

# Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Nonsurgical Treatments



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## Medical Coverage Policy

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## Related Medical/Pharmacy Coverage Policies

[Durable Medical Equipment \(DME\)](#)  
[Noninvasive Home Ventilators](#)  
[Obstructive Sleep Apnea and Other Sleep Related Breathing Disorders Surgical Treatments](#)  
[Orthognathic Surgery](#)  
[Sleep Studies, Adult](#)

## Description

Obstructive sleep apnea (OSA) is a common sleep disorder in which the muscles of the soft palate and throat intermittently relax during sleep, creating an obstruction that blocks the upper airway. This causes breathing to become difficult and noisy (snoring). Individuals with OSA experience cessation of breathing from 10 to 60 seconds at a time, which can occur up to 120 times an hour during sleep. As a result, oxygen levels in the bloodstream decrease, which may lead to abnormal heart rhythms, heart attack, high blood pressure and/or stroke.

Central sleep apnea (CSA) is a disorder characterized by repetitive cessation or decrease of both airflow and ventilatory effort during sleep. It can be primary (eg, idiopathic CSA) or secondary. Examples of secondary CSA include CSA associated with Cheyne-Stokes breathing, a medical condition, a drug or substance or high-altitude periodic breathing. CSA associated with Cheyne-Stokes breathing is particularly common, especially among individuals who have heart failure or have had a stroke.<sup>62</sup>

Depending on which type of sleep study is conducted (facility-based polysomnogram [PSG] or home sleep apnea test [HSAT]), there will be different measurements provided to aid in the diagnosis of OSA, CSA or other sleep related breathing disorders as well as to gauge the severity. Those measurements may include apnea-hypopnea index (AHI), respiratory disturbance index (RDI) and respiratory event index (REI).

Nonsurgical treatments for OSA and other sleep related breathing disorders include, but may not be limited to, the following:

### **Positive Airway Pressure (PAP) Therapy**

There are a number of variations for the devices used to deliver PAP. All devices work similarly by utilizing an air compressor, which forces a flow of air through the nose and into the airway, by way of a light mask worn over the nose during sleep. This prevents collapse of the oropharyngeal passage, which can cause an obstruction of airflow during sleep. Therefore, the goals of PAP therapy are to allow for unobstructed breathing and to improve sleep quality and/or duration.

The original and most utilized treatment is **continuous positive airway pressure (CPAP)**. A CPAP device provides the air flow at a constant, preset pressure; however, the settings can be manually changed by a health care professional.

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. The settings, like with CPAP, can be manually titrated.

An **auto-titrating continuous positive airway pressure (AutoPAP or APAP)** 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 can be used to determine an optimal fixed level of CPAP for long term treatment with conventional CPAP.<sup>39</sup>

Claustrophobia, discomfort or other issues may contribute to poor PAP therapy adherence. Pressure relief technology (**A-Flex, Bi-Flex, C-Flex and C-Flex +**) has been developed for APAP/BiPAP/CPAP devices and provides pressure relief at critical points in the breathing cycle. This technology has become widely used in PAP devices and is purported to increase comfort and compliance with therapy. Some devices have smartcards which can be used to view or verify compliance data of an individual to evaluate the treatment's overall effectiveness.

A **demand positive airway pressure (DPAP)** device responds to the individual's changing oxygen demands based on an analysis of each individual breath. It may be used after a trial of CPAP or BiPAP has been ineffective.

A **variable positive airway pressure device (VPAP)** allows bilevel PAP with higher pressure for inhaling and a lower pressure for exhaling but differs from a regular BiPAP by synchronizing the timing of inspiration and expiration with the individual's breathing. The amount of pressure does not vary. This may be used for individuals who cannot tolerate the constant pressure of CPAP or who have other sleep related respiratory disorders such as CSA or nocturnal hypoxemia related to severe chronic obstructive pulmonary disease (COPD).

