GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Sleep disorders are some of the most common medical problems in the United States, and have a significant impact on quality of life, productivity, and health. There are many different types of sleep-related disorders including sleep apnea, upper airway resistance syndrome, insomnia, narcolepsy, nocturnal movement disorders (e.g., restless leg syndrome and periodic limb movement disorder), unexplained excessive daytime sleepiness, and arousal disorders (parasomnias).

Apnea is defined as a cessation of airflow for at least ten seconds. Hypopnea is defined as an abnormal respiratory event lasting at least ten seconds with at least a thirty percent reduction in thoracoabdominal movement or airflow as compared to baseline and with at least four percent oxygen desaturation. Respiratory effort-related arousals (RERAs) are a sequence of breaths that lasts at least ten seconds, characterized by increasing respiratory effort or flattening of the nasal pressure waveform and leads to an arousal from sleep, but does not meet the criteria of an apnea or hypopnea. The apnea hypopnea index (AHI) is the total number of apneas and hypopneas per hour of sleep. The respiratory disturbance index (RDI) is the total number of events (e.g., apneas, hypopneas and RERA’s) per hour of sleep.

Positive airway pressure (PAP) treatment is the most effective and widespread treatment of OSA. A flow generator delivers pressurized air into the nose and/or mouth, providing a pneumatic splint to the airway, preventing development of subatmospheric collapsing pressure. The flow generator is connected to the patient via connecting tubing and an interface attached to the patient’s face. PAP may be provided using continuous positive airway pressure (CPAP), auto-titrating PAP (APAP), or bi-level positive airway pressure (BPAP).

Continuous positive airway pressure (CPAP) is the most common treatment for sleep apnea in adults. During sleep, the patient wears a mask attached to an air compressor that forces air through the nasal passages, opening the back of the throat. In obstructive sleep apnea, tissues in the upper airway including the tongue, soft palate, and nasal passages sag and block the airway. The pressurized air in CPAP forces the tissues in the upper airway out of the way, allowing normal breathing to occur during sleep.

An auto-titrating continuous positive airway pressure (APAP or AutoPAP) device continuously modifies the positive pressure level during the night, allowing for a decrease in pressure when spells of apnea and hypopneas disappear and an increase in pressure level when they return. APAP devices deliver variable pressure according to the needs of the patient. The pressure required to maintain airway patency changes during a night of sleep depending on body position, sleep stage, nasal obstruction, and ingestion of alcohol or hypnotic agents.

A bilevel positive airway pressure (BiPAP) device blows air at a higher pressure for inhaling and a lower pressure for exhaling. This can be used for individuals who cannot tolerate the high constant pressure with CPAP. BiPAP is not considered a first-line treatment for OSA, but for those who require high levels of PAP, the lower pressure administered during expiration with BiPAP can make treatment easier to tolerate.

POLICY

<table>
<thead>
<tr>
<th>Continuous positive airway pressure (CPAP) devices (E0601) with or without a humidifier (E0561, E0562) do not require prior authorization.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto-titrating PAP (APAP) devices (E0601) with or without a humidifier (E0561, E0562) do not require prior authorization.</td>
</tr>
<tr>
<td>Bi-level positive airway pressure (BiPAP) devices (E0470, E0471, E0472) with or without a humidifier</td>
</tr>
</tbody>
</table>
HMO, PPO, Individual Marketplace, Elite, Advantage

Coverage for positive airway pressure (PAP) devices are subject to the terms, conditions and limitations of the applicable benefit plan’s Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for positive airway pressure (PAP) devices is available, the following conditions of coverage apply.

Continuous positive airway pressure (CPAP) (E0601) or auto-titrating PAP (APAP) (E0601) with or without a humidifier (E0651, E0652) for an initial 90 day period is considered medically necessary for the treatment of OSA in an adult (18 years or older) when EITHER of the following criteria is met:

- apnea/hypopnea index (AHI) or respiratory disturbance index (RDI) or respiratory event index (REI) ≥ 15 as documented by polysomnography (PSG) or home/portable sleep study
- AHI/RDI/REI ≥ 5 and < 15 as documented by PSG or home/portable sleep study, when accompanied by symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, mood disorders or insomnia) or when the individual has hypertension, ischemic heart disease or history of stroke

CPAP (E0601) or APAP (E0601) with or without a humidifier (E0651, E0652) for an initial 90 day period is considered medically necessary for the treatment of OSA in a child when ALL of the following criteria are met:

