Name of Policy:
Management of Obstructive Sleep Apnea Syndrome

Policy #: 065
Category: Surgery/Medical/DME
Latest Review Date: July 2014
Policy Grade: D

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
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 hallmark clinical symptom of obstructive sleep apnea is excessive snoring.

Upper airway resistance syndrome is a variant of obstructive sleep apnea characterized by a partial collapse of the airway resulting in increased resistance to airflow. An increase in the respiratory effort required results in multiple sleep fragmentations as measured by very short alpha EEG arousals (Respiratory event-related arousals (RERAs)). UARS can occur in the absence of snoring and in patients who are not overweight. The resistance to airflow is typically subtle and does not result in apneic or hypopneic events. However, increasingly negative intrathoracic pressure during inspiration can be measured using an esophageal manometer. RERAs can also be detected absent manometry during polysomnography. It has been proposed that UARS is a distinct syndrome from OSA that may be considered a disease of arousal. In the absence of intrathoracic pressure monitoring, a positive response to continuous positive airway pressure (CPAP) has also been used to support the diagnosis.

A polysomnogram is the diagnostic test of choice and a variety of polysomnographic indices have been used to evaluate the patient with sleep apnea. An Apnea/Hypopnea Index (AHI) in adults ≥ 5 to 15 is considered mild OSA, 15 to 30 is considered moderate and > 30 is severe. Pediatric (< 12 years of age) AHI 1 to < 5 is mild, 5 < 10 is moderate and > 10 is severe.

Non-surgical treatment for obstructive sleep apnea or upper airway resistance syndrome includes weight loss, continuous positive airway pressure (CPAP), Bi-Level Positive airway pressure (Bi-PAP), auto-adjusting CPAP (APAP), or orthodontic repositioning. Nasal or oral continuous positive airway pressure (CPAP) is continuous positive airway pressure applied through the nose or via oral appliance. The pressure delivered comes through a flow generator to a mask and supplies a pressure level sufficient to keep the upper airway patent. The pressure used is determined individually with a CPAP trial. 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 positive airway pressure (BiPAP) provides two levels of positive pressure via a mask that augments patient ventilation. BiPAP responds to changes in the individual’s inhalation and exhalation patterns and is normally instituted after a trial of CPAP has proven ineffective.

Another alternative for the treatment of snoring and obstructive sleep apnea is oral appliances. Oral appliances are used for many purposes, including occlusal disorders. Oral appliances offer an alternative for sleep apnea patients dissatisfied with other therapies or unwilling to accept more complex interventions. The appliances may be a mandibular advancing device or tongue retainer that keeps the tongue in an anterior position. Other technologies are available on CPAP as pressure relief technology by reducing the pressure of exhalation and returning to therapeutic pressure just before inhalation. One type is made by Respironics and known as C-Flex; Bi-flex for BiPAP and A-flex as an auto adjusting technology.

Bi-level positive airway pressure-spontaneous timed (BiPAP S/T) is not appropriate for obstructive apnea. It is designed to assist ventilation noninvasively. It is sometimes used for patients with neuromuscular respiratory insufficiency or restrictive lung disease from thoracic...
wall deformity and chronic respiratory failure due to chronic obstructive pulmonary disease (COPD). Other methods of assist ventilation that may be used invasively are not appropriate for obstructive sleep apnea. Additional information regarding BiPAP S/T is available on Blue Cross and Blue Shield of Alabama’s medical policy #203, Respiratory Assist Device, Bi-level Pressure Capability, with Backup Rate Feature (BiPAP® S/T).

Auto-titrating continuous positive airway pressure (auto-CPAP or APAP) utilizes a device that continually adjusts the level of pressure, as needed, to maintain airway patency. It has been investigated, both as a means to establish the required level of therapeutic "fixed" CPAP for long-term use, (as an alternative to sleep laboratory, technician- titrated CPAP), and as a long-term therapeutic alternative to fixed CPAP in adults.

Surgical procedures include: uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency ablation of palatal tissues and a variety of maxillofacial surgeries such as genioglossal advancement, hyoid suspension and mandibular-maxillary advancement (MMA). The uvulopalatopharyngoplasty (UPPP) is the most commonly performed procedure, involving surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient. This procedure enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue.

The laser-assisted uvulopalatoplasty (LAUP) is an outpatient alternative that has been promoted as a treatment of snoring with or without associated obstructive sleep apnea. In this procedure superficial palatal tissues are sequentially reshaped using a CO2 laser and does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient may undergo from three to seven sessions at three to four week intervals. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

Radiofrequency ablation of palatal tissues is similar in concept to LAUP, although a different energy source is used. Radiofrequency is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface, which may be painful. In some situations, radiofrequency of the soft palate and base of tongue are performed together. The Somnoplasty® device is an FDA-approved device that has been used for radiofrequency ablation of palatal tissues and for the base of the tongue.

Uvulectomy is the excision of the uvula and is sometimes performed for snoring.

An enlarged tongue may also be a part of the obstructive airway. A midline glossectomy (MLG) removes redundant tissue at the base of the tongue by making a V-type incision in the tongue to decrease excess tissue.

Genioglossal advancement has the advantage of not altering the jaw position or occlusion. There are several techniques for this procedure. Osteotomies that are performed are angled to include
the geniotubercle. Hyoid suspension and myotomy includes advancement of the hyoid bone anteriorly to the mandible or alternatively advanced onto the laryngeal cartilage. Advancement of the hyoid bone through its attachments draws the epiglottis, vallecula, and tongue base forward. Maxillomandibular advancement includes a standard Le Fort I osteotomy in combination with bilateral sagittal split ramus osteotomies for the simultaneous advancement of the maxilla and mandible. In many cases, advancement geniotomy, with or without hyoid myotomy and suspension, is also performed.

Palatal stiffening procedures include a cautery-assisted palatal stiffening operation (CAPSO), insertion of palatal implants and insertion of palatal implants. The CAPSO procedure uses cautery to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring. The Pillar™ Palatal Implant System (Restore Medical, St. Paul, MN) is an implantable device that has been cleared by the FDA 501(k) process. The device is a cylindrical shaped segment of braided polyester filaments that is permanently implanted submucosally in the soft palate. The labeled indication of the device is as follows: “The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).”

The use of atrial overdrive pacing (AOD) is also being evaluated in the treatment of obstructive sleep apnea. This approach is being tried because of the bradycardia that generally occurs during episodes of apnea.

The Repose™ system is a minimally invasive technique for tongue-base suspension in the treatment of sleep-disordered breathing caused by tongue-base collapse. This procedure involves the insertion of a titanium miniscrew with attached suture to the inner side of the mandible, below the tooth roots. It is indicated for the treatment of OSA and/or snoring.