Devices that purport to clean and disinfect CPAP equipment, using ultraviolet (UV) light or ozone gas to remove germs or allergens have been developed. Currently, no such devices are FDA approved because the safety and efficacy of these devices have not been determined. **SoClean** is an example of this type of device. **(Refer to Coverage Limitations section)**

### **Oral Appliance Therapy**

**Oral appliances (splints)**, sometimes called dental appliances, may be a treatment option for mild to moderate OSA and are intended to maintain an open airway. There are two major types of oral appliances: mandibular advancement splints (MAS) and tongue retaining devices. MAS, also referred to as mandibular repositioning appliances or mandibular advancement devices (MAD), push the lower jaw forward and are the most commonly used oral appliance. Tongue retaining devices prevent the tongue from falling back over the airway. Many oral appliances are custom-made, offering individuals the best fit and treatment outcomes.

New technology is being introduced for 3D printing of oral appliances. Examples of these devices include, but may not be limited to, **Respire Oral Appliance** and **Slow Wave DS8**. At this time, there is no evidence that demonstrates these are equivalent to traditional, custom-made appliances. **(Refer to Coverage Limitations section)**

Oral surgical splints are typically fabricated and used to offer perioperative and/or postoperative support to ensure satisfactory surgical outcomes during orthognathic surgery. **(Refer to Coverage Limitations section)**

Some oral appliances have been developed for the treatment of snoring alone. An example of one of these devices is the **Snore Guard** which resembles an athletic mouthpiece. Suggested as a treatment for snoring, it uses normal body reflexes to maintain an open airway. The device fits snugly on the upper teeth. When the lower jaw closes, the lower teeth close onto the lower ramp of the **Snore Guard**. This keeps the jaw in a normal position, rather than sagging open and back. In addition, the tongue reflexively seeks the small center orifice between the upper and lower ramp. This reflex keeps it from falling back into the throat. Another example of such a product is the **ZYPAH Anti-Snoring Mouthpiece**. Many of these devices can be purchased over-the-counter (OTC). **(Refer to Coverage Limitations section)**

### **Other Nonsurgical Treatment Devices**

**Daytime oral alignment devices** have been introduced to allegedly help an individual perform isometric exercises to return the mandible back to its pretreatment position or help maintain proper mouth alignment after using an overnight sleep apnea device. Some of these devices may require custom fitting and/or other tests may be ordered (eg, laryngeal function studies) to ensure the proper fit. Examples include, but may not be limited to, the **SomMorning Repositioner** and **AM Aligner**. **(Refer to Coverage Limitations section)**

**Expiratory positive airway pressure (EPAP)** is suggested as a treatment for OSA that utilizes the individual's own breathing to create PAP to prevent obstructed breathing. **Bongo Rx, Optipillows EPAP Mask** and **ULTepap** are examples of removable appliances that are placed just inside the nostril and increase pressure inside the nose during exhalation to maintain an open airway during sleep. These appliances may also be referred to as nasal dilators or nasal valve devices. **(Refer to Coverage Limitations section)**

**Nonsurgical electric muscular stimulation** via the **eXciteOSA** device, a daytime option for the treatment of mild OSA, delivers electrical stimulation through a mouthpiece that sits around the tongue. The mouthpiece has four electrodes, two located above the tongue and two located below the tongue. It is used for 20 minutes, once a day, for a period of 6 weeks and once each week thereafter. **eXciteOSA** purportedly works by improving tongue muscle endurance and responsiveness preventing upper airway collapse during sleep.<sup>47</sup> **(Refer to Coverage Limitations section)**

**Oral pressure therapy (OPT)** is comprised of a bedside console, a soft polymer mouthpiece and a flexible tube connecting the mouthpiece to the console. The console creates a vacuum pulling of the soft palate anteriorly and purportedly stabilizes the tongue to reduce obstruction during sleep. The **iNAP One Sleep Therapy System** is an example of OPT. **(Refer to Coverage Limitations section)**

