Devices Used for the Treatment of Obstructive Sleep Apnea in Adults

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Application:	All participating hospitals and providers
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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary devices used for the treatment of obstructive sleep apnea in adults.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus LTSS (DSHP Plus LTSS) members.

Positive Airway Pressure (PAP) Devices – Indicated for use in the treatment of obstructive sleep apnea (OSA). PAP devices may improve quality of life in individuals with OSA in adults. Close follow-up for PAP device usage and problems in individuals with OSA by appropriately trained health care providers is indicated to establish effective utilization patterns and remediate problems if needed**.**

PROCEDURES

A prior authorization may be required.

AUTO-TITRATING POSITIVE AIRWAY PRESSURE (APAP) OR CONTINUOUS POSITIVE AIRWAY PRESSURE (CPAP)

An APAP device or a CPAP device may be considered medically necessary for the treatment of obstructive sleep apnea (OSA) in adults and covered as durable medical equipment when the following criteria are met:

APAP

APAP during a two (2) week trial to initiate and titrate CPAP in adult individuals with a confirmed diagnosis of OSA.

CPAP

Individuals have confirmed diagnosis of OSA (confirmed via a positive facility-based polysomnogram (PSG) or with a positive home/portable sleep test); and

Apnea/hypopnea index (AHI) as follows:

- Greater than or equal to 15 events per hour of sleep in an asymptomatic patient; or
- Greater than five (5) events per hour of sleep in a symptomatic patient (e.g., sleepiness, fatigue and inattention); or
- Signs of disturbed sleep (e.g., snoring, restless sleep, and respiratory pauses).

APAP or CPAP devices that do not meet the above criteria are considered not medically necessary.

BI-LEVEL POSITIVE AIRWAY PRESSURE (BIPAP) WITHOUT BACK-UP RATE

BiPAP without back-up rate may be considered medically necessary for the treatment of OSA in adults and may be considered as durable medical equipment when the following criteria are met:

- Individuals have confirmed diagnosis of OSA (confirmed via a positive facility-based PSG or with a positive home/portable sleep test); and
- AHI greater than or equal to 15 events per hour of sleep in an asymptomatic patient, or
  - Five (5) events per hour of sleep in a symptomatic patient (e.g., sleepiness, fatigue and inattention); or
  - Signs of disturbed sleep (e.g., snoring, restless sleep, and respiratory pauses) and ONE (1) of the following:
    - Individuals have failed a prior trial of CPAP. If the patient is uncomfortable or intolerant of high pressures on CPAP; the patient may be tried on BiPAP. If there are continued obstructive respiratory events at 15 cm H2O of CPAP during the titration study, the patient may be switched to BiPAP; or
    - For whom BiPAP is found to be more effective in the sleep lab.

BiPAP without back-up rate devices not meeting the criteria above as indicated in this policy are not considered medically necessary.

BIPAP WITH BACK-UP RATE

BiPAP device with back-up rate is considered not medically necessary with the primary diagnosis of OSA, in adults.

INTRA-ORAL APPLIANCES

Intraoral appliances (tongue-retaining devices or mandibular advancing/positioning devices) may be considered medically necessary in adult individuals with OSA when ALL of the following criteria are met:

- AHI greater than or equal to 15 events per hour of sleep in an asymptomatic patient or greater than five (5) events per hour of sleep in a symptomatic patient (e.g., sleepiness, fatigue and inattention) or signs of disturbed sleep (e.g., snoring, restless sleep, and respiratory pauses); and
- A trial with CPAP has failed or is contraindicated; and
- The device is prescribed by a treating physician; and
- The device is custom fitted by qualified dental personnel; and
- There is absence of temporomandibular dysfunction or periodontal disease.

Intra-oral devices not meeting the criteria as indicated in this policy are considered not medically necessary.

There are many different types of appliances that basically fit into one of two categories, tongue retaining appliances, and mandibular repositioning appliances. Payment may be made for one (1) appliance. Additional appliances are considered not medically necessary. However, replacement of an oral appliance may be considered medically necessary when the item has reached the end of its five (5) year reasonable use lifetime, or when wear and tear render the item non-functioning and not repairable, and the item is no longer under warranty. It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation.