Winx™ Sleep Therapy System by ApniCure uses platform called Oral Pressure Therapy (OPT) to treat obstructive sleep apnea. OPT is a light oral vacuum delivered by a pressure console through a slim tube which is connected to a soft flexible mouthpiece. The mouthpiece and vacuum work together to gently pull the soft palate forward and stabilize the tongue. This action is proposed to increase the size of the airway and allow for more natural breathing to occur while sleeping. Mouthpieces of different sizes are available. Once the mouthpiece has been determined to be the correct size the patient should be evaluated by a physician to determine the effects of the treatment. The console system tracks and stores on a standard SD card the patients usage to determine compliance.

Policy:
Effective for dates of service on or after June 17, 2014:
Medical Management of OSA
CPAP for Obstructive Sleep Apnea (OSA)
Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA) in adults meets Blue Cross and Blue Shield of Alabama’s coverage criteria for patients who meet either of the following criteria on polysomnography:

Proprietary Information of Blue Cross and Blue Shield of Alabama
Medical Policy #065
1. Apnea Hypopnea Index (AHI) greater than or equal to 15 events per hour; OR
2. AHI greater than or equal to five, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
   - Excessive daytime sleepiness, as documented by either a cumulative or total score of ten or greater on the Epworth Sleepiness scale or inappropriate daytime napping, (e.g., during driving, conversation or eating) or sleepiness that interferes with daily activities; or
   - Impaired cognition or mood disorders; or
   - Hypertension; or
   - Ischemic heart disease, congestive heart failure or history of stroke; or
   - Cardiac arrhythmias; or
   - Pulmonary hypertension; or
   - Insomnia.

Note: Nocturnal polysomnogram testing to determine coverage should be performed in an approved facility.

CPAP for CHILDREN
CPAP for the treatment of obstructive sleep apnea (OSA) in children (17 years of age or younger) meets Blue Cross and Blue Shield of Alabama’s coverage criteria when the following criteria are met:

- There is a documented diagnosis of obstructive sleep apnea (OSA) and polysomnography demonstrates an apnea index (AI) or apnea-hypopnea index (AHI) equal to or greater than one (1); AND
- Adenotonsillectomy has been unsuccessful in relieving OSA; OR
- Adenotonsillar tissue is minimal; OR
- Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., septum deviations, facial abnormalities (craniofacial syndromes), obesity or when adenotonsillectomy is contraindicated.

Compliance Documentation
Compliance documentation should be maintained in the supplier’s record. This documentation should include that the physician certifies the patient is compliant with the treatment and the sleep disorder has improved based on the treatment OR a recorded compliance document indicating proper usage. (≥ 4 hours per night on 70% of the nights during a 30 consecutive day period during the initial 90 days of usage.) (Compliance documentation that extended beyond the 90 days will be reviewed on an individual basis i.e. Accidents, change in physical status, surgery, etc.)

Related Supply Coverage
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Supplies are not covered separately in Alabama when billed during the 10 month rental period or within the first 10 months after the purchase. Supplier should receive a request for additional supplies and should not automatically deliver supplies/accessories on a predetermined routine basis.

**Replacement Devices**

Previously covered devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to be replaced when the following criteria are met: (a repeat sleep study is not required)

- The equipment has suffered irreparable damage (cost more to repair than to replace) and has been in the home for 3 years or longer; OR
- The patient’s condition has changed and a different piece of equipment is determined to be medically necessary.
Replacement devices will not be covered for replacing functioning equipment with a newer more advanced model. (Compliance documentation is not required for replacement equipment.)

Replacement devices should be filed with modifier “RA” to indicate they are not the initial device but a replacement piece of equipment.

Note: The AHI (Apnea Hypopnea Index) is equal to the average number of episodes of apnea and hypopnea per hour of sleep and must be based on a minimum of two hours (unless an emergency protocol was activated) of sleep recorded by polysomnography using actual recorded hours of sleep, (i.e., the AHI may not be extrapolated or projected). The RDI (Respiratory Disturbance Index) may be defined as the number of apneas, hypopneas, and Respiratory event-related arousals (RERAs) per hour of sleep. Respiratory event-related arousals (RERAs) are scored if there is a sequence of breaths lasting at least 10 seconds characterized by increasing respiratory effort or flattening of the nasal pressure waveform leading to an arousal from sleep when the sequence of breaths does not meet criteria for an apnea or hypopnea. is equal to the episodes of apnea and hypopnea per hour of measurement. For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined using either the AASM recommended or alternative definitions.

Leg movement, snoring, respiratory effort related arousals (RERAs), and other sleep disturbances that may be included by some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in this policy. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for the following pieces of DME will be considered not medically necessary if based upon an index that does not score apneas, hypopneas and RERAs separately from other sleep disturbance events (RERAs). Only persons with an AHI and/or RDI, as defined in this policy that meets medical necessity criteria may qualify for coverage.

Oral Devices for Obstructive Sleep Apnea (OSA)
Oral Pressure Therapy (OPT) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational (an example of this therapy is Winx™, Sleep Therapy System by ApnivCure).

Oral appliances for the treatment of obstructive sleep apnea meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met:
- Nocturnal polysomnogram has been performed in an approved facility and a diagnosis of obstructive sleep apnea has been made; AND
- Devices are used in patients who prefer oral appliances to CPAP, who do not respond to CPAP, OR have failed CPAP treatment; and ordered by the physician treating the patient for the diagnosed obstructive sleep apnea: AND
- The device must be fitted by qualified dental personnel (Over the counter devices or prefabricated, even if fitted by dental personnel are not covered).

Oral appliances for snoring do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.
EPAP
Nasal Expiratory Airway Pressure (EPAP) also known as PROVENT does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered investigational.

Please refer to Benefit Applications section of this policy for further information on oral appliance coverage.

Surgical Management of OSA:
Uvulopalatopharyngoplasty (UPPP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when used for the treatment of snoring.
Genioglossal advancement, hyoid suspension and myotomy and other mandibular-maxillary advancement meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of obstructive sleep apnea when the following criteria are met:

- AHI > 20 or oxygen desaturations less than 90% as determined by a nocturnal polysomnogram has been performed in an approved facility.
- Cephalometric abnormalities
- (Clinically Significant) Hypopharyngeal obstruction
- CPAP/BIPAP trial over a period of time (unless RDI less than 5 cannot be achieved) or patient has immediate intolerance (true claustrophobic reaction)
- Otolaryngologist evaluation with appropriate interventions
- If UPPP performed prior to orthognathic surgery, will need to repeat sleep study demonstrating obstructive sleep apnea

Radiofrequency ablation of palatal tissues or radiofrequency volumetric tissue reduction (Somnoplasty) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational for simple snoring, upper airway resistance syndrome and obstructive sleep apnea syndrome.