**Positional sleep therapy devices** (eg, **NightBalance, Night Shift Positioner, Zzoma**) have been developed for individuals who have positional obstructive sleep apnea (POSA). The goal of **NightBalance** and **Night Shift Positioner** is to purportedly detect when an individual is sleeping on their back and send a tactile vibration to a strap positioned around the chest or neck in an effort to prompt the individual to change their sleep position. **Zzoma** is a device that is worn on an individual's back with adjustable Velcro straps that are secured anteriorly on the upper chest. This device purportedly keeps an individual positioned on their side and prevents the individual from laying in a supine position. **(Refer to Coverage Limitations section)**

### Coverage Determination

#### POSITIVE AIRWAY PRESSURE (PAP) THERAPY FOR THE TREATMENT OF OSA

##### APAP or CPAP: Adults

Humana members may be eligible under the Plan for **APAP or CPAP** when the following criteria are met:

- AHI/RDI/REI documentation is based on facility-based polysomnography (PSG) or home sleep apnea testing (HSAT); **AND**
- AHI/RDI/REI greater than or equal to 15 events per hour; **OR**
- AHI/RDI/REI greater than or equal to 5 and less than or equal to 14 events per hour with **ANY** of the following documented symptoms/conditions:
  - Apneic episodes; **OR**
  - Cardiovascular disease (eg, heart failure, hypertension, ischemic heart disease, stroke); **OR**

- Excessive daytime sleepiness (EDS); **OR**
- Impaired cognition; **OR**
- Insomnia; **OR**
- Mood disorders

**APAP or CPAP: Pediatric (17 years of age or younger)**

Humana members may be eligible under the Plan for **APAP or CPAP** when a facility-based PSG documents OSA with **ANY** of the following:

- Contraindications to adenotonsillectomy; **OR**
- Minimal adenotonsillar tissue; **OR**
- Persistent OSA after adenotonsillectomy; **OR**
- Preference for nonsurgical alternative; **OR**
- Stabilization of individual with severe OSA before adenotonsillectomy or other surgical procedure

**Other Positive Airway Pressure (PAP) Devices: Adult and Pediatric**

**BiPAP, DPAP or VPAP** may be considered medically necessary DME for members who failed APAP/CPAP. Failed APAP/CPAP is defined as any of the following (which must be documented in the medical record):

- Claustrophobia; **OR**
- Inability to breathe through the nose; **OR**
- Individual complaints of pressure discomfort at high pressures of APAP/CPAP (greater than 10 cm H<sub>2</sub>O); **OR**
- Pain or discomfort related to the APAP/CPAP appliance which causes intolerance or noncompliance

**POSITIVE AIRWAY PRESSURE (PAP) THERAPY FOR THE TREATMENT OF CSA**

Humana members may be eligible under the Plan for **BiPAP, DPAP or VPAP** for the treatment of central sleep apnea (CSA) when a facility-based PSG documents CSA with **ANY** of the following:

- Greater than or equal to 5 central apneas per hour of sleep with excessive daytime sleepiness (EDS) and awakening with shortness of breath, as well as frequent arousals and awakenings during sleep or insomnia; **OR**
- Greater than or equal to 10 central apneas or hypopneas per hour of sleep with central apneas occurring during the decrescendo portion of a crescendo-decrescendo respiratory pattern that is also accompanied by frequent arousals from sleep and breathing pattern is associated with a serious medical illness (eg, heart failure, renal failure or stroke); **OR**

- Greater than or equal to 10 central apneas or hypopneas per hour of sleep with central apneas occurring during the decrescendo portion of a crescendo-decrescendo respiratory pattern, with the latter accompanied by frequent arousals from sleep and the individual has been taking a long-acting opioid regularly for at least 2 months

**POSITIVE AIRWAY PRESSURE (PAP) THERAPY FOR THE TREATMENT OF COPD**

Humana members may be eligible under the Plan for **BiPAP, DPAP or VPAP** for the treatment of sleep associated hypoventilation (nocturnal hypoxemia) related to COPD when **ALL** of the following criteria are met:

- An arterial blood gas PaCO<sub>2</sub>, done while awake, is greater than or equal to 52 mmHg; **AND**
- OSA and treatment with a CPAP device has been considered and ruled out; **AND**
- Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 liters per minute (LPM) or the individual's prescribed FIO<sub>2</sub> (whichever is higher)

**Continuation of Coverage**

**APAP, BiPAP, CPAP, DPAP or VPAP** are initially authorized for 90 days rental. Compliance may be verified by a smartcard, the ordering physician or the individual's primary care physician. Compliance is defined as usage of at least 4 hours per night for 5 days each week over a 30 day period. Verification of compliance may be requested at any time within the first 90 days of therapy in order to make purchase or extended rental decision.

