPD) and documented sleep disordered breathing when the physician certifies that the desired therapeutic respiratory response was not achieved with the BIPAP device without a set backup rate.

7.3 Effective September 17, 2020: Heated humidification for PAP devices may be considered with documentation of medical necessity. Documentation submitted must support why heated humidification is medically necessary.

7.3.1 Clinical signs and symptoms that may indicate heated humidification is medically necessary include the following:

7.3.1.1. Dry, nonproductive cough

7.3.1.2. Increased airway resistance

7.3.1.3. Increased incidence of infection

7.3.1.4. Increased work of breathing

7.3.1.5. Complaint of substernal pain and airway dryness

7.3.1.6. Thick, dehydrated secretions

7.3.1.7. Receiving mechanical ventilatory support via tracheostomy

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

9. 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: Accessed May 11, 2020
http://www.tmhp.com/Manuals_PDF/TMPPM/TMPPM_Living_Manual_Current/2_Med_Specs_and_Phys_Srvs.pd

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
- Weese-Mayer DE, Berry-Kravis EM, Ceccherini I, et al An Official ATS Clinical Policy Statement: Congenital Central Hypoventilation Syndrome Am J Respir Crit Care Med 2010; 181: 626–644

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