Uvulectomy does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when used for the treatment of snoring.

Midline glossectomy does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of upper airway obstruction syndrome and obstructive sleep apnea syndrome and is considered investigational.

Palatal stiffening procedures, including but not limited to, cautery assisted palatal stiffening operation, and the implantation of palatal implants, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered non-covered in the treatment of snoring alone, and are considered investigational as a treatment for upper airway resistance syndrome or OSA.

Atrial pacing does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Repose tongue suspension system does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Implantable hypoglossal nerve stimulators do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational for all indications, including but not limited to the treatment of OSA.

Simple snoring in the absence of documented obstructive sleep apnea is not considered a medical condition; therefore, any surgical intervention, such as LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered non-covered.
Effective for dates of service on or after May 1, 2014 through June 16, 2014:

**Medical Management of OSA**

**CPAP for Obstructive Sleep Apnea (OSA)**

Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA) in adults meets Blue Cross and Blue Shield of Alabama’s coverage criteria for patients who meet either of the following criteria on polysomnography:

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**Note:** Nocturnal polysomnogram testing to determine coverage should be performed in an approved facility.

**CPAP for CHILDREN**

CPAP for the treatment of obstructive sleep apnea (OSA) in children (17 years of age or younger) meets Blue Cross and Blue Shield of Alabama’s coverage criteria when the following criteria are met:

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**Compliance Documentation**

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**Oral Devices for Obstructive Sleep Apnea (OSA)**

**Oral Pressure Therapy (OPT) does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational (an example of this therapy is Winx™, Sleep Therapy System by ApniCure).

**Oral appliances for the treatment of obstructive sleep apnea meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met:
• Nocturnal polysomnogram has been performed in an approved facility and a diagnosis of obstructive sleep apnea has been made; **AND**
• Devices are used in patients who prefer oral appliances to CPAP, who do not respond to CPAP, OR have failed CPAP treatment; **and** ordered by the physician treating the patient for the diagnosed obstructive sleep apnea: **AND**
• The device must be fitted by qualified dental personnel (Over the counter devices or prefabricated, even if fitted by dental personnel are not covered).

**Oral appliances for snoring do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.
EPAP
Nasal Expiratory Airway Pressure (EPAP) also known as PROVENT does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered investigational.

Please refer to Benefit Applications section of this policy for further information on oral appliance coverage.

Surgical Management of OSA:
Uvulopalatopharyngoplasty (UPPP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when used for the treatment of snoring.
Genioglossal advancement, hyoid suspension and myotomy and other mandibular-maxillary advancement meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of obstructive sleep apnea when the following criteria are met:

- AHI > 20 or oxygen desaturations less than 90% as determined by a nocturnal polysomnogram has been performed in an approved facility.
- Cephalometric abnormalities
- (Clinically Significant) Hypopharyngeal obstruction
- CPAP/BIPAP trial over a period of time (unless RDI less than 5 cannot be achieved) or patient has immediate intolerance (true claustrophobic reaction)
- Otolaryngologist evaluation with appropriate interventions
- If UPPP performed prior to orthognathic surgery, will need to repeat sleep study demonstrating obstructive sleep apnea

Radiofrequency ablation of palatal tissues or radiofrequency volumetric tissue reduction (Somnoplasty) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational for simple snoring, upper airway resistance syndrome and obstructive sleep apnea syndrome.

Uvullectomy does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when used for the treatment of snoring.

Midline glossectomy does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of upper airway obstruction syndrome and obstructive sleep apnea syndrome and is considered investigational.

Palatal stiffening procedures, including but not limited to, cautery assisted palatal stiffening operation, and the implantation of palatal implants, do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered non-covered in the treatment of snoring alone, and are considered investigational as a treatment for upper airway resistance syndrome or OSA.

Atrial pacing does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Repose tongue suspension system does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Simple snoring in the absence of documented obstructive sleep apnea is not considered a medical condition; therefore, any surgical intervention, such as LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered non-covered.
Effective for dates of service on or after June 25, 2012 and prior to April 30, 2014:

Medical Management of OSA
CPAP for Obstructive Sleep Apnea (OSA)
Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA) in adults meets Blue Cross and Blue Shield of Alabama’s coverage criteria for patients who meet either of the following criteria on polysomnography:

1. Apnea Hypopnea Index (AHI) greater than or equal to 15 events per hour; OR
2. AHI greater than or equal to five, and less than 15 events per hour with documentation demonstrating any of the following symptoms:
   - Excessive daytime sleepiness, as documented by either a cumulative or total score of ten or greater on the Epworth Sleepiness scale or inappropriate daytime napping, (e.g., during driving, conversation or eating) or sleepiness that interferes with daily activities; or
   - Impaired cognition or mood disorders; or
   - Hypertension; or
   - Ischemic heart disease, congestive heart failure or history of stroke; or
   - Cardiac arrhythmias; or
   - Pulmonary hypertension; or
   - Insomnia.

Note: Nocturnal polysomnogram testing to determine coverage should be performed in an approved facility.

Note: The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of two hours (unless an emergency protocol was activated) of sleep recorded by polysomnography using actual recorded hours of sleep, (i.e., the AHI may not be extrapolated or projected).

CPAP for CHILDREN
CPAP for the treatment of obstructive sleep apnea (OSA) in children (17 years of age or younger) meets Blue Cross and Blue Shield of Alabama’s coverage criteria when the following criteria are met:

- There is a documented diagnosis of obstructive sleep apnea (OSA) and polysomnography demonstrates an apnea index (AI) or apnea-hypopnea index (AHI) equal to or greater than one (1); AND
- Adenotonsillectomy has been unsuccessful in relieving OSA; OR
- Adenotonsillar tissue is minimal; OR
- Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., septum deviations, facial abnormalities (craniofacial syndromes), obesity or when adenotonsillectomy is contraindicated.

Compliance Documentation
Compliance documentation should be maintained in the supplier’s record. This documentation should include that the physician certifies the patient is compliant with the treatment and the
sleep disorder has improved based on the treatment OR a recorded compliance document indicating proper usage. (≥ 4 hours per night on 70% of the nights during a 30 consecutive day period during the initial 90 days of usage.) (Compliance documentation that extended beyond the 90 days will be reviewed on an individual basis i.e. Accidents, change in physical status, surgery, etc.)

