

# Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Suppliers are to follow The Health Plan requirements for precertification as applicable.

PAP devices require precertification and a physician face-to-face. Approved Medicare certified providers must perform all testing, across all plan designs.

Home-based sleep studies (HST) described in this policy require precertification.

<b>National Coverage Determination Policy</b>	CMS Publication 100-3 Medicare National Coverage Determinations Manual, Chapter 1, Section 240.4
<b>Local Coverage Determination Policy</b>	J-B/C
<b>Effective Date</b>	For service performed on or after 10/31/13
<b>Revision/Review Date</b>	01/19, 10/18, 06/06/18, 07/26/17, 07/01/16, 01/01/15, 09/16/14
<b>The Health Plan</b>	Will follow Jurisdiction J-B/C Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents

## DESCRIPTION

Positive airway pressure is a technique of assisting breathing by maintaining the air pressure in the lungs and air passages, constant and above atmospheric pressure throughout the breathing cycle.

**COVERAGE GUIDELINES**

The term positive airway pressure (PAP) device will refer to both single-level continuous PAP devices (E0601) and a bi-level respiratory assisted device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea. Must be a Type I or Type II sleep study (See Medicare Definitions).

- I. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) when all the criteria below are met.:
  - a. The treating physician and the required face-to-face evaluation have assessed the member for obstructive sleep apnea.
  - b. The member has a Medicare-covered sleep test that meets either of the following criteria,
    1. The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
    2. The AHI or RDI is greater than or equal to 5 and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
      - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
      - b. Hypertension, ischemic heart disease, or history of stroke.
      - c. The member and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.
- II. An E0470 device is covered for those members with OSA who meet the criteria above, in addition to the following:
  - d. An E0601 has been tried and there is documentation showing that the member has failed to meet the therapeutic goals using an E0601 during the titration portion of the study or during home use despite optimal interventions. A new face-to-face or sleep study is not required in this circumstance.

A two-month trial period will be authorized if criteria is met.

**Coverage for Positive Airway Pressure (E0601) for a child (17 years or younger) will be covered in the following circumstances:**

1. OSA diagnosis established by PSG.
2. Child weighs 30 kilograms (66 pounds) or more
3. Adenotonsillectomy was unsuccessful or is contraindicated- the provider is to support with clinical documentation.
4. Definitive surgery is indicated but must await complete dental or facial development- the provider is to support this with clinical documentation.

A two-month trial period will be authorized if criteria is met.

Coverage guidelines for E0470 and E0471 for diagnoses other than OSA can be found in the respiratory assist devices policy. Providers can also find that information at the National Government Services or

CGS website. The links are listed at end of this document. Providers can also refer to Medicare's National Coverage Determination Manual and West Virginia Medicaid Provider Manual.

### **CONTINUED COVERAGE BEYOND THE FIRST TWO MONTHS OF THERAPY**

**Note:** Medicare has a three month trial period, but The Health Plan is asking for a compliance report within two months to ensure proper monitoring by the provider and proper use of device by the member, and to correct any issues the member may have with device sooner than three months. Examples include the proper fitting of masks and pressure setting. The Health Plan does not require the clinical physician piece submitted to extend rental of CPAP or RAD, however, it is recommended that the member follow-up with his/her physician within the time frame Medicare requires to ensure proper physician monitoring. The Health Plan may request that physician assessment under certain situations.

In the event that a member is having trouble with the CPAP or RAD and requires changing the device or extending trial period, the following criteria would apply:

1. Face-to-face clinical re-evaluation by the treating physician with documentation of the problems and recommended interventions, or
2. Information from provider on the changes in mask, fit and education provided to the member.

The Health Plan would authorize an additional month and request a follow up compliance report and physician evaluation demonstrating member is benefiting from therapy. This would meet the three-month trial period allowed by Medicare.

### **Continued Therapy after the Trial Period**

The following Medicare criterion applies across all product lines:

1. The provider must show the member's adherence to therapy to complete capitation of device.

**Note:** Adherence to therapy is defined as use of PAP  $\geq$  4 hours per night on 70 percent of nights during a consecutive 30-day period anytime during the first 3 months of initial usage.

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not meeting coverage guidelines.

