I. Description
Obstructive sleep apnea syndrome (OSA) is characterized by repetitive episodes of upper airway obstruction due to the collapse and obstruction of the upper airway during sleep. The standard diagnostic test for OSA is an attended polysomnogram performed in an accredited sleep laboratory.

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

CPAP involves the administration of air usually through the nose by an external device at a fixed pressure to maintain the patency of the upper airway. APAP adjusts the level of pressure based on the level of resistance, and thus administers a lower mean level of positive pressure during the night. Bi-level PAP is similar to CPAP, but these devices are capable of generating two adjustable pressure levels. It has been hypothesized that both APAP and bi-level PAP are more comfortable for the patient, and thus might improve patient compliance or acceptance. 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. Criteria/Guidelines
A. Continuous positive airway pressure (CPAP) device is covered (subject to Limitations and Administrative Guidelines) for the treatment of obstructive sleep apnea (OSA) when the following criteria are met:

1. The patient has a face-to-face clinical evaluation by the treating physician prior to the sleep test to assess for sleep related breathing disorder. The evaluation should include the following:
   a. Signs and symptoms of sleep disordered breathing, e.g., habitual and disruptive snoring, observed apneas, choking or gasping, excessive daytime sleepiness;
b. Duration of symptoms;
c. Comorbid conditions, e.g., hypertension, ischemic heart disease, stroke;

2. Clinically significant OSA is documented by a polysomnogram performed by an appropriately accredited facility that demonstrates either of the following:
   a. The Apnea-Hypopnea Index (AHI) is greater than or equal to 15 events per hour with; or,
   b. The AHI greater than or equal to five and less than 15 events per hour and documentation of any of the following:
      i. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
      ii. Hypertension, ischemic heart disease, or history of stroke.

Note:
- See appendix A (Section V) for definitions of apnea, hypopnea and apnea-hypopnea index (AHI).
- If the AHI is calculated based on less than 2 hours of sleep, the total number of recorded events used to calculate the AHI 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 30 events without symptoms or greater than or equal to 10 events with symptoms.

3. PAP titration has been initiated (and in most cases completed).

B. Respiratory assist device (RAD) is covered (subject to Limitations and Administrative Guidelines) for the treatment of OSA when both the following criteria are met:
1. Criteria for CPAP device (II.A.1 to 3) are met.
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. 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. 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.
2. Patient has mild to moderate OSA (i.e., AHI greater than or equal to five and less than or equal to 30) and PAP device has been offered and patient declines treatment or PAP device has been tried and could not be tolerated; or
3. Patient has severe OSA (i.e., AHI greater than 30) and RAD (bi-level PAP device) has been tried and could not be tolerated.
4. The device is prescribed by the treating physician following review of the sleep test.
5. The device is provided and billed for by a licensed dentist (DDS or DMD).

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

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

III. Limitations

A. Polysomnogram should be performed in accordance with HMSA Polysomnography-Sleep Studies policy criteria.

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

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

D. 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.

E. 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.

F. 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. Respiratory Assist Devices

G. A RAD with back-up rate (E0471) is for a primary diagnosis of OSA, except when the prescribed inspiratory pressure exceeds the capability of RADs without back-up (generally an inspiratory pressure greater than 25 cm H2O).

H. 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.

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. 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.

K. A7047 (Oral interface used with respiratory suction pump) 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 sleep related breathing disorder.
      b. Polysomnogram results supporting diagnosis of OSA and PAP titration. Therapeutic portion
         of the study showing results of titration of PAP must be submitted.
      c. Documentation supporting that 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 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:
   1. Polysomnogram results supporting diagnosis of OSA.
   2. For mild to moderate OSA, documentation supporting that PAP device has been offered and
      declined by patient or PAP device has been tried and not tolerated; or
   3. For severe OSA, documentation supporting that RAD device has been tried and not tolerated.
   4. Product name, manufacturer/distributor and model of device.

C. Precertification is not required for HMO and PPO members for initial and continued use of
   CPAP for the treatment of OSA when 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 required for QUEST members for initial and continued use of PAP and related
   accessories. See A.1.a and b and 2 above for documentation that must be submitted.

E. 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:
   1. Date that the previous PAP device was provided.
   2. If the device is over five years old, documentation from the supplier’s technician stating
      the problem with the device and that the device cannot be repaired.
   3. If the device is less than five years old, documentation from the manufacturer stating one of the following:
      a. The device has been evaluated and cannot be repaired, or
      b. The device is discontinued/obsolete and is no longer being repaired or parts are no longer available
   4. Name of manufacturer, model number and serial number

F. For CPAP with C-flex and auto-titrating CPAP, code E0601 should be used.
G. The patient and/or their caregiver have received or will receive instruction from the supplier of the PAP device and accessories in the proper use and care of the equipment.
H. For PAP device accessories that are supplied as refills to the original order, suppliers must contact the patient prior to dispensing the refill and not automatically ship on a predetermined basis, even if authorized by the patient or treating physician. This should be done to ensure that the refilled item continues to be necessary, existing supplies are approaching exhaustion, and to confirm any changes to the order. Suppliers must not deliver refills without a valid, documented refill request. Proof of delivery documentation must be maintained for every item.

<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, 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 airway pressure (CPAP) device</td>
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<tr>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment</td>
</tr>
<tr>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment</td>
</tr>
</tbody>
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V. Appendix
A. Definitions
1. Apnea is defined as the cessation of airflow for at least 10 seconds.
2. 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.
3. The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI.

Note: If the AHI is calculated based on less than 2 hours of sleep, the total number of recorded events used to calculate the AHI 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 30 events without symptoms or greater than or equal to 10 events with symptoms.

VI. 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.

VII. References