

Department of Origin: Integrated Healthcare Services	Effective Date: 03/05/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 03/05/24
Clinical Policy Document: Obstructive Sleep Apnea, Non-Surgical Treatment	Replaces Effective Clinical Policy Dated: 06/06/23
Reference #: MC/C011	Page: 1 of 6

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity Criteria – Must satisfy the following: I, and any of II - V

- I. Member is diagnosed with obstructive sleep apnea (OSA) based on sleep study results (in-home or sleep center); and
- II. Requesting *positive airway pressure* (PAP) device – must satisfy any of the following: A or B
 - A. Initial request – must satisfy any of the following: 1 or 2
 1. Member is diagnosed with moderate to severe OSA as defined by an *AHI/RDI/REI* score of greater than or equal to 15; or
 2. Member is diagnosed with mild OSA as defined by an *AHI/RDI/REI* score of greater than or equal to 5 and less than 15, and documentation supports any of the following: a - g
 - a. History of stroke; or
 - b. Hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); or
 - c. Ischemic heart disease; or
 - d. Symptoms of impaired cognition, mood disorders, or insomnia; or
 - e. Excessive daytime sleepiness; or
 - f. Greater than 20 episodes of oxygen desaturation (ie, oxygen saturation of less than 85 %) during a full night sleep study, or any one episode of oxygen desaturation (ie, oxygen saturation of less than 70 %); or
 - g. Oxygen saturation less than or equal to 88% for > 5 minutes.
 - B. Replacement request – must satisfy the following: 1 and 2, and either 3 or 4
 1. Documentation of *adherence* with therapy; and
 2. The device is *malfunctioning*; and
 3. Member has had current *PAP* device for greater than or equal to 5 years; or
 4. The device is out of warranty.

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- III. Requesting custom fit (may be prefabricated or custom-fabricated) oral appliance – must satisfy any of the following: A or B
 - A. Initial request – must satisfy the following: 1, and any of 2 or 3
 1. Must be prescribed by an MD or DO and fitted by a qualified, licensed dentist (DDS or DMD); and
 2. Member has mild to moderate OSA as defined by an *AHI/RDI/REI* score of less than 30; or
 3. *PAP* has been tried with well-supported follow-up including involvement by qualified sleep specialist, and has clearly failed due to any of the following: a - h
 - a. Failure to improve symptoms after a minimum of one month trial; or
 - b. Difficulty tolerating pressure; or
 - c. Intolerance of nasal or mouth interface; or
 - d. Nasal irritation; or
 - e. Claustrophobia; or
 - f. Dry mouth; or
 - g. Removal of *PAP* device unintentionally during sleep; or
 - h. Documentation that *PAP* is contraindicated.
 - B. Replacement request – must satisfy all of the following: 1, and 2 or 3
 1. Documentation of regular follow-up within the previous 12 months; and
 2. Member has had current oral appliance for greater than or equal to 3 years; or
 3. There has been a change in the member's condition.
- IV. Claims for *PAP* and oral device will be allowed within the same 12-month period with supporting documentation, submitted by a qualified sleep specialist, reflecting that the member requires both due to failure of *PAP* alone.
- V. Repeat sleep studies are not medically necessary unless there is documentation that it is being performed for any of the following: A - D
 - A. To determine the effectiveness of a new device; or
 - B. For persistent symptoms of daytime sleepiness; or
 - C. Substantial weight loss (at least 10% of body weight); or
 - D. Change in clinical status (eg, worsening or improvement, abnormal findings on *PAP* download)

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description.

The following are considered investigative (see Investigative List): I – XXI

- I. Adjustable tongue-advancement device (eg, Advance system)

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- II. Apnea triggered muscle stimulation (does not include hypoglossal nerve stimulation)
- III. Cardiac (Atrial) Pacing
- IV. Cautery-Assisted Palatal Stiffening Operation (CAPSO)
- V. Epiglottidectomy
- VI. Expansion sphincteroplasty
- VII. Flexible Positive Airway Pressure (pressure-relief C-PAP [C-Flex, Respirationics])
- VIII. Genioplasty/genial tubercle advancement
- IX. Glossectomy, partial
- X. Injection Snoreplasty
- XI. Laser assisted Uvuloplasty (LAUP)
- XII. Mandibular distraction osteogenesis (MDO)
- XIII. Nasal dilators
- XIV. Obstructive Sleep Apnea (OSA) oral appliance to restore proper mandibular alignment after use of overnight sleep apnea appliance, for prevention of temporomandibular joint dysfunction (such as, but not limited to, the Direct AM Positioner, Morning Repositioner [SomnoMed])
- XV. Palatal Implants (Pillar Procedure)
- XVI. Provent Sleep Apnea Therapy
- XVII. Radiofrequency Volumetric Tissue Reduction of the palate, tongue, or uvula (Somnoplasty/Coblation)
- XVIII. Remotely controlled mandibular positioner
- XIX. Tongue based reduction surgery
- XX. Tongue Based Suspension (eg, Repose or AIRvance)
- XXI. Winx therapy system/oral pressure therapy