**Related Supply Coverage**
The following supplies meet Blue Cross and Blue Shield of Alabama’s criteria for coverage based on the following frequency when the above equipment is determined to be covered:

<table>
<thead>
<tr>
<th>Item</th>
<th>Code</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full face mask, each</td>
<td>A7030</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Chinstrap</td>
<td>A7036</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Combination Oral/Nasal Mask, each</td>
<td>A7027</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Face Mask Interface, replacement for full face mask</td>
<td>A7031</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Filter, disposable</td>
<td>A7038</td>
<td>1 in 90 days</td>
</tr>
<tr>
<td>Headgear/Softcap</td>
<td>A7035</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Nasal interface (mask or cannula type)</td>
<td>A7034</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Nose Pillows (Pair)</td>
<td>A7033</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Oral Interface Used With Positive Airway Pressure Device, Each</td>
<td>A7044</td>
<td>1 in 180 days</td>
</tr>
<tr>
<td>Replacement Cushion for nasal mask interface</td>
<td>A7032</td>
<td>1 in 180 days</td>
</tr>
<tr>
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<td>Tubing/Hose</td>
<td>A7037</td>
<td>1 in 365 days</td>
</tr>
<tr>
<td>Heated tubing</td>
<td>A4604</td>
<td>1 in 365 days</td>
</tr>
<tr>
<td>Non-heated humidifier</td>
<td>E0561</td>
<td>1 every 3 years</td>
</tr>
<tr>
<td>Heated humidifier</td>
<td>E0562</td>
<td>1 every 3 years</td>
</tr>
<tr>
<td>CPAP machine</td>
<td>E0601</td>
<td>1 every 3 years</td>
</tr>
</tbody>
</table>

Supplies are not covered separately in Alabama when billed during the 10 month rental period or within the first 10 months after the purchase.
Supplier should receive a request for additional supplies and should not automatically deliver supplies/accessories on a predetermined routine basis.

Replacement Devices
Previously covered devices meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to be replaced when the following criteria are met: (a repeat sleep study is not required)

- The equipment has suffered irreparable damage (cost more to repair than to replace) and has been in the home for 3 years or longer; OR
- The patient’s condition has changed and a different piece of equipment is determined to be medically necessary.

Replacement devices will not be covered for replacing functioning equipment with a newer more advanced model. (Compliance documentation is not required for replacement equipment.)

Replacement devices should be filed with modifier “RA” to indicate they are not the initial device but a replacement piece of equipment.

**NOTE**: The AHI (Apnea Hypopnea Index) is equal to the average number of episodes of apnea and hypopnea per hour of sleep. The RDI (Respiratory Disturbance Index) is equal to the episodes of apnea and hypopnea per hour of measurement. For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined using either the AASM recommended or alternative definitions.*

Leg movement, snoring, respiratory effort related arousals (RERAs), and other sleep disturbances that may be included by some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in this policy. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for the following pieces of DME will be considered not medically necessary if based upon an index that does not score apneas and hypopneas separately from other sleep disturbance events (RERAs). Only persons with an AHI and/or RDI, as defined in this policy that meets medical necessity criteria may qualify for coverage.

**Oral Devices for Obstructive Sleep Apnea (OSA)**
Oral Pressure Therapy (OPT) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational (an example of this therapy is Winx™, Sleep Therapy System by ApniCure).

Oral appliances for the treatment of obstructive sleep apnea meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met:

- Nocturnal polysomnogram has been performed in an approved facility and a diagnosis of obstructive sleep apnea has been made; AND
- Devices are used in patients who prefer oral appliances to CPAP, who do not respond to CPAP, OR have failed CPAP treatment; and ordered by the physician treating the patient for the diagnosed obstructive sleep apnea: AND
• The device must be fitted by qualified dental personnel (Over the counter devices or prefabricated, even if fitted by dental personnel are not covered)

**Oral appliances for snoring do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

**EPAP**
Nasal Expiratory Airway Pressure (EPAP) also known as PROVENT does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered investigational.

**Please refer to Benefit Applications section of this policy for further information on oral appliance coverage.**

**Surgical Management of OSA:**

**Uvulopalatopharyngoplasty (UPPP) meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

**Laser-assisted uvulopalatoplasty (LAUP) meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.
Laser-assisted uvulopalatoplasty (LAUP) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational when used for the treatment of snoring.

Genioglossal advancement, hyoid suspension and myotomy and other mandibular-maxillary advancement meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of obstructive sleep apnea when the following criteria are met:

- AHI > 20 or oxygen desaturations less than 90% as determined by a nocturnal polysomnogram has been performed in an approved facility;
- Cephalometric abnormalities;
- (Clinically Significant) Hypopharyngeal obstruction;
- CPAP/BIPAP trial over a period of time (unless RDI less than 5 cannot be achieved) or patient has immediate intolerance (true claustrophobic reaction);
- Otolaryngologist evaluation with appropriate interventions;
- If UPPP performed prior to orthognathic surgery, will need to repeat sleep study demonstrating obstructive sleep apnea.

Radiofrequency ablation of palatal tissues or radiofrequency volumetric tissue reduction (Somnoplasty) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational for simple snoring, upper airway resistance syndrome and obstructive sleep apnea syndrome.

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Atrial pacing does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

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Simple snoring in the absence of documented obstructive sleep apnea is not considered a medical condition; therefore, any surgical intervention, such as LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered non-covered.
Effective for dates of service October 1, 2010 through June 24th, 2012:

Medical Management of OSA

CPAP for Obstructive Sleep Apnea (OSA)

Continuous positive airway pressure (CPAP) for the treatment of obstructive sleep apnea (OSA) in adults meets Blue Cross and Blue Shield of Alabama’s coverage criteria for patients who meet either of the following criteria on polysomnography:

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CPAP for CHILDREN

CPAP for the treatment of obstructive sleep apnea (OSA) in children (17 years of age or younger) meets Blue Cross and Blue Shield of Alabama’s coverage criteria when the following criteria are met:

- There is a documented diagnosis of obstructive sleep apnea (OSA) and polysomnography demonstrates an apnea index (AI) or apnea-hypopnea index (AHI) equal to or greater than one (1); AND
- Adenotonsillectomy has been unsuccessful in relieving OSA; OR
- Adenotonsilar tissue is minimal; OR
- Adenotonsillectomy is inappropriate based on OSA being attributable to another underlying cause (e.g., septum deviations, facial abnormalities (craniofacial syndromes), obesity or when adenotonsillectomy is contraindicated.
Compliance Documentation
Compliance documentation should be maintained in the supplier’s record. This documentation should include that the physician certifies the patient is compliant with the treatment and the sleep disorder has improved based on the treatment OR a recorded compliance document indicating proper usage. (≥ 4 hours per night on 70% of the nights during a 30 consecutive day period during the initial 90 days of usage.) (Compliance documentation that extended beyond the 90 days will be reviewed on an individual basis i.e. Accidents, change in physical status, surgery, etc.)

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Supplies are not covered separately in Alabama when billed during the 10 month rental period or within the first 10 months after the purchase.

Supplier should receive a request for additional supplies and should not automatically deliver supplies/accessories on a predetermined routine basis.