- OSA diagnosis established by PSG
- child weighs 30 kilograms (66 pounds) or more
- adenotonsillectomy has been unsuccessful or is contraindicated, or when definitive surgery is indicated but must await complete dental and facial development

Home titration using APAP to determine a fixed CPAP pressure for ongoing treatment is considered medically necessary when ALL of the following criteria are met:

- individual meets the criteria for PAP (detailed in PAP section above)
- individual does not have a comorbid condition that would be expected to degrade the accuracy of auto-titration, such as any of the following:
  - congestive heart failure NYHA Class III or IV (LVEF ≤ 45%)
  - moderate to severe pulmonary disease, such as chronic obstructive pulmonary disease (COPD), documented on pulmonary function studies (PFTs)
  - prior diagnosis of central sleep apnea
  - pulmonary hypertension
  - no evidence of nocturnal oxygen (O2) desaturation* caused by a condition other than OSA (e.g. obesity hypoventilation syndrome [defined as pCO2 > 45 mmHg and pO2 < 60 mmHg on arterial blood gas])

Follow-up home titration using APAP is considered medically necessary when ALL of the following criteria are met:

- no comorbid condition that would be expected to degrade the accuracy of auto-titration
- no evidence of nocturnal oxygen desaturation* caused by a condition other than OSA (as described below)
- procedure to be performed for ANY of the following:
  - to determine whether pressure adjustment is needed when clinical response is insufficient or symptoms return despite a good initial response to PAP
  - substantial weight loss (e.g., 10% of body weight) to determine if adjustment of PAP pressure is indicated
  - substantial weight gain (e.g., 10% of body weight) with return of symptoms despite continued use of CPAP, to determine if adjustment of PAP pressure is indicated

* Significant oxygen desaturation:

- O2 saturation < 80% for > 1% of sleep time or < 90% for > 30% of sleep time during prior diagnostic facility-based study or recording time during prior home sleep apnea test (HSAT)

Bi-level positive airway pressure (BIPAP) without a back-up respiratory rate (E0470), with or without a humidifier (E0651, E0652) for an initial 90 day period is considered medically necessary for the treatment of OSA for an individual with coexisting central hypoventilation or for an individual who requires, but proves intolerant to, high pressures of CPAP or APAP.

BIPAP with a back-up respiratory rate (E0471, E0472) for an initial 90 day period is considered medically necessary for the treatment of treatment-emergent central sleep apnea when ALL of the following criteria are met:
• diagnostic PSG shows five or more predominantly obstructive respiratory events (obstructive or mixed apneas, hypopneas or respiratory effort related arousals [RERAs]) per hour of sleep
• PSG during use of positive airway pressure without a backup rate shows significant resolution of obstructive events and emergence or persistence of central apnea or central hypopnea with all of the following:
  o central apneas and central hypopneas ≥ 5/hour
  o number of central apneas and central hypopneas >50% of total number of apneas and hypopneas.
• the central sleep apnea (CSA) is not better explained by another CSA disorder (e.g., CSA with Cheyne Stokes breathing or CSA due to a medication or substance)

A home trial of Auto Bi-level therapy (E0470) is considered medically necessary in an individual who is documented to have tried and failed CPAP or APAP.

Adaptive servoventilation (E0471, E0472) for an initial 90 day period is considered medically necessary for the treatment of treatment-emergent central sleep apnea when ALL of the following criteria are met:
• individual does not have symptomatic chronic heart failure (i.e., NYHA Class II-IV) and/or reduced left ventricular ejection fraction ≤ 45%, as determined by cardiac assessment conducted prior to initiation of treatment
• diagnostic PSG shows five or more predominantly obstructive respiratory events (obstructive or mixed apneas, hypopneas or respiratory effort related arousals [RERAs]) per hour of sleep
• PSG during use of positive airway pressure without a backup rate shows significant resolution of obstructive events and emergence or persistence of central apnea or central hypopnea with all of the following:
  o central apneas and central hypopneas ≥ 5/hour
  o number of central apneas and central hypopneas >50% of total number of apneas and hypopneas.
• the central sleep apnea (CSA) is not better explained by another CSA disorder (e.g., CSA with Cheyne Stokes breathing or CSA due to a medication or substance).

PAP Adherence
Continued Coverage Beyond the First Three Months (90 days) of Therapy

A medically necessary PAP device beyond the first three months of therapy when, no sooner than the 31st day but no later than the 91st day after initiating therapy, there is objective evidence documenting the member is adhering to PAP therapy.

Note: Objective evidence of adherence for use of the PAP device is defined as use of PAP ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage. (When calculating usage inpatient days are not used in the calculation.)

