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Adult Obstructive Sleep Apnea - UM Clinical Coverage Guidance

PURPOSE

Provide Clinical Guidance for determining what medical services, procedures, devices, and drugs may be eligible for coverage and to evaluate whether a medical procedure or equipment is medically necessary. Providers are responsible for verifying eligibility and benefits before providing services to all Denver Health Medical Plan (DHMP) members.

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by DHMP and may not be covered by all DHMP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a Member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

- The terms of the applicable benefit document in effect on the date of service.
- Any applicable laws and regulations.
- Any relevant collateral source materials including coverage policies.
- The specific facts of the particular situation.

Contact DHMP Customer Service to discuss plan benefits more specifically.

SCOPE

This Clinical Coverage Guidance applies to DHMP Utilization Management Department and all lines of business.

DEFINITIONS

Authorization - Approval that is given by DHMP that is associated with a number that is given to a request when it has been reviewed for appropriateness, which is to be attached to the referral for certain procedures. Some referrals require an authorization number and others do not.

Criteria - Systematically developed, objective and evidence-based written statements of decision-making

criteria that are used to assess the appropriateness of specific health care decisions, services, settings, and outcomes.

Effectuation - Compliance with a reversal of the Medicare health plan's original adverse organization determination. Compliance may entail payment of a claim, authorization for a service, or provision of services.

Enrollee - A Medicare Advantage eligible individual who has elected a Medicare Advantage plan offered by an MA organization.

Emergency Medical Condition – A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in:

- Serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of the woman or her unborn child;
- Serious impairment to bodily functions; or
- Serious dysfunction of any bodily organ or part (42 C.F.R. §422.113(b)).

Experimental or Investigational Services –

- Any treatment, procedure, drug or device that has been reviewed and found by the Department to be experimental or investigational or
- The treatment, procedure, drug or device has been reviewed by the Company and found not to meet all of the "eligible for coverage criteria" below with respect to the particular illness or disease to be treated, or a treatment, procedure, drug or device. Eligible for coverage criteria include:
 - The treatment, procedure, drug or device shall have final approval from the Food and Drug Administration (FDA), if applicable;
 - The scientific evidence as published in peer-reviewed literature shall permit conclusions concerning the effect of the treatment, procedure, drug or device on health outcomes;
 - The treatment, procedure, drug or device must improve or maintain the net health outcome;
- The treatment, procedure, drug or device must be as beneficial as any established alternative; and
- The improvements in health outcomes must be attainable outside the investigational settings.
- Additionally, the treatment, procedure, drug or device shall be medically necessary and not excluded by any other contract exclusion.

Licensed Clinical Criteria – Established written criteria used for selected Utilization Management decisions.

MCG Health™ Care guidelines - Nationally-accepted, evidence-based clinical guidelines that support clinical decisions and care planning activities.

Medicare Coverage Database - The Medicare Coverage Database contains all National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), local articles and proposed NCD decisions. The database also includes several other types of National Coverage policy related documents, including National Coverage Analyses (NCAs), Coding Analyses for Labs (CLAs), Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) proceedings and Medicare coverage guideline documents. Although CHP+ and MCD plans are not restricted by Medicare Coverage Determinations, the determinations are well researched and provide a frame of reference for making appropriate decisions.

Out-of-Network (OON) - is any facility outside of Denver Health Medical Center for all lines of business exclusive of POS.

Network – Health Care Practitioners that the plan contracts with for a member's care.

Organization Determination - Any determination made by a Medicare health plan with respect to any of the following:

- Payment for temporarily out of the area renal dialysis services, emergency services, post-stabilization care, or urgently needed services,
- Payment for any other health services furnished by a provider other than DHMP that the enrollee believes are covered under Medicare, or, if not covered under Medicare, should have been furnished, arranged for, or reimbursed by DHMP,
- DHMP's refusal to provide or pay for services, in whole or in part, including the type or level of services that the enrollee believes should be furnished or arranged for by DHMP,
- Discontinuation of a service if the enrollee believes that continuation of the services is medically necessary, or
- Failure of DHMP to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide the enrollee with timely notice of an adverse determination, such that a delay would adversely affect the health of the enrollee.

Quality Improvement Organization (QIO) - Organizations comprised of practicing doctors and other health care experts under contract to the Federal government to monitor and improve the care given to Medicare enrollees. QIOs review complaints raised by enrollees about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Medicare health plans, and ambulatory surgical centers. The QIOs also review continued stay denials for enrollees receiving care in acute inpatient hospital facilities as well as coverage terminations in SNFs, HHAs and CORFs.

Quality of Care Issue - A quality of care complaint may be filed through the Medicare health plan's grievance process and/or a QIO. A QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by a Medicare health plan meets professionally recognized standards of health care, including whether appropriate health care services have been provided and whether services have been provided in appropriate settings.