Over the counter (OTC) or prefabricated intra-oral appliances to treat OSA are not considered to be appropriate therapy for OSA in any clinical situation and, therefore, are noncovered.

Note: CPAP has been shown to have greater effectiveness than oral appliances in general. This difference in efficacy is more pronounced for individuals with severe OSA, as oral appliances have been shown to be less efficacious in individuals with severe OSA than they are in individuals with mild-moderate OSA. Therefore, it is particularly important that individuals with severe OSA should have an initial trial of CPAP and that all reasonable attempts are made to continue treatment with CPAP, prior to the decision to switch to an oral appliance.

NASAL EXPIRATORY POSITIVE AIRWAY PRESSURE (EPAP)

Nasal EPAP devices (e.g., Provent™, Theravent™) are considered experimental/investigational, and therefore, noncovered.

ORAL PRESSURE THERAPY (OPT)

OPT devices (e.g., Winx® Sleep Therapy System) are considered experimental/investigational and, therefore, noncovered.

DAYTIME ELECTRICAL STIMULATION DEVICES

Daytime electrical stimulation (eXciteOSA) of the tongue is considered experimental/investigation and, therefore, noncovered because the safety and/or effectiveness of this service cannot be established by review of the available published peer-review literature.

PAYMENT FOR THE RENTAL OF A PAP DEVICE

Payment will be made for the rental of a PAP device for the first three (3) months (rental period) from the original start date of therapy, when the above clinical criteria are met. Device expenses incurred during the first three (3) months of rental will be applied to the purchase price. Payment will be made for the purchase of the device when **both** of the following criteria are met:

- Documented compliance with objective findings (i.e., compliance chip, tele monitoring, computer software) of device usage for three (3) consecutive months; **and**
- The patient is experiencing success in treatment.

Throughout the PAP device rental period, the durable medical equipment (DME) supplier must check that the individual is compliant with use of the device. If the device isn't being used as prescribed, the DME supplier should contact the individual's physician and discuss removal of the device. If the physician agrees that removal of the machine is warranted, the supplier must remove the machine and discontinue billing for the rental. However, if the individual is found to be using the PAP device as directed and is achieving the desired results, the DME supplier must contact the individual's physician near the end of the rental period and ask the doctor to prescribe the purchase of the device. Noncompliance, with the prescribed PAP therapy will render the PAP device as a noncovered service.

Compliance monitoring equipment for CPAPs, APAPs, or BiPAPs (e.g., smart card, compliance chip, telemonitoring, and computer software) is considered an integral component of the function of the device and is not eligible for separate reimbursement.

CONTINUED USE BEYOND THE FIRST THREE (3) MONTHS OF THERAPY

The medical records must also document objective findings of compliance information, (i.e., compliance chip, tele monitoring, computer software), confirming that the individual has been adhering to PAP therapy and is benefiting from its use. Adherence to therapy is defined as use of PAP greater than or equal to four (4) hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

REPLACEMENT OF PAP DEVICES

Replacements of PAP devices for individuals with an existing diagnosis of OSA do not need a compliance chip if documentation of previous compliance, (i.e., compliance chip, tele monitoring, computer software), has been confirmed in the medical record.

CLEANING DEVICES

PAP devices have directions from the manufacturing company included for cleaning. CPAP sanitizer cleaning systems are considered convenience items and therefore noncovered.

ACCESSORIES

LINERS

Liners are not interfaces for use with a PAP mask. Liners are products placed between the individual's skin and the PAP mask interface and are made of cloth, silicone or other materials. These are not considered "interfaces" as defined in this policy.

Liners must not be billed as replacement interface for a PAP mask or as a replacement cushion for use on nasal mask interface.

A liner used in conjunction with a PAP mask is considered a comfort and convenience item and is considered a noncovered item or service.

There is no additional payment for liners used with a PAP mask.

Accessories used with a positive airway pressure (PAP) device may be considered medically necessary when the criteria for the device are met. If the criteria are not met, the accessories are considered not medically necessary.

A replacement cushion/pillow is not billable when supplying an ongoing replacement of the frame with cushion/pillow. Billing for each individual component is considered unbundling of these supplies. The allowance of a replacement mask interface every month is considered an exception and documentation should support the medical necessity.