If the above criterion is not met, continued coverage of a PAP device and related accessories will be considered not medically necessary.

PAP device loaner rental for up to 30 days is considered medically necessary when BOTH of the following criteria are met:
• demonstrated compliant use of the device
• description of malfunction and documentation that equipment has been sent for repair/assessment

PAP treatment for any other indication is considered experimental, investigational or unproven.

Oral pressure therapy (e.g., Winx® Sleep Therapy System) is considered experimental, investigational or unproven.

ANY ONE of the following interfaces for use with PAP device is considered medically necessary:
• nasal mask (A7027)
• nasal pillows/prongs (A7034)
• full face mask (A7030)
• Oracle™ Oral Mask (Payne & Raykel Healthcare, Irvine, CA) (A7044)

A replacement of any of the above interfaces for use with PAP device is considered medically necessary at a frequency of no more often than every three months.

An interface consisting of a boil and bite mouthpiece connected to nasal inserts (e.g., CPAP PRO® [Stevenson Industries, Inc., Simi Valley, CA]) is considered experimental, investigational or unproven.
In general, duplicate equipment (e.g., travel PAP) is considered a convenience item and not medically necessary. Replacement of a medically necessary PAP device is considered medically necessary only when reasonable wear and tear renders the item nonfunctioning and not repairable and the item is no longer under warranty.

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODE</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>94660</td>
<td>Continuous positive airway pressure ventilation (CPAP), initiation and management</td>
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</table>

<table>
<thead>
<tr>
<th>HCPCS CODE</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4604</td>
<td>Tubing with integrated heating element for use with positive airway pressure device</td>
</tr>
<tr>
<td>A7027</td>
<td>Combination oral/nasal mask, used with continuous positive airway pressure device, each</td>
</tr>
<tr>
<td>A7028</td>
<td>Oral cushion for combination oral/nasal mask, replacement only, each</td>
</tr>
<tr>
<td>A7029</td>
<td>Nasal pillows for combination oral/nasal mask, replacement only, pair</td>
</tr>
<tr>
<td>A7030</td>
<td>Full face mask used with positive airway pressure device, each</td>
</tr>
<tr>
<td>A7031</td>
<td>Face mask interface, replacement for full face mask, each</td>
</tr>
<tr>
<td>A7032</td>
<td>Cushion for use on nasal mask interface, replacement only, each</td>
</tr>
<tr>
<td>A7033</td>
<td>Pillow for use on nasal cannula type interface, replacement only, pair</td>
</tr>
<tr>
<td>A7034</td>
<td>Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap</td>
</tr>
<tr>
<td>A7035</td>
<td>Headgear used with positive airway pressure device</td>
</tr>
<tr>
<td>A7036</td>
<td>Chinstrap used with positive airway pressure device</td>
</tr>
<tr>
<td>A7037</td>
<td>Tubing used with positive airway pressure device</td>
</tr>
<tr>
<td>A7038</td>
<td>Filter, disposable, used with positive airway pressure device</td>
</tr>
<tr>
<td>A7039</td>
<td>Filter, non-disposable, used with positive airway pressure device</td>
</tr>
<tr>
<td>A7044</td>
<td>Oral interface used with positive airway pressure device, each</td>
</tr>
<tr>
<td>A7045</td>
<td>Exhalation port with or without swivel used with accessories for positive airway devices, replacement only</td>
</tr>
<tr>
<td>A7046</td>
<td>Water chamber for humidifier, used with positive airway pressure device, replacement, each</td>
</tr>
<tr>
<td>E0470</td>
<td>Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)</td>
</tr>
<tr>
<td>E0471</td>
<td>Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, eg, nasal or facial mask (intermittent assist device with continuous positive airway pressure device)</td>
</tr>
<tr>
<td>E0472</td>
<td>Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, eg, tracheostomy tube (intermittent assist device with continuous positive airway pressure device)</td>
</tr>
<tr>
<td>E0561</td>
<td>Humidifier, non-heated, used with positive airway pressure device</td>
</tr>
<tr>
<td>E0562</td>
<td>Humidifier, heated, used with positive airway pressure device</td>
</tr>
<tr>
<td>E0601</td>
<td>Continuous airway pressure (CPAP) device</td>
</tr>
</tbody>
</table>

**REVISION HISTORY EXPLANATION**
01/01/11: No changes
04/10/18: Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.

**REFERENCES/RESOURCES**
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid [http://jfs.ohio.gov/](http://jfs.ohio.gov/)
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.