MEDICAL POLICY – 2.01.532
Intraoral Appliances for the Treatment of Obstructive Sleep Apnea

Effective Date: Apr. 1, 2017
Last Revised: Mar. 14, 2017
Replaces: 2.01.503 (in part)

RELATED MEDICAL POLICIES:
1.01.524 Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea
2.01.503 Polysomnography and Home Sleep Study for Diagnosis of Obstructive Sleep Apnea
7.01.554 Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome

Introduction

Sleep apnea is a condition that causes a person to stop breathing for short periods of time during sleep. There are several ways to treat it, including using a specific type of device worn in the mouth (intraoral appliance). This dental appliance slightly moves the tongue and jaw forward, the end result being more air coming into the airway. These appliances look similar to mouth guards to prevent teeth grinding or to realign teeth. This policy describes when an intraoral device for sleep apnea is covered in adults.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intraoral appliances for adults</strong></td>
<td>Mandibular advancement oral appliances to reduce upper airway collapsibility or tongue retaining devices are considered medically necessary in adult patients (those age 18 years and older) who have sleep test results where one of the criteria outlined below have been met.</td>
</tr>
</tbody>
</table>

For intra oral appliances such as oral airway dilators, oral orthotics, oral airway devices or mandibular advancement devices – the following criteria must be met:

- A physician with additional training in sleep disorders must evaluate the patient and order this appliance

AND

- The apneic/hypopneic index (AHI) is greater than or equal to 15 events per hour and up to a maximum of 30 events per hour, including a minimum of 30 events documented per sleep study

OR

- The AHI is greater than or equal to 5 events per hour and less than 15 events per hour, including a minimum of 10 events documented per sleep study

AND

  o Documented history of stroke

OR

  o Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg)

OR

  o Documented ischemic heart disease

OR

  o Documented symptoms of impaired cognition, mood disorders, or insomnia

OR

  o Excessive daytime sleepiness (documented by either Epworth greater than 10 or MSLT less than 6)

OR

  o Greater than 20 episodes of desaturation (i.e., oxygen saturation of less than 85%) during a full night sleep study, or any 1 episode of oxygen desaturation (i.e., oxygen
<table>
<thead>
<tr>
<th>Equipment</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>saturation of less than 70%</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>o Obesity (BMI greater than 35)</td>
</tr>
<tr>
<td></td>
<td>• If the AHI is greater than 30 events per hour and meets either of the following:</td>
</tr>
<tr>
<td></td>
<td>o The patient is not able to tolerate a positive airway pressure (PAP) device</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>o The use of the PAP device is contraindicated</td>
</tr>
<tr>
<td>Intraoral appliances for children</td>
<td>Mandibular advancement oral appliances to reduce upper airway collapsibility or tongue retaining devices are considered not medically necessary as they are not recommended for pediatric patients (those under 18 years of age) due to lack of mature bite development.</td>
</tr>
</tbody>
</table>

**Coding**

<table>
<thead>
<tr>
<th>HCPCS</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0485</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment</td>
</tr>
<tr>
<td>E0486</td>
<td>Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Related Information**

Obstructive Sleep Apnea (OSA) is defined as:

- **Mild OSA:** AHI greater than 5/hr. and less than 15/hr
- **Moderate OSA:** AHI of 15/hr. or greater and 30/hr. or less
- **Severe OSA:** AHI of greater than 30/hr
Evidence Review

A 2013 randomized cross-over trial by Phillips et al. found similar health outcomes after 1 month of CPAP or oral appliance therapy (OAT) in 126 patients (82% with moderate to severe OSA, AHI >15). CPAP was more effective than mandibular advancement therapy in reducing AHI (CPAP AHI=4.5, OAT AHI=11.1), but patient-reported compliance was higher with OAT (6.5 vs. 5.2 hours/night). Neither treatment improved the primary outcome of 24-hour ambulatory blood pressure, except in a subgroup of patients who were initially hypertensive. The 2 treatments resulted in similar improvements in sleepiness (improvement of 1.6 to 1.9), FOSQ (improvement of 1.0), some measures on driving simulator performance, and disease-specific quality of life (QOL). OAT was superior to CPAP in 4 domains on the SF-36.

In 2013, a systematic review and meta-analysis was performed to compare the outcomes of oral appliances (OAs) with those of CPAP in treatment of patients with obstructive sleep apnea (OSA). The conclusions showed CPAP yielded better polysomnography outcomes, especially in reducing AHI, than OAs, indicating that OAs were less effective than CPAP in improving sleep-disordered breathing. However, similar results from OAs and CPAP in terms of clinical and other related outcomes were found, suggesting that it would appear proper to offer OAs to patients who are unable or unwilling to persist with CPAP.