**Replacement Devices**

**Previously covered devices meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage to be replaced when the following criteria are met: (a repeat sleep study is not required)

- The equipment has suffered irreparable damage (cost more to repair than to replace) and has been in the home for 3 years or longer; OR
- The patient’s condition has changed and a different piece of equipment is determined to be medically necessary.

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**Replacement devices should be filed** with modifier “RA” to indicate they are not the initial device but a replacement piece of equipment.

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Leg movement, snoring, respiratory effort related arousals (RERAs), and other sleep disturbances that may be included by some polysomnographic facilities are not considered to meet the AHI and/or RDI definition in this policy. Although AHI and RDI have been used interchangeably, some facilities use the term RDI to describe a calculation that includes these other sleep disturbances. Requests for the following pieces of DME will be considered not medically necessary if based upon an index that does not score apneas and hypopneas separately from other sleep disturbance events (RERAs). Only persons with an AHI and/or RDI, as defined in this policy that meets medical necessity criteria may qualify for coverage.

**Oral Devices for Obstructive Sleep Apnea (OSA):**

**Oral appliances for the treatment of obstructive sleep apnea meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when all of the following criteria are met:

- Nocturnal polysomnogram has been performed in an approved facility and a diagnosis of obstructive sleep apnea has been made; **AND**
- Devices are used in patients with mild to moderate sleep apnea (See Key Points) who prefer oral appliances to CPAP, who do not respond to CPAP, OR have failed CPAP treatment; **and** ordered by the physician treating the patient for the diagnosed obstructive sleep apnea: **AND**
- The device must be fitted by qualified dental personnel (Over the counter devices or prefabricated, even if fitted by dental personnel are not covered)
Oral appliances for snoring do not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered investigational.

EPAP
Nasal Expiratory Airway Pressure (EPAP) also known as PROVENT does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered investigational.

Please refer to Benefit Applications section of this policy for further information on oral appliance coverage.

Surgical Management of OSA:
Uvulopalatopharyngoplasty (UPPP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when treatment options have been discussed with the patient including but not limited to: weight loss, Continuous Positive Airway Pressure (CPAP), Bi-Level Positive Airway Pressure (BIPAP), medications and alternative surgical procedures. The following conditions and criteria must be met:

- Diagnosis of obstructive sleep apnea is made with a polysomnogram study performed at an approved sleep study center (not an at home study) and there is documentation of an Apnea-Hypopnea Index (AHI) greater than or equal to 15.

- Physical examination that includes but is not limited to: anterior rhinoscopy; endoscopic examination of nose, pharynx, and hypopharynx; evaluation of the nasal septum and nasal turbinates; evaluation of nasal polyps or other masses; Muller’s maneuver and evaluation of the tonsillar/adenoidal tissue; anatomical evaluation for cephalometric disproportion.

Laser-assisted uvulopalatoplasty (LAUP) does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used for the treatment of snoring.

Genioglossal advancement, hyoid suspension and myotomy and other mandibular-maxillary advancement meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of obstructive sleep apnea when the following criteria are met:
• AHI > 20 or oxygen desaturations less than 90% as determined by a nocturnal polysomnogram has been performed in an approved facility.
• Cephalometric abnormalities
• (Clinically Significant) Hypopharyngeal obstruction
• CPAP/BIPAP trial over a period of time (unless RDI less than 5 cannot be achieved) or patient has immediate intolerance (true claustrophobic reaction)
• Otolaryngologist evaluation with appropriate interventions
• If UPPP performed prior to orthognathic surgery, will need to repeat sleep study demonstrating obstructive sleep apnea

**Radiofrequency ablation of palatal tissues or radiofrequency volumetric tissue reduction (Somnoplasty) does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** for simple snoring, upper airway resistance syndrome and obstructive sleep apnea syndrome.

**Uvullectomy does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** when used for the treatment of snoring.

**Midline glossectomy does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for the treatment of upper airway obstruction syndrome and obstructive sleep apnea syndrome and is considered **investigational**.

**Palatal stiffening procedures**, including but not limited to, cautery assisted palatal stiffening operation, and the implantation of palatal implants, **do not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and are considered **non-covered** in the treatment of snoring alone, and are considered **investigational** as a treatment for upper airway resistance syndrome or OSA.

**Atrial pacing does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**Repose tongue suspension system does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational**.

**Simple snoring in the absence of documented obstructive sleep apnea** is not considered a medical condition; therefore, any surgical intervention, such as LAUP, radiofrequency volumetric tissue reduction of the palate, or palatal stiffening procedures, does not meet Blue Cross and Blue Shield of Alabama’s coverage criteria and is considered **non-covered**.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member’s contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*
**Key Points:**

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 hallmark clinical symptom of obstructive sleep apnea is excessive snoring.

A polysomnogram is the diagnostic test of choice and a variety of polysomnographic indices have been used to evaluate the patient with sleep apnea. An Apnea/Hypopnea Index (AHI) in adults ≥ 5 to 15 is considered mild OSA, 15 to 30 is considered moderate and > 30 is severe. Pediatric (< 12 years of age) AHI 1 to < 5 is mild, 5 < 10 is moderate and > 10 is severe.

Non-surgical treatment for obstructive sleep apnea or upper airway resistance syndrome includes weight loss, continuous positive airway pressure (CPAP), Bi-Level Positive airway pressure (Bi-PAP), auto-adjusting CPAP (APAP), or orthodontic repositioning. Nasal or oral continuous positive airway pressure (CPAP) is continuous positive airway pressure applied through the nose or via oral appliance. The pressure delivered comes through a flow generator to a mask and supplies a pressure level sufficient to keep the upper airway patent. The pressure used is determined individually with a CPAP trial. 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 positive airway pressure (BiPAP) provides two levels of positive pressure via a mask that augments patient ventilation. BiPAP responds to changes in the individual’s inhalation and exhalation patterns and is normally instituted after a trial of CPAP has proven ineffective.

Another alternative for the treatment of snoring and obstructive sleep apnea is oral appliances. Oral appliances are used for many purposes, including occlusal disorders. Oral appliances offer an alternative for sleep apnea patients dissatisfied with other therapies or unwilling to accept more complex interventions. The appliances may be a mandibular advancing device or tongue retainer that keeps the tongue in an anterior position. Other technologies are available on CPAP as pressure relief technology by reducing the pressure of exhalation and returning to therapeutic pressure just before inhalation. One type is made by Respironics and known as C-Flex; Bi-flex for BiPAP and A-flex as an auto adjusting technology.