Note: See table below for the usual maximum amount of accessories considered to be medically necessary. A replacement device is not covered if due to misuse or abuse and is considered a noncovered service.

ACCESSORIES		
A4604	1 per 3 months	Tubing with integrated heating element for use with positive airway pressure device.
A7027	1 per 3 months	Combination oral/nasal mask, used with continuous positive airway pressure device, each.
A7028	2 per 1 month	Oral cushion for combination oral/nasal mask, replacement only, each.
A7029	2 per 1 month	Nasal pillows for combination oral/nasal mask, replacement only, pair.
A7030	1 per 3 months	Full face mask used with positive airway pressure device, each.
A7031	1 per 1 month	Face mask interface, replacement for full face mask, each.
A7032	2 per 1 month	Cushion for use on nasal mask interface, replacement only, each.
A7033	2 per 1 month	Pillow for use on nasal cannula type interface, replacement only, pair.
A7034	1 per 3 months	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap.
A7035	1 per 6 months	Headgear used with positive airway pressure device.
A7036	1 per 6 months	Chinstrap used with positive airway pressure device.
A7037	1 per 3 months	Tubing used with positive airway pressure device.
A7038	2 per 1 month	Filter, disposable, used with positive airway pressure device.
A7039	1 per 6 months	Filter, non-disposable, used with positive airway pressure device.
A7044	1 per 3 months	Oral interface used with positive airway pressure device, each.
A7045	1 per 3 months	Exhalation port with or without swivel used with accessories for positive airway pressure devices, replacement only.
A7046	1 per 6 months	Water chamber for humidifier, used with positive airway pressure device, replacement, each.

* Allows for a 10-day delivery before run-out

** Allowing for a 3-month supply

Quantities of supplies greater than those identified as the usual maximum amounts are considered not medically necessary.

Regardless of utilization, a supplier must not dispense more than a three (3) month quantity at a time.

Either a heated humidifier or a nonheated humidifier may be considered medically necessary for use with a covered PAP device when prescribed by the treating physician to meet the needs of the individual.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/Investigational (E/I) services are not covered regardless of place of service.

A device used for the treatment of obstructive sleep apnea in adults is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
E0601	Continuous positive airway pressure (CPAP) device.
E0470	Respiratory assist device, bi-level pressure capability, without back up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device).
E0471	Respiratory assist device, bi-level pressure capability, with back up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device).
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.
A4604	Tubing with integrated heating element for use with positive airway pressure device.
A7002	Tubing, used with suction pump, each.
A7027	Combination oral/nasal mask, used with continuous positive airway pressure device, each.
A7028	Oral cushion for combination oral/nasal mask, replacement only, each.
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair.
A7030	Full face mask used with positive airway pressure device, each.
A7033	Pillow for use on nasal cannula type interface, replacement only, pair.
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap.

A7035	Headgear used with positive airway pressure device.
A7036	Chinstrap used with positive airway pressure device.
A7037	Tubing used with positive airway pressure device.
A7038	Filter, disposable, used with positive airway pressure device.
A7039	Filter, non-disposable, used with positive airway pressure device.
A7044	Oral interface used with positive airway pressure device, each.
A7045	Exhalation port with or without swivel used with accessories for positive airway devices, replacement only.
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each.
A7047	Oral interface used with respiratory suction pump, each.
E0561	Humidifier, non-heated, used with positive airway pressure device.
E0562	Humidifier, heated, used with positive airway pressure device.
E0600	Respiratory suction pump, home model, portable or stationary, electric.
E1399	Durable medical equipment, miscellaneous.

COVERED DIAGNOSIS CODES FOR PROCEDURE CODE E0601

Codes						
G47.33						

NON COVERED DIAGNOSIS CODES FOR PROCEDURE CODE E0471

Codes						
G47.33						

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

09/20/2021	Approved in Medical Policy Committee.
05/02/2022	Annual review; updated codes; approved in Medical Policy Committee.
05/24/2022	Approved in QI/UM.
03/22/2023	Annual review; approved in Medical Policy Committee
03/28/2023	Approval QI/UM