Pediatric Patients

In the pediatric population, chronic snoring is abnormal. “Pediatric sleep-disordered breathing is a continuum, with primary snoring at one end, and complete upper airway obstruction, hypoxemia, and obstructive hypoventilation at the other.” Sleep disordered breathing symptoms are often attributed to enlarged tonsils and adenoids, but multiple possible anatomic obstructions need to be properly evaluated. Craniofacial and occlusal disharmony may be a significant underlying factor in the development and progression of pediatric sleep disorders.

Properly assessing facial and dental morphometric associations requires a comprehensive orthodontic evaluation as well as a pediatric [ENT] assessment for potential airway obstructions including enlarged tonsils and adenoids. “In contrast to sleep–disordered breathing or sleep apnea in adults, which is predominantly associated with obesity, sleep-disordered breathing symptoms is in this pediatric cohort primarily associated with adenotonsillar hypertrophy, morphologic features related to a long and narrow face [dolichofacial, height mandibular plane.
angle, narrow palate, and severe crowding in the maxilla and the mandible] allergies, frequent
colds, and habitual mouth breathing.”

A primary concern is that indiscriminate use of a mandibular advancement device (MAD) [E0486]
“in a growing child and/or adolescent may result in dramatic skeletal and dentofacial changes”. The
limited benefits of a MAD, can be far outweighed by dramatic and unplanned craniofacial skeletal
changes in a growing individual. The causes for sleep-disordered breathing symptoms in young adults are so varied that comprehensive medical/orthodontic workup is essential before any course of therapy is warranted.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

The American Academy of Craniofacial Pain (AACP)

The American Academy of Craniofacial Pain (AACP) Task Force on Mandibular Advancement Oral Appliance Therapy for Snoring and Obstructive Sleep Apnea published a position paper in 2013. The position paper states that oral appliance therapy is recognized as an effective therapy for many with primary snoring and mild to moderate OSA, as well as those with more severe OSA who cannot tolerate PAP therapies, but that oral appliance therapy has the potential to cause adverse effects including temporomandibular joint (TMJ) pain and dysfunction. The authors recommend that dentists engaged in, or who wish to engage in, the assessment and management of patients with snoring and OSA using mandibular advancement oral appliances should be properly trained and experienced in the assessment, diagnosis and management of TMJ and craniofacial pain.

National Institute for Health and Clinical Excellence (NICE)

National Institute for Health and Clinical Excellence (NICE) in 2008, issued guidance on CPAP
treatment of OSA, based on a review of the literature and expert opinion. The recommendations included:

- CPAP treatments aim to reduce daytime sleepiness by reducing the number of episodes of apnea/hypopnea experienced during sleep. The alternatives to CPAP are lifestyle management, dental devices, and surgery. Lifestyle management involves helping people to lose weight, stop smoking and/or decrease alcohol consumption. Dental devices are designed to keep the upper airway open during sleep. The efficacy of dental devices has
been established in clinical trials, but these devices are traditionally viewed as a treatment option only for mild and moderate OSAHS. Surgery involves resection of the uvula and redundant retrolingual soft tissue. However, there is a lack of evidence of clinical effectiveness, and surgery is not routinely used in clinical practice.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/14</td>
<td>New policy. Intraoral appliance information pulled from policy 2.01.503. Policy held for provider notification and will become effective October 23, 2014.</td>
</tr>
<tr>
<td>10/23/14</td>
<td>Reissue policy as updates are now effective; reference to previous version removed.</td>
</tr>
<tr>
<td>05/27/15</td>
<td>Annual Review. Policy updated with literature review. Definition of OSA added to Policy section; no change in policy statements.</td>
</tr>
</tbody>
</table>
### Historical Notes

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/11/16</td>
<td>Annual Review. No change in policy statements. Policy moved to new format.</td>
</tr>
<tr>
<td>03/14/17</td>
<td>Annual Review. References 7, 8, and 9 were added. Statement added to clarify non-application to pediatric patients; oral devices are considered not medically necessary as they are not recommended for this patient population. Age of pediatric patient clarified as under age 18.</td>
</tr>
</tbody>
</table>

### Disclaimer

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2017 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera 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:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the 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 S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost.

Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
بيحوي هذا الإشعار معلومات هامة. قد يحوي هذا الإشعار معلومات مهمة بخصوص طالب أو عملية التي تريد الحصول عليها من خلال Premera Blue Cross. يتم تحديد الإشعار في هذا الإشعار. يتم تحديد إجراءات في ترتيب معيار للحصول على معلومات الصحة والرعاية في دفع التكاليف. يتضمن الحصول على هذه المعلومات والمساعدة بكلية كريت ياف أن تكون عندك أي كلمة. إتصل بـ 800-722-1471 (TTY: 800-842-5357) وإخراج الموظف.

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

Cushite (Oromoo):
የሥጫው እየጫው እና የአማርኛው ያለው ያካና በPremera Blue Cross ከደን አስቀርበት. ያካና ከደን ለማስታወቂያ ማስታወቂያ ይጭጭው ያስገነዝበት. Premera Blue Cross ከደን ዜወከት ያለውን ከወጡ ያስገነዝበት. ለማስታወቂያ ያቀርበውን በ800-722-1471 (TTY: 800-842-5357) ይወጣው.

Creole (Kreyòl ayisyen):
Daytoy a Pakdaar ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaar mabalin nga adda ket naglaon iti Napateg nga impormasion maijangepp iti aplikayon nyenno coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a palsa iti daytoy a pakdaar. Mabalin nga adda rumbeng nga aramideny nga adda sakkay dagiti partikular a naituding nga adda aldaw tapno mapagaliyandeyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong iti bukodyo a paygasao nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

German (Deutsche):

Hmong (Hmong):
Tsaob ntawv tshaj xo no muaj cov ntxiab lus tseem ceeb. Tej zuam tsab ntawv tshaj xo no muaj cov ntxiab lus tseem ceeb tsox koj daint ntawv thov kev pob los yog koj qhov kev pob cuam los ntawv Premera Blue Cross. Tej zuam muaj cov shub tseem ceeb uss rau hauv daint ntawv no. Tej zuam koy jyuva taa u qee yam ush pob koj us tis pub dhuav cov cajy nyong uas teey tsox rau hauv daint ntawv no. Tej zuam koj jyuva taa u qee yam ush pob koj us tis pub dhuav cov cajy nyong uas teey tsox rau hauv daint ntawv no. Tej zuam koj jyuva taa u qee yam ush pob koj us tis pub dhuav cov cajy nyong uas teey tsox rau hauv daint ntawv no. Tej zuam koj jyuva taa u qee yam ush pob koj us tis pub dhuav cov cajy nyong uas teey tsox rau hauv daint ntawv no. Tej zuam koj jyuva taa u qee yam ush pob koj us tis pub dhuav cov cajy nyong uas teey tsox rau hauv daint ntawv no. Tej zuam koj jyuva taa u qee yam ush pob koj us tis pub dhuav cov cajy nyong uas teey tsox rau hauv daint ntawv no.

Italian (Italian):

Spanish (Español):
Este aviso contiene información importante. Este aviso puede contener información importante sobre tu solicitud o cobertura a través de Premera Blue Cross. Podrían ser esenciales fecha clave en este aviso. Podrías necesitar hacer un intervento antes de una fecha determinada para que puedas mantener tu cobertura o ayuda. Tienes derecho a obtener estas informaciones e asistencia en tu idioma gratuitamente. Llamar 800-722-1471 (TTY: 800-842-5357).
Este Aviso contiene información importante. 

Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

TAGALOG (Tagalog):
Ang Paunawa na ito ay naglalaan ng mahalagang impormasyon. Ang paunawa na ito ay maaring nagagamit ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Magaling ang mga mahalagang petsa na dapat magsalita sa iyong aplikasyon o pagsakop sa kalusugang tulong na walang gasto. Kung kaya, hindi dapat magsalita ang iyong aplikasyon o pagsakop sa kalusugang tulong na walang gasto.

CHINESE (Chinese):

ЗАПИСЬ ОБЯЗАТЕЛЬНАЯ. ЗАПИСЬ ОБЯЗАТЕЛЬНАЯ. ЗАПИСЬ ОБЯЗАТЕЛЬНАЯ. ЗАПИСЬ ОБЯЗАТЕЛЬНАЯ. ЗАПИСЬ ОБЯЗАТЕЛЬНАЯ. ЗАПИСЬ ОБЯЗАТЕЛЬНАЯ.

Трудной ситуации может быть важная информация. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

RUSSIAN (Russian):

В настоящем уведомлении содержится важная информация. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

SPANISH (Spanish):

Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

UKRAINIAN (Ukrainian):

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховочого покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).