Bi-level positive airway pressure-spontaneous timed (BiPAP S/T) is not appropriate for obstructive apnea. It is designed to assist ventilation noninvasively. It is sometimes used for patients with neuromuscular respiratory insufficiency or restrictive lung disease from thoracic wall deformity and chronic respiratory failure due to chronic obstructive pulmonary disease (COPD). Other methods of assist ventilation that may be used invasively are not appropriate for obstructive sleep apnea. Additional information regarding BiPAP S/T is available on Blue Cross and Blue Shield of Alabama’s medical policy #203, Respiratory Assist Device, Bi-level Pressure Capability, with Backup Rate Feature (BiPAP® S/T).

Auto-titrating continuous positive airway pressure (auto-CPAP or APAP) utilizes a device that continually adjusts the level of pressure, as needed, to maintain airway patency. It has been investigated, both as a means to establish the required level of therapeutic "fixed" CPAP for long-term use, (as an alternative to sleep laboratory, technician- titrated CPAP), and as a long-term therapeutic alternative to fixed CPAP in adults.
Surgical procedures include: uvulopalatopharyngoplasty (UPPP), laser-assisted uvulopalatoplasty (LAUP), radiofrequency ablation of palatal tissues and a variety of maxillofacial surgeries such as genioglossal advancement, hyoid suspension and mandibular-maxillary advancement (MMA). The uvulopalatopharyngoplasty (UPPP) is the most commonly performed procedure, involving surgical resection of the mucosa and submucosa of the soft palate, tonsillar fossa, and the lateral aspect of the uvula. The amount of tissue removed is individualized for each patient. This procedure enlarges the oropharynx but cannot correct obstructions in the hypopharynx. Additional procedures include hyoid suspensions, maxillary and mandibular osteotomies, or modification of the tongue.

The laser-assisted uvulopalatoplasty (LAUP) is an outpatient alternative that has been promoted as a treatment of snoring with or without associated obstructive sleep apnea. In this procedure superficial palatal tissues are sequentially reshaped using a CO2 laser and does not remove or alter tonsils or lateral pharyngeal wall tissues. The patient may undergo from three to seven sessions at three to four week intervals. LAUP cannot be considered an equivalent procedure to the standard UPPP, with the laser simply representing a surgical tool that the physician may opt to use. LAUP is considered a unique procedure, which raises its own issues of safety and, in particular, effectiveness.

Radiofrequency ablation of palatal tissues is similar in concept to LAUP, although a different energy source is used. Radiofrequency is used to produce thermal lesions within the tissues rather than using a laser to ablate the tissue surface, which may be painful. In some situations, radiofrequency of the soft palate and base of tongue are performed together. The Somnoplasty® device is an FDA-approved device that has been used for radiofrequency ablation of palatal tissues and for the base of the tongue.

Uvulectomy is the excision of the uvula and is sometimes performed for snoring.

An enlarged tongue may also be a part of the obstructive airway. A midline glossectomy (MLG) removes redundant tissue at the base of the tongue by making a V-type incision in the tongue to decrease excess tissue.

Genioglossal advancement has the advantage of not altering the jaw position or occlusion. There are several techniques for this procedure. Osteotomies that are performed are angled to include the geniotubercle. Hyoid suspension and myotomy includes advancement of the hyoid bone anteriorly to the mandible or alternatively advanced onto the laryngeal cartilage. Advancement of the hyoid bone through its attachments draws the epiglottis, vallecula, and tongue base forward. Maxillomandibular advancement includes a standard Le Fort I osteotomy in combination with bilateral sagittal split ramus osteotomies for the simultaneous advancement of the maxilla and mandible. In many cases, advancement geniotomy, with or without hyoid myotomy and suspension, is also performed.

Palatal stiffening procedures include a cautery-assisted palatal stiffening operation (CAPSO), insertion of palatal implants and insertion of palatal implants. The CAPSO procedure uses cautery to induce a midline palatal scar designed to stiffen the soft palate to eliminate excessive snoring. The Pillar™ Palatal Implant System (Restore Medical, St. Paul, MN) is an implantable
device that has been cleared by the FDA 501(k) process. The device is a cylindrical shaped segment of braided polyester filaments that is permanently implanted submucosally in the soft palate. The labeled indication of the device is as follows: “The Pillar™ Palatal Implant System is intended for the reduction of the incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).”

The use of atrial overdrive pacing (AOD) is also being evaluated in the treatment of obstructive sleep apnea. This approach is being tried because of the bradycardia that generally occurs during episodes of apnea.

The Repose™ system is a minimally invasive technique for tongue-base suspension in the treatment of sleep-disordered breathing caused by tongue-base collapse. This procedure involves the insertion of a titanium miniscrew with attached suture to the inner side of the mandible, below the tooth roots. It is indicated for the treatment of OSA and/or snoring.

In 2013, Handler et al reported a systematic review of tongue suspension versus hypopharyngeal surgery for the treatment of OSA. The review included 27 studies reporting on four separate procedures: tongue suspension alone, tongue suspension + UPPP, genioglossus advancement (GA) + UPPP, and genioglossus advancement + hyoid suspension (GAHM) + UPPP. A successful treatment was defined as a 50% decrease in the RDI or AHI and a postoperative RDI or AHI less than 20. Tongue suspension alone (6 studies, 82 patients) had a success rate of 36.6%, while the success rate of tongue suspension + UPPP (8 studies, 167 patients) was 62.3%. A success rate of 61.1% was found for GA + UPPP (7 studies, 151 patients) and for GAHM + UPPP (12 studies, 467 patients). The adverse effects of tongue suspension appear to be milder than GA or GAHM and are reversible. Most of the studies identified in this review were level IV evidence (case series).

One level II RCT included in the systematic review compared two tongue base surgeries (RFA or tongue-base suspension) combined with UPPP for moderate to severe sleep apnea (AHI >15). In the tongue suspension + UPPP group (n=28), the mean AHI decreased from 33.1 to 15.1 events per hour. The success rate for the combined procedure (defined as a >50% reduction, final AHI<15, and ESS<11) was 57.1%, compared with a success rate of 51.7% in the UPPP + RFA group (p=0.79). Body mass index (BMI) was the main predictor of success, with a success rate for tongue base suspension + UPPP of only 10% in patients with a BMI between 30 and <35 kg/m². Morbidity and complications were higher with the tongue suspension procedure compared with RFA.

