SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Description:

**Adult:**
Individual 18 years of age or older.

**Child:**
Individual under 18 years of age.

**Obstructive Sleep Apnea Syndrome (OSAS):**
OSAS is a condition characterized by repetitive episodes of upper airway obstruction that occurs during sleep due to collapse of the upper airway. It is usually associated with a reduction in blood oxygen saturation. OSAS may also be referred to as obstructive sleep apnea (OSA).

**Upper Airway Resistance Syndrome (UARS):**
A variant of OSAS that is characterized by a partial collapse of the airway resulting in increased resistance to airflow. The increased respiratory effort is associated with multiple sleep fragmentations, as measured by very short alpha electroencephalographic (EEG) arousals (Respiratory Event Related Arousals or RERAs).

**Medical Management of OSAS:**
Proposed treatments for adults may include weight loss, avoidance of stimulants, body position adjustment, oral appliances and various types of positive pressure therapy (i.e., fixed continuous positive airway pressure [CPAP], bi-level positive airway pressure [BiPAP] or auto-adjusting continuous positive airway pressure [APAP, also referred to as auto-adjusting CPAP] or expiratory positive airway pressure [EPAP e.g., Provent® Therapy]) or negative pressure therapy known as oral pressure therapy (OPT e.g., Winx® System). Oral appliances (OA) can be categorized as mandibular advancing/positioning devices, tongue fixation devices, night guards, occlusal orthotic devices and occlusal guards/splints. **Appliances are custom made by a laboratory or similar provider.**

For most children, surgery (adenotonsillectomy) is the first-line treatment for OSAS.

**Surgical Management of OSAS and UARS:**
Proposed treatments for adults include hyoid suspension, laser-assisted uvulopalatoplasty (LAUP) maxillofacial surgery, including mandibular-maxillary advancement (MMA), palatal implant (device implanted into soft palate), somnoplasty (radiofrequency volumetric tissue reduction of tongue and palatal tissue), uvulopalatopharyngoplasty (UPPP), hypoglossal nerve stimulation (HGNS) and surgical modification of the tongue, e.g., genioglossus advancement or tongue base suspension. **Oral surgical splints are used postoperatively and are custom made by the surgeon.**

For children, the first-line treatment is generally adenotonsillectomy.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Description: (cont.)

Apneic-Hypopneic Index (AHI):
The number of episodes of apnea and hypopnea per hour of sleep as recorded by a polysomnography. The polysomnography must be performed by a certified sleep laboratory, either in an overnight laboratory or home setting, and reviewed by a certified practitioner and BCBSAZ eligible provider. AHI may also be referred to as respiratory disturbance index (RDI).

Excessive Daytime Sleepiness:
A condition evidenced in adults by an Epworth Sleepiness Scale greater than 10, inappropriate daytime napping (e.g., during driving or eating), or sleepiness that interferes with daily activities and is not explained by other conditions. In a child, it may be expressed as learning difficulties or other daytime neurobehavioral problems.

Respiratory Disturbance Index (RDI):
The number of episodes of apnea and hypopnea per hour of sleep as recorded by a polysomnography. The polysomnography must be performed by a certified sleep laboratory, either in an overnight laboratory or home setting, and reviewed by a certified practitioner and BCBSAZ eligible provider. RDI may also be referred to as apneic-hypopneic index (AHI). RDI may be defined as the number of apneas, hypopneas and Respiratory Event Related Arousals (RERAs) per hour of sleep.

Respiratory Event Related Arousals (RERAs):
Increased respiratory effort associated with multiple sleep fragmentations as measured by very short alpha electroencephalographic (EEG) arousals. The resistance to airflow is usually subtle and does not result in score-able apneic or hypopneic episodes. 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 apnea or hypopnea.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Description: (cont.)

Sleep Studies:
The simultaneous recording of physiological variables during sleep. Polysomnography is another name for sleep study. Sleep studies may be done in a healthcare facility or in the home setting. If done in the home setting, they may or may not be attended by a technologist. Sleep studies may be used to assist in the diagnosis of OSAS.