**Smartcards are an integral component of PAP management and are therefore not separately reimbursable.**

**Telecommunication or wireless transmission for PAP monitoring is considered integral to the primary procedure and not separately reimbursable.**

**It is the Plan's option to determine if the DME item shall be rented or purchased. If the cost of renting the item is more than the cost to buy it, only the cost of the purchase is considered to be a covered expense. In either case (rent or purchase), total covered expenses shall not exceed the purchase price. In the event the Plan determines to purchase the DME, any amount paid as rent for such equipment will be credited toward the purchase price.**

**Repair or Replacement of PAP Therapy Equipment**

Repair of the equipment (including parts) may be subject to the manufacturer's warranty and limitations in the member's certificate regarding durable medical equipment (DME). Please consult the member's individual certificate regarding Plan coverage for repairs and replacement of DME. In the absence of

certificate language, please refer to the Repair/Replacement section of the [Durable Medical Equipment \(DME\)](#) Medical Coverage Policy.

**Duplicate Equipment**

Please consult the member's individual certificate regarding Plan coverage for duplicate or similar equipment, which includes, but may not be limited to, equipment with the same function for use in another location (eg, school, second residence, travel, work) as it may be excluded by certificate. In the absence of a certificate exclusion, this is considered not medically necessary as defined in the member's individual certificate.

**ORAL APPLIANCES (Continuous Open Airway Therapy)**

Oral and/or dental appliances (splints) may be excluded as noncovered items as defined in the member's individual certificate. Please refer to the member's individual certificate of coverage.

**An individual undergoing treatment with oral appliances for OSA may also need to undergo dental work such as dentures or bridgework. Even if these services are medically necessary, they are generally NOT covered under the Plan and may be excluded as noncovered items as defined in the member's individual certificate. Please refer to the member's individual certificate of coverage.**

**Commercial Plan members: all requests for oral appliances require review by a medical director when other therapy (APAP, BiPAP, CPAP, DPAP, VPAP) is currently in use.**

Humana members may be eligible under the Plan for a **custom made nonsurgical** oral appliance when the following criteria are met:

- AHI/RDI/REI documentation is based on facility-based polysomnography (PSG) or home sleep apnea testing (HSAT);

**AND** any of the following:

- For an individual diagnosed with [severe OSA](#)<sup>\*</sup>, an initial trial and [failure](#) of APAP/CPAP for a minimum of 30 days has occurred; **OR**
- AHI/RDI/REI of 15 to 30 events per hour; **OR**
- AHI/RDI/REI greater than or equal to 5 and less than or equal to 14 events per hour with **ANY** of the following documented symptoms/diseases:
  - Apneic episodes; **OR**
  - Cardiovascular disease (eg, heart failure, hypertension, ischemic heart disease, stroke); **OR**
  - Excessive daytime sleepiness (EDS); **OR**
  - Impaired cognition; **OR**

- Insomnia; **OR**
- Mood disorders

\*Severe OSA is defined as AHI/RDI/REI of greater than 30 events per hour.

### **Repair or Replacement of Oral Appliances**

Replacement of an oral appliance may be covered if it is needed due to a change in the individual's mouth structure or excessive wear that makes the current equipment nonfunctional. Repair and replacement of oral appliances may be excluded by certificate. Please refer to member's individual certificate of coverage.