Winx™ Sleep Therapy System by ApniCure uses platform called Oral Pressure Therapy (OPT) to treat obstructive sleep apnea. OPT is a light oral vacuum delivered by a pressure console through a slim tube which is connected to a soft flexible mouthpiece. The mouthpiece and vacuum work together to gently pull the soft palate forward and stabilize the tongue. This action is proposed to increase the size of the airway and allow for more natural breathing to occur while sleeping. Mouthpieces of different sizes are available. Once the mouthpiece has been determined to be the correct size the patient should be evaluated by a physician to determine the effects of the treatment. The console system tracks and stores on a standard SD card the patients usage to determine compliance.
In 2014, the STAR Trial Group reported 12-month outcomes from a multicenter single-arm study (NCT01161420, n=126) of the Inspire® Upper Airway Stimulation system. Patients were included if the AHI score from the screening PSG was at least 20 and no more than 50 events per hour. At 12 months after implantation 66% of the participants met the co-primary outcome of at least a 50% decrease in AHI with a final AHI of less than 20 events per hour, and 75% met the co-primary outcome of a reduction in the oxygen desaturation index score of 25% or more. The median AHI decreased from 29.3 to 9.0 events per hour (mean, 32.0 to 15.3) and the oxygen desaturation index score (number of times per hour that SO2 drops by 4% or more) decreased from 25.4 to 7.4 events per hour (mean, 29.9 to 13.9). The mean ESS decreased from 11.6 to 7.0. The first 46 patients who responded to therapy were then randomized to either continued therapy or withdrawal from therapy. After seven days, AHI of the continued treatment group remained stable from a mean of 7.2 to 8.9 events per hour, whereas the mean AHI in the withdrawal group increased from 7.6 to 25.8. Eighteen percent of participants had temporary tongue weakness and 21% reported tongue soreness, including abrasion, which resulted from stimulation-induced tongue motion over the lower teeth.

A series of 31 patients implanted with the Apnex hypoglossal nerve stimulation system (HGNS®) was reported in 2014. The system is currently being studied in a Phase III randomized controlled trial (www.clinicaltrials.gov NCT01446601). Both groups will undergo implantation of the HGNS® system. The experimental group will have the system turned on at one month postimplant and the control arm will have the system turned on at seven months postimplant. The study has an estimated enrollment of 132 patients with completion of data collection in 2013 and final study completion expected October 2017.

**Key Words:**
Uvulopalatopharyngoplasty, UPPP, UP-3, laser-assisted palatoplasty, LAUP, continuous positive airway pressure, CPAP, Bi-level positive airway pressure, BiPAP, somnoplasty, radiofrequency ablation, obstructive sleep apnea syndrome, OSA, OSAS, upper airway resistance syndrome, UARS, uvulectomy, genioglossal advancement, hyoid suspension and myotomy, maxillomandibular advancement, palatal implants, Pillar™, snoring, cautery-assisted palatal stiffening, auto-titrated CPAP, auto-adjusting CPAP, APAP, oral appliances, OA, mandibular repositioning device, MRA, atrial pacing, BiPAP BiFlex, Repose, C-Flex, A-Flex, Auto-CPAP, PROVENT EPAP, nasal expiratory positive airway pressure, Winx™ Sleep Therapy System, ApniCure, Oral Pressure Therapy (OPT), Inspire II Upper Airway Stimulation System

**Approved by Governing Bodies:**
The Somnoplasty System received FDA (510K) approval in September 1997. It is intended for use in the coagulation of soft tissue in the inferior turbinate for the treatment of chronic hypertrophic rhinitis.

The Pillar™ Palatal Implant System (Restore Medical, St. Paul, MN) is an implantable device that has been cleared by the FDA 501(k) process in late 2002. The labeled indication of the device is as follows: “The Pillar™ Palatal Implant System is intended for the reduction of the
incidence of airway obstructions in patients suffering from mild to moderate OSA (obstructive sleep apnea).”

PROVENT (Ventus Medical) is a nasal expiratory resistance valve (EPAP) which received marketing clearance as a 510K through the FDA in 2010 for the treatment of OSA. PROVENT is a single use device containing valves that are inserted into the nostrils and secured with tape.

The American Academy of Pediatrics (AAP) published a 2012 clinical practice guideline on the diagnosis and management of childhood OSA. AAP recommends that if a child has OSA, a clinical examination consistent with adenotonsillar hypertrophy, and does not have a contraindication to surgery, the clinician should recommend adenotonsillectomy as the first line of treatment. AAP recommends that patients should be referred for CPAP management if symptoms/signs or objective evidence of OAS persists after adenotonsillectomy or if adenotonsillectomy is not performed. Weight loss should be recommended in addition to other therapy if a child/adolescent with OSA is overweight or obese (Strength: Recommendation).

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS) has a 2014 revised policy statement on surgical management of OSA. Procedures the AAO-HNS supports as effective and not considered investigational when part of a comprehensive approach in the medical and surgical management of adults with OSA include tracheotomy, nasal and pharyngeal airway surgery, tonsillectomy and adenoidectomy, palatal advancement, UPPP, UPP (including laser assisted and other techniques), genioglossal advancement, hystoid myotomy, midline glossectomy, tongue suspension, and maxillary and mandibular advancement. Links are provided to position statements on nasal surgery and OSA, midline glossectomy, tongue suspension, genioglossus advancement, hystoid myotomy, and UPPP. In the 2012 position statement on UPPP, AAO-HNS concluded that UPPP is a valid treatment of OSA. Either simultaneous or serial surgical procedures are considered medically necessary and effective for patients with mild to severe obstructive sleep apnea. A 2012 position statement recommends tongue suspension as effective when considered as part of a comprehensive approach in the medical and surgical management of adult patients with mild OSA and in adult patients with moderate and severe OSA who have evidence of tongue base or associated hypopharyngeal obstruction. AAO-HNS notes that results appear to diminish in obese patients, and this technique should receive a weaker recommendation for these patients.

In 2012, the American Society for Metabolic and Bariatric Surgery published guidelines on the perioperative management of OSA. The guideline states that OSA is strongly associated with obesity with the incidence of OSA in the morbidly obese population being reported to be between 38% and 88%. They recommend bariatric surgery be the initial treatment of choice for OSA in this population, as opposed to surgical procedures directed at the mandible or tissues of the palate.

FDA Approved
Airvance® (Medtronic; formally the Repose™ Bone Screw System from Influence) was cleared for marketing through the 510(k) process in 1999 with intended use for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone using a bone screw with pre-threaded suture. It is indicated for the treatment of OSA and/or snoring. The Encore™ Tongue Suspension System (Siesta Medical) received clearance for marketing in 2011.
citing the PRELUDE III Tongue Suspension System (Siesta Medical) as a predicate device. FDA product codes: LRK, ORY.

The Inspire II Upper Airway Stimulation System (Inspire Medical Systems) received FDA approval in May 2014. In 2011, Apnex Medical received FDA approval to conduct a randomized investigational device exemption trial for the Hypoglossal Nerve Stimulation (HGNS®) System.

Winx™ Sleep Therapy System, received 510 K clearance from the FDA on May 18, 2012, for the treatment of obstructed sleep apnea.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

**Effective October 1, 2011,** Monsanto Group numbers 01342, 39317, 47426, and 50164: special benefit considerations apply.
Pre-certification: Not applicable

**Effective October 1, 2010,** electronic pre-determinations will be available for Alabama providers. The online pre-determination form can be accessed through ProviderAccess on the Blue Cross and Blue Shield of Alabama web site.