Sleep studies include sleep staging to assess arousals from sleep and determination of the frequency of apneas and hypopneas from channels measuring oxygen desaturation, respiratory airflow and respiratory effort. Cardiac, muscle, brain and ocular function may also be recorded. Actigraphy, a technique to record and analyze body movement, may also be a component of a sleep study. Available devices include:

- Type I device: full-channel nocturnal polysomnography. The sleep study using this device is performed in a healthcare facility and a technologist is in attendance.
- Type II device: portable monitor using a minimum of 7 channels. The sleep study using this device is performed in the home and may be attended or unattended.
- Type III device: portable monitor using a minimum of 4 channels. The sleep study using this device is performed in the home and may be attended or unattended.
- Type IV device: portable monitor using a minimum of 3 channels. The sleep study using this device is performed in the home, may be attended or unattended and may be referred to as the Watch-PAT device.

Criteria:

For diagnosis and medical management of Obstructive Sleep Apnea Syndrome, see BCBSAZ Medical Coverage Guideline #O782, “Diagnosis and Medical Management of Obstructive Sleep Apnea Syndrome”.

For implantable neurostimulator for the treatment of central sleep apnea, see BCBSAZ Medical Coverage Guideline #O968, “Implantable Neurostimulator for the Treatment of Central Sleep Apnea”.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Criteria: (cont.)

Definitions, Clinically Significant:

Clinically Significant Obstructive Sleep Apnea Syndrome (OSAS):

- Obstructive sleep apnea syndrome is considered clinically significant with documentation of ONE of the following:

1. Adult with documentation of ONE of the following:
   - Apneic-hypopneic index (AHI) or respiratory disturbance index (RDI) of 15
   - AHI or RDI between 5 and 14 with documentation of ANY of the following associated symptoms:
     - Excessive daytime sleepiness
     - History of stroke
     - Hypertension
     - Impaired cognition
     - Insomnia
     - Ischemic heart disease
     - Mood disorders

2. Child with documentation of ONE of the following:
   - Apneic-hypopneic index (AHI) or respiratory disturbance index (RDI) of 5 or more
   - AHI or RDI between 1.5 and 4 with documentation of ANY of the following associated symptoms:
     - Behavioral problems
     - Excessive daytime sleepiness
     - Hyperactivity
Definitions, Clinically Significant: (cont.)

Clinically Significant Upper Airway Resistance Syndrome (UARS):

- Upper airway resistance syndrome is considered clinically significant with documentation of greater than or equal to 10 episodes of electroencephalogram (EEG) arousal per hour of sleep in association with negative intrathoracic pressures.

Treatment of OSAS and UARS:

- The following palatopharyngoplasty procedures for the treatment of clinically significant OSAS or clinically significant UARS in an adult who has failed an adequate trial of CPAP or APAP device or failed an adequate trial of an OA is considered medically necessary.

  1. Uvulopalatopharyngoplasty (UPPP)
  2. Uvulopharyngoplasty
  3. Uvulopalatal flap
  4. Expansion sphincterpharyngoplasty
  5. Lateral pharyngoplasty
  6. Palatal advancement pharyngoplasty
  7. Relocation pharyngoplasty

- Uvulopalatopharyngoplasty (UPPP) for the treatment of clinically significant OSAS or clinically significant UARS in a child is considered medically necessary with documentation of ALL of the following:

  1. Pediatric surgical specialist recommends the procedure
  2. Adenotonsillectomy has been performed and child cannot tolerate the use of a CPAP device
  3. ONE of the following:
     - Thick, soft palate and long uvula present
     - Trisomy 21
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Criteria: (cont.)

Treatment of OSAS and UARS: (cont.)

- The following procedures for the treatment of clinically significant OSAS or clinically significant UARS in an adult are considered medically necessary with documentation of ALL of the following:
  1. Objective hypopharyngeal obstruction
  2. Failure of an adequate trial of CPAP, APAP or OA

  These procedures include:
  - Hyoid suspension
  - Maxillofacial surgery, including mandibular-maxillary advancement (MMA)
  - Surgical modification of the tongue (e.g., genioglossus advancement)

- Adenotonsillectomy for the treatment of clinically significant OSAS and hypertrophic tonsils or clinically significant UARS and hypertrophic tonsils in a child is considered medically necessary.

