Positive Airway Pressure and Oral Devices for the Treatment of Obstructive Sleep Apnea

I. Description
Sleep-disordered breathing consists of several separate disorders, including obstructive sleep apnea (OSA), central sleep apnea (CSA), both with and without Cheyne-Stokes respiration, and sleep-related hypoventilation, in which abnormal breathing events during sleep are associated with adverse clinical outcomes. Obstructive sleep apnea (OSA), the most common sleep-related breathing disorder, is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The evaluation of OSA should be by clinical evaluation and overnight monitoring, either by attended polysomnography (PSG) or home sleep apnea testing (HSAT) under qualified supervision. OSA diagnosed by PSG or HSAT may be followed by a trial of auto-adjusting positive airway pressure (APAP). Early follow-up after initiation of therapy is recommended.

Medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of various types of positive airway pressure (PAP) devices. PAP devices include fixed continuous airway pressure (CPAP), CPAP devices that reduce pressure at the beginning of exhalation (CPAP with C-Flex), auto-adjusting CPAP (APAP), bi-level positive airway pressure (bi-level PAP) and adaptive servo-ventilation (ASV). Bi-level PAP, ASV, and APAP devices are also referred to as respiratory assist devices (RAD).

PAP therapy is the mainstay of therapy for adults with OSA. It involves the administration of air usually through the nose by an external device to maintain the patency of the upper airway. CPAP delivers a single, fixed pressure throughout the respiratory cycle. APAP adjusts the level of pressure as needed to maintain airway patency and then decreases the pressure if no abnormal respiratory events are detected within a set period of time. Bi-level PAP delivers a preset inspiratory positive airway pressure (IPAP) and expiratory positive airway pressure (EPAP). ASV uses a servocontroller that automatically adjust pressure by breath-to-breath analysis to maintain a steady minute ventilation. Oral appliances can be broadly categorized as mandibular advancing/positioning devices or tongue-retaining devices. Oral appliances can either be "off the shelf" or custom made for the patient by a dental laboratory or similar provider.

II. Policy Criteria
A. Continuous positive airway pressure (CPAP) and Auto-adjusting positive airway pressure (APAP) devices are covered (subject to Limitations and Administrative Guidelines) for an initial three month trial period for the treatment of obstructive sleep apnea (OSA) when the following criteria are met:
1. Assessment for medical conditions associated with sleep-disordered breathing;
2. Clinically significant OSA is documented by a sleep study performed by an appropriately accredited facility:
   a. For adults, a facility-based PSG demonstrates an Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) greater than or equal to 5 per hour; or HSAT demonstrates an Apnea Hypopnea Index (AHI) or Respiratory Event Index (REI) greater than or equal to 5 per hour and less than 30 per hour.
   b. For children (age less than 18 years old), a facility-based PSG demonstrates an Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) greater than or equal to 1 per hour.

Note: See Appendix for definitions of apnea, hypopnea, Apnea-Hypopnea Index (AHI), Respiratory Event Index (REI) and Respiratory Disturbance Index (RDI).

3. CPAP will not be covered unless PAP titration has been initiated (and in most cases completed).
   a. If PAP cannot be titrated during supervised polysomnography performed in a sleep laboratory, then either a repeat PSG or auto-adjusting CPAP will be covered, subject to the criteria in the HMSA Polysomnography and Sleep Studies policy.
   b. Auto-adjusting positive airway pressure (APAP) is also covered for PAP titration in the home setting when the diagnostic study demonstrates OSA and there are no contraindications to home titration, subject to the criteria in the HMSA Polysomnography and Sleep Studies policy.

B. Respiratory assist device (RAD) is covered (subject to Limitations and Administrative Guidelines) for the treatment of OSA when all of the following criteria are met:
   1. Criteria for CPAP device (II.A.1-3) are met; and
   2. CPAP device has been tried and proven ineffective or not tolerated based on a therapeutic trial conducted in either a facility or home setting. Ineffective is defined as documented failure to meet therapeutic goals using a CPAP device during the titration portion of a facility-based study or during home use despite optimal therapy, i.e., proper mask selection and fitting and appropriate pressure settings.