Members who fail the trial period can re qualify for a PAP device but must have both:

1. Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and
2. Repeat sleep test in a facility-based setting (Type 1 study).

In some situations, The Health Plan may authorize an additional month on a case-by-case basis past the initial trial period. In order to capitate the device, the provider must submit an updated compliance download and a physician evaluation with request for extension.

If the member is still having compliance issues, and after the extension, the compliance report shows that the member remains noncompliant, the PAP will be denied.

The provider is to notify The Health Plan if the PAP device is discontinued.

### **Changing from CPAP to a Bi-level Device**

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not change the length of the trial period. If an E0601 device has been used for more than three months and the patient is switched to an E0470, a new face-to-face with the physician or physician extender is required, but a new sleep test is not required. A new three-month trial would begin for use of the E0470.

A new capped rental period will begin when the physician orders the member to switch from a CPAP device to a bi-level device and the coverage criteria for the bi-level device are met. Suppliers must notify The Health Plan for a new precertification and reason for the change. The appropriate modifier on the claim for that initial month should be RPKH modifier. This indicates a new capped rental period has begun.

Providers must pre-certify a change in PAP devices, the reason for a change and must document what issues were addressed prior to the change. Must include information as to:

1. Equipment fit and comfort and that the interface has been determined and is being used without difficulties. The interface will be used with the E0740.
2. What pressure settings were tried and failed with E0601.

If the coverage guidelines are met, an additional month rental will be authorized and a new compliance report will be required to complete capitation of the E0740.

### **Changing from Bi-level to CPAP**

If the member switches from a bi-level device to a CPAP device, during the capped rental period, a new capped rental period will not begin. The previous capped rental period for the bi-level device will resume where it left off prior to the change in equipment. Provider should append the RR modifier and the appropriate monthly modifier (KI or KJ) to the claim.

### **CONCURRENT PAP AND OXYGEN**

Members must meet both policies for oxygen and PAP. See oxygen policy for further information. An overnight pulse oximetry study alone would not qualify for oxygen with a diagnosis of OSA.

Please refer to the following link for complete information.

[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ContrId=140&ver=8&ContrVer=2&CntrctrSelected=140\\*2&Cntrctr=140&name=CGS+Administrators%2c+LLC+\(18003%2c+DME+MAC\)&DocType=Active&LCntrctr=140\\*2&bc=AgACAAQAAAAAA%3d%3d&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718&ContrId=140&ver=8&ContrVer=2&CntrctrSelected=140*2&Cntrctr=140&name=CGS+Administrators%2c+LLC+(18003%2c+DME+MAC)&DocType=Active&LCntrctr=140*2&bc=AgACAAQAAAAAA%3d%3d&)

### **NEW MEMBERS**

For new members who received a PAP device prior to enrollment and are seeking either ongoing coverage of rental of the device, or a replacement PAP device and/or accessories, both of the following coverage requirements must be met:

1. The qualifying sleep test. There must be documentation that the member meets the coverage criteria for the device at the time of request; and

2. Clinical evaluation. A current face-to-face evaluation by their treating physician who documents in the member's medical record that.
  - a. The member has a diagnosis of obstructive sleep apnea; and,
  - b. The member is continuing to use the device.

If the device is past the three month trial period, but purchase price has not been met, The Health Plan reserves the right to request the compliance report.

If the machine is still within The Health Plan's capped rental period when a member enters The Health Plan, The Health Plan will reimburse for the remainder of the contracted rental period.

Providers are reminded that if a PAP device is not received under The Health Plan insurance, an initial precertification is required for accessories.

### NONCOVERAGE STATEMENT

A bi-level positive airway pressure device with back-up rate (E0471) is not medically necessary if the primary diagnosis is OSA. If E0471 is billed and primary diagnosis is OSA, it will be denied as not meeting coverage guidelines.

The **ApniCure, Inc. Winx® Sleep Therapy System** is not covered, as Medicare does not provide reimbursement for a suction device provided for obstructive sleep apnea. See suction pump policy.

A liner is a device which is placed between the patient's skin and the PAP mask interface. Liners used with a PAP mask are made of cloth, silicone, or other materials. A liner used in conjunction with a PAP mask is considered a comfort/convenience item. HCPCS code **A9270**.