- The following procedures for the treatment of clinically significant OSAS or clinically significant UARS are considered medically necessary with documentation of ALL of the following:
  1. Individual with craniofacial syndrome
  2. Procedure recommended by a surgical specialist

  These procedures include, but are not limited to:
  - Craniofacial advancement
  - Tracheotomy/tracheostomy

- If above criteria not met, surgical treatment of OSAS or UARS is considered not medically necessary.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Criteria: (cont.)

Treatment of OSAS and UARS: (cont.)

➢ Implantable hypoglossal nerve stimulators for all indications, including but not limited to, the treatment of OSAS or UARS are considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting.

Devices include, but are not limited to:

- Inspire® Upper Airway Stimulation (UAS)

➢ The following procedures for the treatment of OSAS or UARS are considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome.

These procedures include, but are not limited to:

- Laser-assisted uvulopalatoplasty (LAUP)
- Palatal stiffening procedures including, but not limited to, cautery-assisted palatal stiffening operation, injection of a sclerosing agent, and the implantation of palatal implants
- Somnoplasty (radiofrequency volumetric tissue reduction of tongue and palatal tissue)
- Tongue base suspension
- All other minimally-invasive surgical procedures not described above
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Criteria: (cont.)

Treatment of Snoring:

➢ Treatment of snoring is considered not medically necessary (simple snoring in the absence of documented OSAS is not considered a medical condition).

These treatments include, but are not limited to:

- Hyoid suspension
- Injection snoreplasty
- Laser-assisted uvulopalatoplasty (LAUP)
- Maxillofacial surgery, including mandibular-maxillary advancement
- Palatal stiffening with insertion of palatal implant
- Somnoplasty (radiofrequency volumetric tissue reduction of tongue and palatal tissue
- Surgical modification of the tongue (e.g., genioglossus advancement)
- Tongue base suspension
- Uvulopalatopharyngoplasty (UPPP)

Resources:

Literature reviewed 10/30/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 06/19/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Resources: (cont.)


SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Resources: (cont.)


SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Resources: (cont.)


FDA Premarket Approval Database for Inspire Upper Airway Stimulation (UAS):

- FDA-approved indication: Inspire Upper Airway Stimulation (UAS) is used to treat a subset of patients with moderate to severe Obstructive Sleep Apnea (OSA) (Apnea-hypopnea Index [AHI] of greater or equal to 15 and less than or equal to 65). Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate Positive Airway Pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ’s Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ’s Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe’é atah nilníígíí Blue Cross Blue Shield of Arizona haada yít’éego bina’ííd’ilkidgo éí dodago Háida bijá aniyeedííi t’áadool le’é yina’ííd’ilkidgo beeha’áanii hóoló díí t’áá hazaad’ehí háká a’doowolgo bee ha’á doo baách ilínígódíí. Atá’ halné’ígíí kojí bích’é’ hodillihíí 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viên, xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شريك تساعدك أسلحة بخصوص الضرورية بلغتك من دون أي تكلفة للتحدث مع مترجم النصل ب 877-475-4799.
SURGICAL TREATMENT OF SNORING AND OBSTRUCTIVE SLEEP APNEA SYNDROME (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang ibang tinitulungan, ay may mga katarungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makahawa ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 하시려면 877-475-4799로 전화해주시십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizonaについてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799までお電話ください。

Farsi:

به زبان شما می‌توانید اطلاعات به طور رایگان دریافت نمایید 877-475-4799. [سامانه حاوی کمک‌یابی]

Assyrian:

Blue Cross Blue Shield of Arizona می‌توانید به زبان ژباکت زبانکوچ باشید تا اطلاعات رایگان دریافت نمایید 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณหรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถติดต่อกับพวกเขาในภาษาของคุณโดยไม่เสียค่าใช้จ่าย โทร 877-475-4799.