Coverage for oral appliances is limited to one appliance every three years and repairs are covered as necessary. Inclusive in the global fee for the device: initial evaluation, oral/dental impressions, diagnostic casting, fabrication of the application, initial fitting, patient education and teaching of use of the device and 90 days for follow-up office visits and adjustment of appliance/device.

**Current Coding:**
CPT codes:
- 21120 Genioplasty; augmentation (autograft, allograft, prosthetic material)
- 21121 Genioplasty; sliding osteotomy, single piece
- 21122 Genioplasty; sliding osteotomies, two or more osteotomies (e.g., wedge excision or bone wedge reversal for asymmetrical chin)
- 21123 Genioplasty; sliding, augmentation with interpositional bone grafts (includes obtaining autografts)
- 21199 Osteotomy, mandible, segmental with genioglossal advancement
- 21299 Unlisted craniofacial and maxillofacial procedure
- 21685 Hyoid myotomy and suspension (Effective 01/01/2004)
- 41120 Glossectomy; less than one-half tongue (Effective 01/01/2004)
41130 Glossectomy; hemiglossectomy (Effective 01/01/2004)
41512 Tongue base suspension, permanent suture technique (Effective 01/01/2009)
41530 Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session (Effective 01/01/2009)
42120 Resection of palate or extensive resection of lesion (Effective 01/01/2004)
42140 Uvullectomy, excision of uvula (Effective 01/01/2004)
42145 Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty) (Effective 01/01/2004)
42299 Unlisted procedure, Palate or Uvula (Effective 01/01/2004)

HCPCS Codes:

A7047 Oral interface used with respiratory suction pump, each (Effective 01/01/2014)
E0470 Respiratory assist device, bi-level pressure capability, without backup rate feature, used with non-invasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device) (Effective 01/01/2004)
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) (Effective 01/01/2004)
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) (Effective 01/01/2004)
E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment. (Effective 01/01/2006)
E0486 Oral device/appliance used to reduce upper airway collapsibility, adjustable or on-adjustable, custom fabricated, includes fitting and adjustment (Effective 01/01/2006)
E0561 Humidifier, non-heated, used with positive airway pressure device (Effective 01/01/2004)
E0562 Humidifier, heated, used with positive airway pressure device (Effective 01/01/2004)
E0601 Continuous airway pressure (CPAP) device—(This code should also be used to bill the APAP devices.) (Effective 01/01/2004)
E1399 Unlisted code – This should be used to report the Winx™ system and all associated supplies
K0553 Combination oral/nasal mask, used with continuous positive airway pressure device, each (Effective 07/01/2007)
K0554 Oral cushion for combination oral/nasal mask, replacement only, each (Effective 07/01/2007)
K0555 Nasal pillows for combination oral/nasal mask, replacement only, pair (Effective 07/01/2007)
S2080 (Invalid for Medicare 2002) Laser-assisted Uvulopalatoplasty (LAUP) (Effective 01/01/2004)

Previous Coding:

Effective for dates of service on or after January 1, 2005:
0088T Submucosal radiofrequency tissue volume reduction of tongue base, one or more sites, per session (i.e., for treatment of obstructive sleep apnea syndrome (Deleted effective January 1, 2009)
S8260 Oral orthotic for treatment of sleep apnea, includes fitting, fabrication, and materials (Deleted effective April 1, 2006)

References:


Council on Cardiovascular Nursing in Collaboration with the National Heart, Lung, and Blood Institute National Center on Sleep Disorders Research (National Institutes of Health. JACC 2008; 52: 686-717.


84. Wassmuth Z, Mair E, Loube D and Leonard D. Cautery assisted palatal stiffening

Policy History:
Medical Policy Group, August 2002
Medical Policy Administration Committee, September 2002
Available for comment December 18, 2002-February 3, 2003
Medical Policy Group, October 2003 (1)
Medical Policy Group, October 2004
Medical Policy Group, February 2005 (3)
Medical Policy Administration Committee, July 2005
Available for comment August 6-September 19, 2005
Medical Policy Group, October 2005 (1)
Medical Policy Administration Committee, October 2005
Available for comment October 24-December 7, 2005
Medical Policy Group, July 2006 (1)
Medical Policy Administration Committee, August 2006
Available for comment August 4-September 18, 2006
Medical Policy Group, February 2007
Medical Policy Group, July 2007 (1)
Medical Policy Administration Committee, July 2007
Available for comment July 27-August 15, 2007
Medical Policy Group, August 2007 (1)
Medical Policy Administration Committee, August 2007
Available for comment August 16-September 29, 2007
Medical Policy Group, February 2009 (1)
Medical Policy Group, March 2010 (3): Policy update regarding Medical management, and clarification, References added, Key Points
Medical Policy Administration Committee April 2010
Available for comment March 24-May 7, 2010
Medical Policy Group, June 2010 (3)
Medical Policy Administration Committee, July 2010
Medical Policy Group, July 2010 (3)
Medical Policy Administration Committee, August 2010
Available for comment August 6-September 18, 2010
Medical Review Group, March 2011 (3)
Medical Policy Administration Committee, March 2011
Available for comment April 4 – May 18, 2011
Medical Policy Group, July 2011; Update to Benefit Application Section –Monsanto Grp
Medical Policy Group, April 2012 (3): Updated Policy to add oral devices (Provent), Key Points, Approved by Governing Bodies, & References
Medical Policy Administration Committee; May 2012
Available for comment May 10 through June 25, 2012
Medical Policy Group, May 2012 (3): Updated Key Points and References
Medical Policy Group, May 2012 (3): Added information regarding non-coverage of the Winx™ System, Oral Pressure Therapy (by ApniCure)
Available for comment June 14 through July 30, 2012
Medical Policy Panel, May 2013
Medical Policy Group, May 2013 (3): 2013 Updates – no new literature available for review through April 17, 2013; no changes in policy statement
Medical Policy Group, April 2014 (5): Updated Maximums for CPAP tubing; Policy section reworked and organized to include Medical and Surgical management of OSA under new effective date.
Medical Policy Administration Committee May 2014
Available for comment May 6 through June 19, 2014
Medical Policy panel, May 2014
Medical Policy Group, June 2014(5): Updated Policy statement adding investigational statement for hypoglossal nerve stimulation; Key word, Key Points, Approved by Governing Bodies, & References updated with literature review through April 25, 2014.
Medical Policy Administration Committee June 2014
Available for comment June 19 through August 2, 2014
Medical Policy Group, July 2014(5): Updated policy statement to included RERA(respiratory event-related arousals) in the definition of RDI; Rearranged and added information under description and added reference July 2014.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.