Reconsideration - An enrollee's first step in the appeal process after an adverse organization determination; a Medicare health plan or independent review entity may reevaluate an adverse organization determination, the findings upon which it was based, and any other evidence submitted or obtained.

Representative - An individual appointed by an enrollee or other party, or authorized under State or other applicable law, to act on behalf of an enrollee or other party involved in an appeal or grievance. Unless otherwise stated, the representative will have all the rights and responsibilities of an enrollee or party in obtaining an organization determination, filing a grievance, or in dealing with any of the levels of the appeals process.

Referral - A written request for service signed by the member's Primary Care Physician (PCP) or network specialist.

Urgent - An urgent or expedited request as a determination request in which waiting for a decision under the standard time frame could place the members life, health, or ability to regain maximum function in serious jeopardy.

Utilization Management (UM) - The function wherein use, consumption, and outcomes of services, along with level and intensity of care, are reviewed using Utilization Review techniques for their appropriateness.

Utilization Review - A set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services, referrals, procedures, or settings.

PROCESS

CLINICAL COVERAGE GUIDELINE

Denver Health Medical Plan considers the diagnosis and treatment of obstructive sleep apnea (OSA) in adults aged 18 and older medically necessary according to the criteria outlined below.

I. Diagnosis

Denver Health Medical Plan considers attended full-channel nocturnal polysomnography (NPSG) performed in a healthcare facility medically necessary for diagnosis in members with symptoms suggestive of obstructive sleep apnea, when attended NPSG is used as part of a comprehensive sleep evaluation with adequate follow-up, and member has one or more of the following indications for attended NPSG:

- A. Member has at least **one of the following** comorbid medical conditions that degrade the accuracy of portable monitoring:
1. moderate to severe pulmonary disease (for example, COPD or asthma) (with nocturnal oxygen use or daytime hypercapnia with documented arterial blood gasses showing pO₂ less than 60 or pCO₂ greater than 45),
 2. neuromuscular disease (e.g., Parkinson's disease, spina bifida, myotonic dystrophy, amyotrophic lateral sclerosis),
 3. stroke with residual respiratory effects,
 4. epilepsy,
 5. congestive heart failure (NYHA class III or IV or LVEF less than 45%),
 6. pulmonary hypertension (mean pulmonary artery pressure > 25 mm Hg),
 7. chronic opioid medication use,
 8. super obesity (BMI greater than 45, or pulmonary function studies show obesity hypoventilation syndrome (BMI greater than 35 plus arterial blood gas with PCO₂ greater than 45, or BMI greater than 35 plus inability to lie flat in bed)); or
- B. Member has **one or more of the following** comorbid sleep disorders:
1. periodic limb movement disorder (involuntary, jerking movements of the legs during sleep causing excessive daytime sleepiness (EDS) due to sleep fragmentation),
 2. parasomnias that are unusual or atypical because of the individual's age at onset, the time, duration or frequency of occurrence of the behavior including, but not limited to: nocturnal seizures, psychogenic dissociative states, REM sleep behavior disorder, sleep talking and/or confused arousals,
 3. severe insomnia,
 4. narcolepsy,
 5. central sleep apnea or complex sleep apnea; **or**

C. Member has negative or technically inadequate portable monitoring results; **or**

- D. Member has low pretest probability of obstructive sleep apnea (normal BMI (less than 30), normal airway (Mallampati score 1 or 2), no snoring, and normal neck circumference (less than 17 inches in men, and less than 16 inches in women)); **or**
- E. Member lacks the mobility or dexterity to use portable monitoring equipment safely at home.

Note: Where attended NPSG is indicated, a split-night study NPSG is considered medically necessary, in which the final portion of the NPSG is used to titrate continuous positive airway pressure (CPAP) if the Apnea Hypopnea Index (AHI) is greater than 15 in first 2 hours of a diagnostic sleep study. An additional full-night CPAP titration NPSG is considered medically necessary only if the AHI is less than or equal to 15 during the first 2 hours of a diagnostic sleep study, or if the split-night study did not allow for the abolishment of the vast majority of obstructive respiratory events (see section III below).

II. Unattended (Home) Sleep Studies

Denver Health Medical Plan considers unattended (home) sleep studies using any of the following diagnostic techniques medically necessary for members with symptoms suggestive of OSA (see appendix) when the home sleep study is used as part of a comprehensive sleep evaluation:

- A. Sleep monitoring using a Type II device; **or**
- B. Sleep monitoring using a Type III device; **or**
- C. Sleep monitoring using a Type IV(A) device, measuring airflow and at least 2 other channels and providing measurement of apnea-hypopnea index (AHI); **or**
- D. Sleep monitoring using a device that measures 3 or more channels that include pulse oximetry, actigraphy, and peripheral arterial tone.