C. The use of CPAP or RAD beyond the first three months of therapy is covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:
   1. Face-to-face clinical reevaluation by the treating physician has been performed between the 31st and 91st day of use and improvement in symptoms has been documented in the medical record (note: a supplier-generated form is not sufficient); and
   2. Direct download of data from the device has been performed and adherence has been documented in the medical record by physician and/or kept on file by supplier. Compliance data should be collected on a monthly basis during the initial three months of PAP therapy, until adequate adherence to PAP therapy is established. If the member’s adherence is less than 70% during any 30-day period, the supplier and treating physician are expected to address the issues limiting adherence, with the intention of achieving adherence of greater than 70% by the end of the third month. Adherence to therapy is defined as use of PAP device greater than or equal to four hours per night on 70% of nights during a consecutive thirty day period anytime during the first three months of initial usage; or
   3. Direct download of data from the device has been performed and adherence during the third month of usage has been documented in the medical record by the physician and/or kept on file by the supplier. Adherence is defined as use of PAP device greater
than or equal to four hours per night on 70% of nights during a thirty day consecutive period during the third month of usage.

D. Patients who do not qualify for continuation of PAP device beyond the first three months of therapy are eligible for a one month trial extension for a PAP device, but must have a face-to-face clinical reevaluation by the treating clinician. The evaluation should include the following:

1. Determination of the etiology of the failure to respond or adhere to PAP therapy;
2. Patient education regarding the proper use of the equipment and benefits of PAP therapy; and
3. A prompt and intensive effort to improve PAP use (e.g., re-fitting of mask).
4. Within the 1 month extension, evidence of compliance must be documented and submitted for approval of continuing use.

E. Custom-fitted or custom-fabricated oral appliances, including tongue retaining or mandibular advancing/positioning devices, are covered (subject to Limitations and Administrative Guidelines) for the treatment of OSA when the following criteria are met:

1. Criteria for PAP device are met (II.A-B);
2. Patient has mild to moderate OSA (AHI/REI/RDI > 5 or < 30) and PAP device has been declined or not tolerated; or in patients with severe OSA (AHI/REI/RDI > 30) PAP device is not tolerated.
3. The device is prescribed by the treating physician following review of the sleep test.
4. The device is provided and billed for by a licensed dentist (DDS or DMD);

F. Accessories used with a PAP device are covered when coverage criteria for the PAP device are met.

G. A non-heated or heated humidifier is covered when ordered by the treating physician for use with a covered PAP device.

III. Limitations

A. A PAP device is covered only as a capped rental item.

B. Accessories and humidifiers used with a PAP device are not covered when coverage criteria for the PAP device are not met.

C. If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

D. A RAD with back-up rate (E0471) is not covered for a primary diagnosis of OSA, unless the prescribed inspiratory pressure exceeds the capability of RADs without back-up (generally an inspiratory pressure greater than 25 cm H2O).

E. If a PAP device reaches its five-year life expectancy but is in good working order and meets the patient’s medical needs, a replacement device will not be covered.

F. The use of home oxygen therapy as the sole treatment of OSA (i.e., in the absence of positive airway pressure) is not covered as it is not the most appropriate level of service.

G. An oral interface used with respiratory suction pump (HCPCS code A7047) is not covered as it is not known to be effective in improving health outcomes.

IV. Administrative Guidelines

A. Precertification is required for initial and continued use of RAD (Bi-level PAP).

1. For initial use, the following documentation from the medical record must be submitted:
   a. Face-to-face clinical evaluation by the treating physician prior to the sleep test to assess the patient for a sleep related breathing disorder;
   b. Polysomnogram results supporting diagnosis of OSA; and
c. Results from the therapeutic portion of the study showing the PAP titration results; and

d. Documentation supporting that a CPAP device has been tried and proven ineffective or not tolerated based on a therapeutic trial conducted in either a facility or home setting. If the trial was conducted in a home setting, a face-to-face clinical evaluation by the treating physician documenting ineffectiveness of or intolerance to CPAP device must be submitted.

2. For continued use, documentation supporting adherence to therapy must be submitted.

B. Precertification is required for oral appliances. The following documentation from the medical record must be submitted with all requests for oral appliances:
   1. Polysomnogram results supporting diagnosis of OSA;
   2. Product name, manufacturer/distributor and model of device; and
   3. For mild to moderate OSA, documentation supporting that a PAP device has been offered and declined by the patient or a PAP device has been tried and not tolerated; or
   4. For severe OSA, documentation supporting that a RAD device has been tried and not tolerated.

C. Precertification is not required for HMO and PPO members for initial and continued use of CPAP for the treatment of OSA when all criteria are met. Documentation supporting medical necessity should be legible, maintained in the patient's medical record, and made available to HMSA upon request. HMSA reserves the right to perform retrospective review using the above criteria to validate if services rendered met payment determination criteria.