## **Coverage Limitations**

### **Positive Airway Pressure (PAP) Therapy**

Humana members may **NOT** be eligible under the Plan for **APAP, BiPAP, CPAP, DPAP or VPAP** for any other indications other than those listed above. These are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **PAP therapy or oral appliance for upper airway resistance syndrome (UARS)**. These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **CPAP cleaner** for any indication. Although it may be prescribed by a health care practitioner, CPAP cleaning products are also available without a prescription and may be obtained OTC and are therefore generally excluded by certificate. In the absence of a certificate exclusion for OTC items, **CPAP cleaner** is considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

### **Oral Appliance Therapy**

Humana members may **NOT** be eligible under the Plan for **oral appliance therapy** for any indications other than those listed above including, but not limited to the following:

- Oral appliance created via 3D printing technology; **OR**
- Oral appliance that is **NOT** custom made or those intended for temporary use; **OR**
- **Surgical** splint used for OSA treatment; **OR**
- Treatment of snoring alone without OSA

OTC items, whether prescribed or unprescribed are generally excluded by certificate. In the absence of a certificate exclusion, OTC items are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

**Other Nonsurgical OSA Treatment Devices**

Humana members may **NOT** be eligible under the Plan for these **other nonsurgical OSA treatment devices** for any indications or procedures other than those listed above. This includes, but may not be limited to, the following:

- Daytime alignment device and/or laryngeal function studies to assess fit of the device; **OR**
- EPAP devices; **OR**
- Nonsurgical electric muscular stimulation; **OR**
- Oral pressure therapy

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for the **Optipillows EPAP Mask** for any indication. Although this device may be prescribed by a health care practitioner, **Optipillows EPAP Mask** is available without a prescription and may be obtained over-the-counter (OTC) and is therefore generally excluded by certificate. In the absence of a certificate exclusion for OTC items, this device is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **positional sleep therapy devices** for any indication. Although they may be prescribed by a health care practitioner, positional sleep therapy devices are also available without a prescription and may be obtained OTC and are therefore generally excluded by certificate. In the absence of a certificate exclusion for OTC items, positional sleep therapy devices are considered not medically necessary as defined in the member’s individual certificate. Please refer to the member’s individual certificate for the specific definition.

**Coding Information**

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
21085	Impression and custom preparation; oral surgical splint	
21089	Unlisted maxillofacial prosthetic procedure	

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92520	Laryngeal function studies (ie, aerodynamic testing and acoustic testing)	
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management	
<b>CPT® Category III Code(s)</b>	<b>Description</b>	<b>Comments</b>
No code(s) identified		
<b>HCPCS Code(s)</b>	<b>Description</b>	<b>Comments</b>
A4604	Tubing with integrated heating element for use with positive airway pressure device	
A7002	Tubing, used with suction pump, each	
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each	
A7028	Oral cushion for combination oral/nasal mask, replacement only, each	
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair	
A7030	Full face mask used with positive airway pressure device, each	
A7031	Face mask interface, replacement for full face mask, each	
A7032	Cushion for use on nasal mask interface, replacement only, each	
A7033	Pillow for use on nasal cannula type interface, replacement only, pair	
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap	
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, nondisposable, 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	
A7047	Oral interface used with respiratory suction pump, each	
A7049	Expiratory positive airway pressure intranasal resistance valve	

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A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified	
E0470	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)	
E0471	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)	
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)	
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, prefabricated, includes fitting and adjustment	
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or nonadjustable, custom fabricated, includes fitting and adjustment	
E0490	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote	
E0491	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply	
E0492	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application	
E0493	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply	
E0530	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type	
E0561	Humidifier, nonheated, used with positive airway pressure device	
E0562	Humidifier, heated, used with positive airway pressure device	
E0600	Respiratory suction pump, home model, portable or stationary, electric	
E0601	Continuous positive airway pressure (CPAP) device	

E1399	Durable medical equipment, miscellaneous	
K1001	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type	
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment	
K1028	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle for the reduction of snoring and obstructive sleep apnea, controlled by phone application	
K1029	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply	
K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility	<b>New Code Effective 04/01/2024</b>

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## **Change Summary**

- 04/25/2024 Annual Review, No Coverage Change.