Ventilators described by codes E0450, E0460-E0464 are not covered when used for conditions described in this policy. **Please refer to The Health Plan's Ventilator policy for coverage guidelines.**

Integrated or modular monitoring devices are not separately payable. **HCPCS code A9279.**

**The STUD (Sleep Therapy under Disk Decompression), coded A44XX,** is not covered.

### REPAIR, REPLACEMENT AND REASONABLE USEFUL LIFEIME

The Health Plan will follow Medicare's five year reasonable useful lifetime (RUL) rule, therefore a PAP or RAD will not be replaced within the five year RUL for normal wear and tear issues. The Health Plan will only cover the cost of repairs up to, but not exceeding cost of a replacement, in accordance with Medicare guidelines.

The Health Plan will replace a PAP device within the 5 year RUL if it meets under lost, stolen, broken d/t, natural disaster, or bankruptcy criteria.

If a PAP device is replaced during the five year RUL because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a PAP device is replaced following the five year RUL, there must be a face-to-face evaluation by the treating physician that documents that the member continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

A precertification would be required in all the situations indicated above.

CPAP repairs require precertification and will be reviewed on a case-by-case basis. Manufacturer’s invoices are required for reimbursement of parts.

**CODING INFORMATION**

**CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.**

**HCPCS MODIFIERS**

<b>EY</b>	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
<b>GA</b>	WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, INDIVIDUAL CASE.
<b>GZ</b>	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE AND NECESSARY
<b>KX</b>	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET

**HCPCS CODES  
EQUIPMENT**

<b>E0470</b>	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)
<b>E0471</b>	RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITH BACK-UP RATE FEATURE, USED WITH NONINVASIVE INTERFACE, E.G., NASAL OR FACIAL MASK (INTERMITTENT ASSIST DEVICE WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE)
<b>E0601</b>	CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP) DEVICE

**HCPCS CODES  
ACCESSORIES**

<b>A44XX</b>	BELT, STRAP, SLEEVE, GARMENT, OR COVERING, ANY TYPE. New code for the STUD(Sleep Therapy Under Disk Decompression) device
<b>A4604</b>	TUBING WITH INTEGRATED HEATING ELEMENT FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>A7027</b>	COMBINATION ORAL/NASAL MASK, USED WITH CONTINUOUS POSITIVE AIRWAY PRESSURE DEVICE, EACH

<b>A7028</b>	ORAL CUSHION FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, EACH
<b>A7029</b>	NASAL PILLOWS FOR COMBINATION ORAL/NASAL MASK, REPLACEMENT ONLY, PAIR
<b>A7030</b>	FULL FACE MASK USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH
<b>A7031</b>	FACE MASK INTERFACE, REPLACEMENT FOR FULL FACE MASK, EACH
<b>A7032</b>	CUSHION FOR USE ON NASAL MASK INTERFACE, REPLACEMENT ONLY, EACH
<b>A7033</b>	PILLOW FOR USE ON NASAL CANNULA TYPE INTERFACE, REPLACEMENT ONLY, PAIR
<b>A7034</b>	NASAL INTERFACE (MASK OR CANNULA TYPE) USED WITH POSITIVE AIRWAY PRESSURE DEVICE, WITH OR WITHOUT HEAD STRAP
<b>A7035</b>	HEADGEAR USED WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>A7036</b>	CHINSTRAP USED WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>A7037</b>	TUBING USED WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>A7038</b>	FILTER, DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>A7039</b>	FILTER, NON DISPOSABLE, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>A7044</b>	ORAL INTERFACE USED WITH POSITIVE AIRWAY PRESSURE DEVICE, EACH
<b>A7045</b>	EXHALATION PORT WITH OR WITHOUT SWIVEL USED WITH ACCESSORIES FOR POSITIVE AIRWAY DEVICES, REPLACEMENT ONLY
<b>A7046</b>	WATER CHAMBER FOR HUMIDIFIER, USED WITH POSITIVE AIRWAY PRESSURE DEVICE, REPLACEMENT, EACH
<b>A9270</b>	NON-COVERED ITEM OR SERVICE
<b>A9279</b>	MONITORING FEATURE/DEVICE, STAND ALONE OR ALL INTEGRATED, ANY TYPE, INCLUDES ALL ACCESSORIES, COMPONENTS AND ELECTRONICS, NOT OTHERWISE CLASSIFIED
<b>E0561</b>	HUMIDIFIER, NON-HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE
<b>E0562</b>	HUMIDIFIER, HEATED, USED WITH POSITIVE AIRWAY PRESSURE DEVICE

The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage.

**ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY**

<b>G47.33</b>	OBSTRUCTIVE SLEEP APNEA (ADULT) (PEDIATRIC).
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Diagnosis and ICD-10 that either support or do not support medical necessity are indicated above.

**DOCUMENTATION REQUIREMENTS**

For the purposes of this policy, it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records,

hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports.

This documentation must be available with precertification.

Medicare has made changes to its requirements for dispensing orders, detailed written orders, and proof of delivery. The Health Plan will require the following:

1. Physician detailed written order. Order must include the following:
  - a. Member's name
  - b. Date
  - c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required
  - d. Order must include diagnosis code
  - e. Physician signature with date. Date stamps are not appropriate
  - f. Quantity of items required and duration: A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.

Physicians shall document the face-to-face clinical evaluations and re-evaluations in a detailed narrative note in their charts in the format that they use for other entries. For the initial evaluation, the report would commonly document pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

#### History

- Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches;
- Duration of symptoms
- Validated sleep hygiene inventory such as the Epworth Sleepiness Scale  
(See *appendices*)

Providers can review a copy of the Epworth Sleepiness Scale on the National Government Services website by clicking the link below: <http://ngsmedicare.com>

#### Physical Exam

- Focused cardiopulmonary and upper airway system evaluation
- Neck circumference
- Body mass index (BMI)

For members changing from an E0601 to E0470 due to ineffective therapy while on E0601 (either during a facility-based titration or in the home setting), the treating physician must document:

- Multiple interface options have been tried and the current interface is most comfortable to the member and will be used with the E0470; and,
- The pressure settings of the E0601 fail to adequately control the symptoms of OSA, improve sleep quality, or reduce the AHI/RDI to acceptable levels.

**Note:** If templates or forms are submitted, (e.g. a Medicare Certificate of Medical Necessity, and/or a provider created form), and all of the required information is not included, The Health Plan reserves the right to request the medical record, that may include, but not limited to, the physician office notes, hospital and nursing facility records, home health records.

**Note:** Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician. Some providers have created forms which have not been approved by CMS which they end to physicians and ask them to complete. Even if the physician completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record as noted above.

Documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating physician and included in the member's medical record. This information is to be submitted with precertification after the trial period.

Providers of the positive airway pressure device are responsible to help educate physicians on the type of information that is required to document a patient's need for PAP therapy.

#### **PAP DEVICES PROVIDED TO A MEMBER WHILE IN A PART A FACILITY STAY**

Reimbursement for a PAP device provided to a member while the member is covered in a Part A facility (hospital, LTAC, or SNF) is based on specific contract information with the individual facility. PAP therapy is usually included in the reimbursement for Part A facilities.

#### **EQUIPMENT RETAINED FROM A PRIOR PAYOR:**

The Health Plan will not pay in excess of the contracted purchase price for any item in this policy. If the provider is seeking payment from The Health Plan, the item must be precerted and The Health Plan will pay the remaining rental months up to purchase price- if member meets guidelines above.

#### **BILLING GUIDELINES**

##### **ACCESSORIES**

**The Health Plan is following the Medicare allowable for accessories across all plan designs, except for MHT, where The Health Plan will follow West Virginia Medicaid's allowable limits where applicable.**

Accessories used with a PAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be denied.

The following table represents the usual maximum amount of accessories expected to be medically necessary:

accessory	maximum amount		accessory	maximum amount
A4604	1 per 3 months		A7034	1 per 3 months
A7027	1 per 3 months		A7035	1 per 6 months
A7028	2 per 1 month		A7036	1 per 6 months
A7029	2 per 1 month		A7037	1 per 3 month
A7030	1 per 3 months		A7038	2 per 1 month
A7031	1 per 1 month		A7039	1 per 6 months
A7032	2 per 1 month		A7046	1 per 6 months
A7033	2 per 1 month			

Quantities of supplies greater than those described in the policy, as the usual maximum amounts, will be denied unless there is supportive clinical documentation explaining the medical need for the excess supplies.