D. Precertification is not required for PAP replacement when IV.H. (below) is met.

E. Precertification is required for QUEST Integration members for initial and continued use of PAP. See criteria II.A.1. and II.A.2.a. & 2b. above for documentation that must be submitted.

F. Polysomnogram and home/portable studies should be performed in accordance with HMSA Polysomnography-Sleep Studies policy criteria.

G. This policy only applies to the use of RAD for the treatment of OSA. For other diagnoses (including central and complex sleep apnea), refer to Medicare LCD for Respiratory Assist Devices.

H. In general, Medicare criteria for repairs and replacement apply (see Noridian/Medicare DME Supplier Manual Chapter 5) Durable Medical Equipment, Prosthetics, Orthotics, and Supplies. The following documentation must be submitted with all repair and replacement requests:
   1. Date that the previous PAP device was provided;
   2. Name of manufacturer, model number and serial number;
   3. If the device is over five years old, documentation from the supplier’s technician stating the device has been evaluated and is malfunctioning.
   4. If the device is less than five years old, documentation from the supplier stating one of the following:
      a. The device has been evaluated by the manufacturer and cannot be repaired; or
      b. The device has been evaluated by the supplier’s technician and is malfunctioning and the device is discontinued/obsolete and is no longer being repaired or parts are no longer available.

I. A repeat sleep study is not necessary for replacement of a PAP device. Medical record documentation must support that the patient continues to use PAP device.

J. HCPCS code E0601 should be used for a CPAP device with C-flex and autotitration features.

K. CPT code 94660 (CPAP initiation and management) and HCPCS code A9279 (monitoring feature/device, stand-alone or integrated, any type) are not separately payable to suppliers as the reimbursement for these items is included in the reimbursement for the PAP device.
L. PAP device suppliers must provide each patient and/or their caregiver with instruction in the proper use and care of the patient’s PAP device and accessories.

M. All suppliers must maintain records on each patient’s PAP device compliance and must cease billing for all devices and related accessories and supplies as soon as a patient discontinues use of the PAP device.

N. Suppliers must contact the patient before dispensing any refills to the original order and may not automatically ship refills on a predetermined basis, even if authorized by the patient or treating physician. Suppliers must confirm that the refilled item continues to be necessary, existing supplies are approaching exhaustion, and the order is up to date. Suppliers must not deliver refills without a valid, documented refill request. Proof of delivery documentation must be maintained for every item.

### Codes that require precertification:

<table>
<thead>
<tr>
<th>HCPCS codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0470</td>
<td>Respiratory assist device, bi-level pressure capability, without backup 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 backup 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>E0601</td>
<td>Continuous positive airway pressure (CPAP) device for QUEST</td>
</tr>
<tr>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment</td>
</tr>
<tr>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment</td>
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</tbody>
</table>

### Codes that do not require precertification, but are related to this service:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<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>
</tbody>
</table>
A7035 | Headgear used with positive airway pressure device
A7036 | Chinstrap used with positive airway pressure device
A7037 | Tubing used with positive airway pressure device
A7038 | Filter, disposable, used with positive airway pressure device
A7039 | Filter, non-disposable, used with positive airway pressure device
A7044 | Oral interface used with positive airway pressure device, each
A7045 | Exhalation port with or without swivel used with accessories for positive airway devices, replacement only
A7046 | Water chamber for humidifier, used with positive airway pressure device, replacement, each
E0561 | Humidifier, non-heated, used with positive airway pressure device
E0562 | Humidifier, heated, used with positive airway pressure device

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References


VII. Appendix

Definitions

A. Apnea is defined as the cessation of airflow for at least 10 seconds.

B. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

C. Respiratory event related arousal (RERA) is defined as a series of respiratory cycles of increasing/decreasing effort or flattening, recorded by nasal manometry and leading to an arousal that cannot be defined as apnea or hypopnea, with a duration greater than or equal to 10 seconds.

D. The Apnea-Hypopnea Index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep. The Respiratory Disturbance Index (RDI) is defined as the average number of episodes of apneas, hypopneas, and respiratory event related arousals per hour of sleep. The Respiratory Event Index (REI) is defined as the average number of episodes of apnea and hypopnea per hour of monitoring; this represents the frequency of apneas and hypopneas derived from HSAT.

Note: If the AHI or RDI is calculated based on less than 2 hours of sleep, the total number of recorded events used to calculate the AHI or RDI must be at least the number of events that would have been required in a 2 hours period (i.e., must reach greater than or equal to 10 events).