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), Bi-level Positive Airway Pressure (BIPAP) devices and Back-Up Ventilator 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. A CPAP or BPAP device without a set backup rate may be considered for an initial three month rental period with prior authorization. Following the initial three month rental period, if the CPAP or RAD without a set backup rate is effective, the device may be considered for purchase. Both devices may also be considered for continued rental with renewal at six month intervals up to 12 months.
   - 3.1. A CPAP or BPAP 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.
     - 3.1.1. 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:
       - 3.1.1.1. The provider was in-network at the time of initial rental request
       - 3.1.1.2. The member received the requested services through a prior authorization from either another Managed Care Organization (MCO) or Fee for Service FFS) provider.
4. A RAD (BPAP) device with a set backup respiratory may be considered for an initial 3 month rental period with prior authorization and will be considered for rental only.
   - 4.1. Following a 3 month trial rental continued authorization will require documentation that:

4.1.1. The member's symptoms are improved with the usage of the device

4.1.2. The member is complaint with device usage

5. Humidification devices (heated or non-heated) for use with a CPAP or RAD device may be a benefit with prior authorization when medically necessary. Heated humidifiers (procedure code E0562) are used for members with bypassed upper airways, members receiving mechanical ventilatory support, and members with high flow positive airway pressure devices.

5.1. Documentation submitted must support why humidification is medically necessary for use with positive pressure ventilation.

5.1.1. Clinical signs and symptoms that may be an indication that heated humidification is medically necessary include (but are not limited to) the following:

5.1.1.1. Dry, nonproductive cough

5.1.1.2. Increased airway resistance

5.1.1.3. Increased incidence of infection

5.1.1.4. Increased work of breathing

5.1.1.5. Complaint of substernal pain and/or airway dryness

5.1.1.6. Thick, dehydrated secretions

5.1.1.7. History of recurrent epistaxis (nosebleeds)

5.1.1.8. History of deviated nasal septum

6. Initial Request for a **Continuous Positive Airway Pressure (CPAP) or auto-titrating CPAP System**

6.1 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:

6.1.1 For members who are 17 years of age and younger, polysomnography results documenting an apnea-hypopnea index (AHI) greater than one event per hour may be used to establish medical necessity.

6.1.2 For members who are 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

6.1.3 For members who are 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:

6.1.3.1 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

6.1.3.2 Symptoms of impaired cognition, mood disorders, or insomnia

6.1.3.3 Hypertension (systolic blood pressure greater than 140 mm Hg or diastolic blood pressure greater than 90 mm Hg)

6.1.3.4. Ischemic heart disease or previous myocardial infarction

6.1.3.5. History of stroke

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

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

6.1.3.8. Pulmonary hypertension

6.1.4. Observation during hospitalization 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.

6.1.5. Auto-titrating CPAP may be considered if the member meets medical necessity criteria for CPAP but an optimal level of CPAP was not determined.

6.2 To establish medical necessity for purchase or continued rental of a CPAP device – the following documentation must be provided:

6.2.1 The member'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.

6.2.2 The member's symptoms and/or findings of sleep disordered breathing, as documented by the treating physician, are improved with use of the CPAP.

6.2.2.1 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.

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

6.2.2.1.1.1 Down Syndrome

6.2.2.1.1.2. Achondroplasia

6.2.2.1.1.3. Severe obstructive sleep apnea

6.2.2.1.1.4. Psychiatric illness

6.2.2.1.1.5. Autism

7. Members with sleep disordered breathing may qualify for **a BPAP device WITHOUT a backup rate if:**

7.1.1. Member has a diagnosis of:

7.1.1.1. Obstructive sleep apnea (OSA) **AND** the member meets the criteria for CPAP **AND** CPAP failed to be effective in treating the member's OSA or is considered contraindicated due to the member's other medical conditions (such as severe neuromuscular disease or heart failure).

7.1.1.2. 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**

7.1.1.2.1. Significant respiratory insufficiency is documented by one of the following:

7.1.1.2.2. 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)

7.1.1.2.3. 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

7.1.1.2.4. TcCO2 value of 50 or more for ≥ 25% of the total sleep time

7.1.1.2.5. Maximal inspiratory pressure less than 60 cm H20

7.1.1.2.6. Forced vital capacity less than 50 percent of predicted volume

7.1.1. 3 Sleep study documents obstructive sleep apnea and CPAP is considered contraindicated due to the member's weakness and/or pulmonary restriction.

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

7.1.1.4.1. 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

7.1.1.4.2. 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)

7.1.1.4.3. Documentation of rationale for why CPAP alone would not be effective.

7.2. Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA)

7.2.1 Central Sleep Apnea (CSA) or Complex Sleep Apnea (CompSA) is characterized by the development of central apneas or central hypopneas during pressure titrations performed in a sleep lab titration study for CPAP or BPAP without a backup rate.

7.2.2 BPAP 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:

7.2.2.1. The member has a diagnosis of CSA or CompSA

7.2.2.2. The sleep study documents one of the following:

7.2.2.2.1. The sum total of central hypopneas plus central apneas is greater than 50 percent of the total apneas and hypopneas rate; **Or**

7.2.2.2.2. 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

7.2.2.5. Documentation ruling out CPAP as effective therapy if either OSA or CSA is a component of the initially observed sleep associated hypoventilation

7.3. Hypoventilation Syndrome

7.3.1. BPAP without a backup rate may be considered for treatment of hypoventilation syndrome with prior authorization when **ALL** of the following criteria are met:

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

7.3.1.2. Spirometry shows a forced expired volume in 1 sec (FEV1) or the forced vital capacity (FVC) greater than or equal to 70 percent

7.3.1.3. 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

7.3.1.4. TcCO2 or EtCO2 of 50 or more for ≥ 25% of the total sleep time.

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

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

9. Mechanical Ventilation

9.1. Invasive and noninvasive ventilators (procedure codes E0465, E0466, and E0467do not require prior authorization.

9.2. Back-Up Mechanical Ventilator

9.2.1. 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.

9.2.2. Requests for a back-up ventilator in the home must meet **both** the following criteria to be considered medically necessary:

9.2.2.1. The member cannot maintain spontaneous ventilations for four or more consecutive hours.

9.2.2.2. The member lives in an area where a replacement ventilator cannot be provided within two hours.

9.2.3. Prior authorization requests for a back-up ventilator must include **ALL** of the following documentation:

9.2.3.1. The amount of time the member is able to maintain spontaneous ventilation.

9.2.3.2. The distance and/or delivery time of a replacement ventilator to the member's home

9.2.4 All requests for a back-up ventilator in the home must be sent to a medical director for review.

10. 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.

11. 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 – April 2021: Durable Medical Equipment, Medical Supplies, and Nutritional Products Handbook. Accessed April 8, 2021 https://www.tmhp.com/sites/default/files/microsites/provider-manuals/tmppm/html/index.html#t=TMPPM%2F2_DME_and_Supplies%2F2_DME_and_Supplies.htm%23XREF_13012_Durable_Medical

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

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