A supplier must not dispense more than a three- month quantity of PAP accessories at a time.

For auto-titrating single-level CPAP devices, use HCPCS code E0601.

Liners are not interfaces for use with a PAP mask. They should be billed A9270 (noncovered item or service). They should not be billed as replacement features of a PAP mask such as A7031 (face mask interface, replacement for full-face mask, each) or A7032 (cushion for use on nasal mask interface, replacement only, each). There is no additional payment for liners used with a PAP mask.

**DISPENSING SUPPLIES**

A member or their caregiver must specifically request refills of PAP accessories before they are dispensed. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the member has "authorized" this in advance. The Health Plan is following Medicare guidelines for supplies provided on a reoccurring basis.

Providers are required to contact members prior to dispensing supplies and or medications and not automatically ship supplies. Contact with member must not take place prior to 14 calendar days of delivery and delivery is to be no sooner than 10 calendar days of end of usage. (Refer to CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.5.6 for more information.)

**Note to The Health Plan providers:** Shipment of supplies in greater quantity that what is being used by member will not be reimbursed.

Either a non -heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating physician for use with a covered PAP (E0470 or E0601) device.

Accessories are separately reimbursable at the time of initial issue and when replaced.

Providers are reminded to follow appropriate practice standards when refilling accessories.

For Medicare member's, providers can refer to [ngsmedicare.com](https://ngsmedicare.com) and/ or [cgsmedicare.com](https://cgsmedicare.com) sites for listing of the appropriate documentation expected to be kept on file by provider. Providers can also refer to Medicare's National Coverage Determination Manual and West Virginia Medicaid Provider Manual.

### **KX, GA, and GZ MODIFIERS**

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If the coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim reimbursement is based on contract and timely filing policies of The Health Plan.

### **ADVANCED BENEFICIARY NOTICE**

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

**NOTE:** Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be done prior to the dispensing of the device. The provider must submit the waiver or ABN to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

### **PRICING, DATA ANALYSIS, AND CODING (PDAC)**

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Suppliers should contact the PDAC contractor for guidance on the correct coding of these items. [dmepdac.com/](https://dmepdac.com/)

### **MEDICARE DEFINITIONS AND DESCRIPTION**

#### **Sleep Tests**

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a Medicare-covered sleep test (Type I, II, III, IV, other). A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study), or an inpatient hospital based, or a home sleep test (HST) (Types II, III, IV, other). The test must be ordered by the member's treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

**A Type I sleep test** is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with physician review, interpretation, and a report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

**An HST** is performed unattended in the member's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

- A. Type II device – monitors and records a minimum of seven channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or,
- B. Type III device – monitors and records a minimum of four channels: respiratory movement/effort, airflow, ECG / heart rate and oxygen saturation; or,
- C. Type IV device – monitors and records a minimum of three channels, one of which is airflow; or,
- D. Other – devices that monitor and record a minimum of three channels that include actigraphy, oximetry and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device-by-device basis (See Appendix B for list of approved devices in this category).
- E. Not all HST's are acceptable for evaluation of Central Sleep Apnea or Complex Sleep Apnea. Physicians are responsible to order the appropriate testing.

For PAP devices, all members who undergo a HST must, prior to having the test, receive instruction on how to properly apply a portable sleep monitoring device. This instruction must be provided by the entity conducting the HST and may not be performed by a DME supplier. Patient instruction may be accomplished by either:

1. Face-to-face demonstration of the portable sleep monitoring device's application and use; or,
2. Video or telephonic instruction, with 24-hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

For PAP devices all HST (Type II, III, IV, other) must be interpreted by a physician who holds either:

1. Current certification in sleep medicine by the American Board of Sleep Medicine (ABSM); or,
2. Current subspecialty certification in sleep medicine by a board member of the ABMS; or
3. Completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or
4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

For PAP devices with coverage based on a facility-based polysomnogram (Type I) performed, the interpreting physician must meet one of the requirements listed above (1-4) for credentialing.