Note: Sleep studies using devices that do not provide a measurement of apnea-hypopnea index (AHI) and oxygen saturation are considered not medically necessary because they do not provide sufficient information to prescribe treatment.

Repeat home sleep testing on multiple consecutive nights has no proven value.

III. Attended Nocturnal Polysomnography (NPSG)

Denver Health Medical Plan considers an Attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility is considered medically necessary for persons diagnosed with obstructive sleep apnea who have any of the following indications for attended

NPSG:

- A. To titrate CPAP in persons diagnosed with clinically significant OSA for whom in-laboratory NPSG was medically necessary, but who were unable to undergo a split-night study because they had an insufficient AHI (less than 15) during the first two hours of an attended NPSG; **or**
- B. To titrate CPAP in persons with clinically significant OSA for whom in-laboratory NPSG was medically necessary, and who underwent a split-night study that did not abolish the vast majority of obstructive respiratory events; **or**
- C. To monitor results from CPAP in persons with OSA who have persistent significant symptoms (disturbed sleep with significant arousals) despite documented AHI less than 5 on CPAP and documented compliance with CPAP (CPAP used for 70 percent of nights for four or more hours per night, for two or more months); **or**
- D. To confirm diagnosis of obstructive sleep apnea prior to surgical modifications of the upper airway.

IV. Repeat Sleep Study Indications

It may be necessary to perform repeat sleep studies up to twice a year for any of the following indications.

(Note: where repeat testing is indicated, attended full-channel nocturnal polysomnography (NPSG) (Type I device) performed in a healthcare facility is considered medically necessary for persons who meet criteria for attended NPSG in section I above; in all other cases, unattended (home) sleep studies are considered medically necessary):

- A. To determine whether positive airway pressure treatment (i.e., CPAP, bilevel positive airway pressure (BiPAP), demand positive airway pressure (DPAP), variable positive airway pressure (VPAP), or auto-titrating positive airway pressure (AutoPAP)) continues to be effective in persons with new or persistent symptoms, after interrogation of current positive airway pressure device; **or**
- B. To determine whether positive airway pressure treatment settings need to be changed in persons with new or persistent symptoms, after interrogation of current positive airway pressure device. (Note: This criterion does not apply to AutoPAP devices, as these devices are automatically titrated and do not require manual adjustment of treatment settings.); **or**
- C. For persons with substantial weight loss (loss of 10 percent or more body weight) or some other change in their medical condition that would affect the need for continued positive airway pressure treatment (e.g., heart attack, stroke, heart failure), to determine whether continued treatment with positive airway pressure treatment is necessary; **or**
- D. To assess treatment response after upper airway surgical procedures and after initial treatment with oral appliances.

Note: A home sleep study is performed over multiple nights with a single interpretation is considered a single sleep study for purposes of reimbursement.

Note: Repeat sleep testing (home or attended sleep studies) for persons getting replacement CPAP equipment is considered not medically necessary unless the member also has one of the indications for repeat testing listed above.

V. Treatment

Treatment of snoring alone, without significant OSA, is not considered medically necessary.

- A. Continuous Positive Airway Pressure (CPAP) It is expected that members receive lifestyle advice where applicable (i.e., helping people to lose weight, stop smoking and/or decrease alcohol consumption).

Denver Health Medical Plan considers CPAP, autoPAP (APAP) medically necessary DME for members with a positive facility-base NPSG, or with a positive home sleep test including as defined by either of the following criteria:

1. Member's apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events/hour with a minimum of 30 events; **or**
2. AHI or RDI greater than or equal to 5 and less than 15 events/hour with a minimum of 10 events and at least **one** of the following is met:
 - a. Documented history of stroke; **or**
 - b. Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); **or**

- c. Documented ischemic heart disease; **or**
- d. Documented symptoms of impaired cognition, mood disorders, or insomnia; **or**
- e. Excessive daytime sleepiness (documented by either Epworth greater than 10 (see appendix); **or**
- f. Greater than 20 episodes of oxygen desaturation (i.e., oxygen saturation of less than 85 %) during a full night sleep study, **or**
- g. any one episode of oxygen desaturation (i.e., oxygen saturation of less than 70 %).

These alternatives to CPAP may also be considered medically necessary for OSA members with concomitant breathing disorders, which include restrictive thoracic disorders, COPD, and nocturnal hypoventilation:

B. BiPAP without a backup rate feature, BiPAP with pressure relief technology (Bi-Flex), DPAP, VPAP are considered medically necessary DME for members who are intolerant to CPAP or AutoPAP, or for whom CPAP or AutoPAP is ineffective. Ineffective is defined as documented failure to meet therapeutic goals using CPAP or AutoPAP during the titration portion of a facility-based study or during home use despite optimal therapy (i.e., proper mask selection and fitting and appropriate pressure settings). The records must document that both of the following medical necessity criteria are met:

1. An appropriate interface for the CPAP and Auto-PAP has been properly fit and the member is using it without difficulty; **and**
2. The current pressure setting of the CPAP or AutoPAP prevents the member from tolerating the therapy and lower pressure settings of the CPAP or AutoPAP were tried but failed to:
 - a. Adequately control the symptoms of OSA; **or**
 - b. Improve sleep quality; **or**
 - c. Reduce the AHI/RDI to acceptable levels.