DEFINITIONS:

Adherence:

5/7 nights or 70%

Apnea:

Transient cessation of respiration

Apnea Hypopnea Index (AHI):

Average number of episodes of *apnea* and/or *hypopnea* per hour of sleep

Epworth Sleepiness Scale:

A scale used to indicate the likelihood of falling asleep in the following commonly encountered situations by assigning a score between 0 (none) and 3 (high chance). The scores are summed; a total greater than 10 is considered abnormal.

- Sitting and reading
- Watching TV
- Sitting, inactive, in a public place, i.e., theater
- As a passenger in a car for an hour without a break
- Lying down to rest in the afternoon when circumstances permit
- Sitting and talking to someone
- In a car, while stopped for a few minutes in traffic

Hypopnea:

Abnormally slow or especially shallow respiration

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Malfunctioning:

The failure of a device to meet its performance specifications or otherwise perform as intended. Performance specifications include all claims made in the labeling for the device.

Obstructive Sleep Apnea Types (from AASM):

- *AHI* of 5-14: Mild OSA; Involuntary sleepiness during activities that require little attention (eg, watching TV, reading)
- *AHI* of 15-29: Moderate OSA; Involuntary sleepiness during activities that require some attention (eg, meetings, presentations)
- *AHI* of 30 or greater: Severe OSA; Involuntary sleepiness during activities that require more active attention (eg, talking, driving)

Positive Airway Pressure (PAP):

A PAP machine works by gently blowing pressurized room air through the airway at a pressure high enough to keep the throat open. This pressurized air acts as a sort of splint. The pressure is set according to the patient's needs, high enough to ensure that the airway is fully open when the sleeper inhales but not so high that the sleeper is disturbed by the sensation. (The obstructions of the airway occur during sleep but not during waking hours partly because all muscles, including the muscles in the throat, relax during sleep.) The delivery of positive airway pressure is available in many forms, such as basic CPAP, bilevel positive airway pressure (BiPAP), automatically titrating positive airway pressure, and demand positive airway pressure.

Rapid eye movement (REM) RDI:

RDI during REM sleep

Respiratory Disturbance Index (RDI):

Average number of respiratory disturbances per hour (*apneas*, *hypopneas*, and respiratory event-related arousals [RERAs])

Respiratory Event Index (REI):

Average number of episodes of *apnea* and/or *hypopnea* per total recording time in hours

BACKGROUND:

Obstructive Sleep Apnea (OSA) is a disorder in which complete or partial obstruction of the airway during sleep causes loud snoring, oxyhemoglobin desaturations, and frequent arousals.

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Prior Authorization: No

CODING:

HCPSC: 2024

PAP

E0470 Respiratory assist device, bi-level pressure capability, without backup rate feature, used with noninvasive interface, eg, nasal or facial mask

E0601 Continuous positive airway pressure (CPAP) device

Oral device/appliances

D7880 Occlusal orthotic device

D8210 Removable appliance therapy

D9947 Custom sleep apnea appliance fabrication and placement

E0485 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment

E0486 Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment

K1027 Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment

REFERENCES:

1. Integrated Healthcare Services Process Manual UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. Clinical Policy: Orthognathic Surgery (MC/B002)
4. Clinical Policy: Obstructive Sleep Apnea, Surgical Treatment in Adults (MC/C007)
5. Clinical Policy: Durable Medical Equipment, Prosthetics, Orthotics and Supplies (MP/D004)
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DOCUMENT HISTORY:

Created Date: 01/06/20
Reviewed Date: 01/05/21, 12/21/21, 12/21/22, 12/19/23
Revised Date: 03/20/20, 09/07/22, 05/23/23

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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:

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PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist 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, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

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주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).