A DME supplier may perform no aspect of an HST, including but not limited to delivery and/or pickup of the device. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests.

A **respiratory cycle** is defined as an inspiration, followed by expiration.

A **single-level continuous positive airway pressure** (CPAP) device (E0601) delivers a constant level of positive air pressure (within a single respiratory cycle) by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

A **bi-level respiratory assist device without backup rate** (E0470) allows independent setting of inspiratory and expiratory pressures to deliver positive airway pressure within a single respiratory cycle by way of tubing and a noninvasive interface (such as a nasal, oral, or facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs.

A **bi-level respiratory assist device with backup rate** (E0471) allows an independent setting of inspiratory and expiratory pressures to deliver positive airway pressure within a single respiratory cycle by way of tubing and a noninvasive interface (such as a nasal or oral facial mask) to assist spontaneous respiratory efforts and supplement the volume of inspired air into the lungs. In addition, E0471 devices have a timed backup feature to deliver this air pressure whenever sufficient spontaneous inspiratory efforts fail to occur.

Code **A4604** describes tubing used with a heated humidifier and has a heated wire running the length of the tubing. It is designed for use with a positive airway pressure device and a non-invasive interface, i.e., nasal, facemask, nasal cannula, or oral interface.

Code **A7032** is used for a replacement nasal mask interface that goes around the nose, but not into the nostrils. **The unit of service for this code is “each.”**

Code **A7033** is used for a replacement nasal cannula-type interface. This interface extends a short distance into the nostrils. The unit of service for this code is “pair.” For some products, there are two physically separate cushions or “pillows” – one for each nostril. Two cushions/pillows equals one unit of service of A7033. For other products, the interface is a single piece with two protrusions that extend into the nostrils. **One of these interfaces equals one unit of service of A7033.**

Code **A7027** (combination oral/nasal mask, used with continuous positive airway pressure device, each) is a two-piece system with separate elements for oral and nasal use. **One unit of service for A7027 includes both the oral and the nasal components.**

**The ApniCure, Inc. Winx® Sleep Therapy System** uses continuous low suction delivered to the oral cavity via a fitted mouthpiece to move the soft tissue and increase the size of the airway in the retropharynx and oral cavity. The product consists of a system console, connecting tubing and an oral interface (mouthpiece). Product coding was assigned in the January 2014 HCPCS code update.

Console - E0600 (RESPIRATORY SUCTION PUMP, HOME MODEL, PORTABLE OR STATIONARY, ELECTRIC)

Tubing - A7002 (TUBING, USED WITH SUCTION PUMP, EACH)

Oral interface - A7047 (ORAL INTERFACE USED WITH RESPIRATORY SUCTION PUMP, EACH)

**A7047** was created to describe the oral interface used as part of the Winx or similar systems. This code is not to be used for oral appliances used to treat OSA or for any other type of oral suction appliances. Do not use the oral appliance HCPCS codes E0485 or E0486 for this interface.

**STUD-Sleep Therapy under Disk Decompression:** the STUD treats and heals numerous sleep disorders, particularly mild-to-moderate Obstructive Sleep Apnea (OSA), and assists in lowering Positive Airway Pressure (PAP) when treating moderate-to-severe sleep apnea, when using PAP therapy. The prefabricated, over-the-counter STUD device is comprised of a headband that is made of soft, flexible interface material. The headband attaches via elastic straps to the “upper extremity Orthosis” or yoke that is made of stretchable neoprene foam-based materials, which runs behind the neck and attaches to

over-the-shoulder elastic straps, which, in turn, attach to leg bands worn on the upper thigh. Together, these components provide cervical disk decompression by arching the cervical vertebrae posteriorly, which produces interactive pressure and reduces the load on the intervertebral cervical disks. This repositions and opens the airway, elongating and firming the pharyngeal tissue, treating OSA and snoring while optimizing oxygen intake. The STUD is worn at night during sleep, providing therapy for sleep disorders. It can also be worn during the day for more aggressive daytime treatment for posture improvement, or as a preventive measure

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