A BiPAP device with a backup rate feature is considered experimental and investigational for obstructive sleep apnea.

* A nasal interface (mask or cannula type) may be used with a positive airway pressure device, with or without a head strap as an alternative to a full-face mask. However, upgraded face mask is considered medically necessary only if there is documentation that the member needs a different mask because he/she cannot maintain CPAP pressures or that in order to get the pressure the mask needs to be so tight as to generate pressure sores.

Replacement of positive airway pressure devices is considered medically necessary at the end of their 5-year reasonable useful lifetime (RUL). Replacement of these items is considered medically necessary prior to the end of the 5-year RUL due to a change in the member's condition. Replacement needed due to misuse or abuse are not covered.

Note: Denver Health Medical Plan follows Medicare DME MAC rules with respect to the usual medically necessary quantity of supplies for positive airway pressure devices.

C. Continued Medical Necessity of Positive Airway Pressure Devices Beyond Initial Authorization Period
Continued use of a positive airway pressure device beyond the initial authorization period is considered

medically necessary if the treating physician documents that the member is benefiting from positive airway pressure therapy.

Documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical reevaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; **and**
2. Objective evidence of adherence to use of the positive airway pressure device, reviewed by the treating physician. Adherence to therapy is defined as use of positive airway pressure four (4) or more hours per night on at least 70% of nights during a consecutive thirty (30) day period anytime during the initial period of usage.

D. Oral Appliances (Other) Mandibular advancement oral appliances to reduce upper airway collapsibility or tongue retaining devices are considered medically necessary for members who have sleep test results that meets one of the following criteria:

1. The AHI or RDI is greater than or equal to 15 events per hour with a minimum of 30 events; or
2. The AHI or RDI is greater than or equal to 5 and less than 15 events per hour with a minimum of 10 events and documentation of:
 - a. Documented history of stroke; or
 - b. Documented hypertension (systolic blood pressure greater than 140 mm Hg and/or diastolic blood pressure greater than 90 mm Hg); or
 - c. Documented ischemic heart disease; or
 - d. Documented symptoms of impaired cognition, mood disorders, or insomnia; or
 - e. Excessive daytime sleepiness (documented by either Epworth greater than 10 or MSLT less than 6); or
 - f. Greater than 20 episodes of oxygen 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 saturation of less than 70 %).
3. If the AHI is greater than 30 or the RDI is greater than 30 and meets either of the following:
 - a. The member is not able to tolerate a positive airway pressure (PAP) device; or
 - b. The use of a PAP device is contraindicated.

An oral pressure appliance (OPAP) is considered medically necessary DME only on an **exception** basis for members who are unable to tolerate a standard nasal/face mask due to facial discomfort, sinus pain, or claustrophobia from masks.

E. Oral Appliances

Oral appliances to reduce upper airway collapsibility are considered experimental and investigational for indications other than OSA.

Oral appliances are considered experimental and investigational for treatment of upper airway resistance syndrome. (UARS)

Oral appliances for snoring (e.g., Snore Guard) are considered not medically necessary treatment of

disease, as snoring is not considered a disease.

Compliance monitors for oral appliances have no proven value.

Notes: For purposes of this policy, apnea is defined as a cessation of airflow for at least 10 seconds. Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least a 30 % reduction in thoraco-abdominal movement or airflow as compared to baseline, and with at least a 4 % oxygen desaturation.

The apnea-hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. Sleep time can only be measured in a Type I (facility-based polysomnogram) or Type II sleep study. Thus, the AHI is reported only in Type I or Type II sleep studies.

The respiratory disturbance index (RDI) is equal to the episodes of apnea and hypopnea per hour of recording without the use of a positive airway pressure device. The RDI is reported in Type III, Type IV, and other home sleep studies.

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 positive airway pressure devices will be considered not medically necessary if based upon an index that does not score apneas and hypopneas separately from other sleep disturbance events.

Only persons with an AHI and/or RDI, as defined in this policy that meets medical necessity criteria may qualify for a positive airway pressure device.

DOCUMENTATION/RECORDS

None

EXTERNAL REFERENCES

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DHMP/DHHA RELATED DOCUMENTS

None

Attachments

No Attachments

Approval Signatures

Approver	Date
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Applicability

Denver Health Medical Plan (DHMP)