Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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(See policy history boxes for previous effective dates)

Title: Positive Pressure Airway Devices

Description/Background

Positive airway pressure (PAP) is a method of respiratory ventilation used primarily in the treatment of sleep apnea. There are multiple types of positive pressure airway devices. Some positive airway pressure devices work better than others for specific conditions. Apnea can be either obstructive sleep apnea (OSA), central sleep apnea (CSA) or a combination of both OSA and CSA.

Apnea is a chronic health issue. Treatment with a positive pressure airway device is a highly effective treatment for obstructive sleep apnea. For some individuals improvement in the quality of sleep and the quality of life are noticeable after a single night's use. Often, the individual's sleep partner also benefits due to the decrease in their partner's snoring.

Obstructive Sleep Apnea:
OSA is a common disorder where one or more pauses occur in breathing or a person has very shallow breathing during sleep. Pauses in breathing can last from a few seconds to minutes. Most often pauses occur five to 30 times or more an hour. Typically, normal breathing then starts again, sometimes with a loud snort or choking sound. The most common type of sleep apnea is OSA. Most sleep apnea occurs when the airway has collapsed or becomes blocked during sleep. This obstruction is what causes the shallow breathing or pauses. When breathing resumes, air then squeezes past the blockage and can cause loud snoring. OSA is a chronic condition that disrupts sleep three or more nights each week. This results in poor sleep quality and that can lead to daytime sleepiness. Sleep apnea is one of the leading causes of excessive daytime sleepiness.

Symptoms of sleep apnea in children may present somewhat differently than in adults, depending upon age. Common symptoms during sleep includes: snoring, difficulty breathing, snorting or choking sounds, abnormal motor activity, heavy sweating, arousal from sleep, nightmares and bed-wetting at an inappropriate age. Daytime symptoms caused by the disruption of normal sleep and repeated nocturnal oxygen desaturation include daytime

sleepiness, irritability, hyperactivity, disciplinary problems, learning problems and headaches. In addition, chronic breathing through the mouth may indicate nasal obstruction. Many times, symptoms may be in relation to adenotonsillary hypertrophy and the symptoms are usually treated by removing the hypertrophic adenotonsilar tissue.

The American Academy of Pediatrics (AAP) developed practice guidelines in 2002 related to the diagnosis and management of childhood obstructive sleep apnea syndrome (OSAS). OSAS is a common condition in childhood and can result in severe complications if left untreated. Since 2002, there has been a considerable increase in publication and research on the topic and the guidelines were revised in 2012. This practice guideline focused on uncomplicated childhood OSAS, that is, OSAS associated with adenotonsillar hypertrophy and/or obesity in an otherwise healthy child who is being treated in the primary care setting. One result of the revised guideline is that continuous positive airway pressure is recommended as treatment if adenotonsillectomy is not performed or if ASAS persists postoperatively.

Central Sleep Apnea:
Central apnea causes breathing to stop because the brain temporarily stops sending signals to the muscles that control breathing. The brain stem has many functions including control over respiration. Disease or damage in the brain stem can result in problems with normal breathing during sleep or when awake. Central apnea can occur in both adults and children.

Some of the conditions that can affect brain stem function include:
- Bulbar poliomyelitis
- Complications of cervical spine surgery
- Encephalitis
- Neurodegenerative illnesses such as Parkinson's disease
- Radiation of the cervical spine
- Severe arthritis and degenerative changes in the cervical spine or the base of the skull
- Stroke affecting the brain stem
- Primary hypoventilation syndrome
- Congestive heart failure
- Medications such as painkillers

Different positive airway pressure devices work differently and may have different advantages for the types or reasons for the apnea as illustrated in the table below.

Positive Pressure Device	**How it works**	**Advantages**
CPAP (Continuous Positive Airway Pressure)	• Continuous positive airway pressure (CPAP) has become the first line of treatment for: OSA, some forms of CSA • Works by creating a "pneumatic splint" for the upper airway, preventing the soft tissues of the upper airway from narrowing and collapsing • Pressurized air is sent from a flow generator through air tubing and a mask to the face - through to the upper airway	• Improvement in the quality of sleep • Improvement in the quality of life • Patient's sleep partner also benefits from markedly improved sleep quality, due to the amelioration of the patient's loud snoring

APAP (Auto-adjusting positive airway pressure)	• An intelligent therapeutic device that automatically titrates the amount of pressure delivered to the patient in response to airway events such as: – Apneas – Hypopneas – Flow limitation – Snoring • Delivers mean pressures below that of a CPAP device; generating only the pressure that is necessary at any given time • Decreases pressure between event-laden periods • May be particularly suited to patients with: REM-related apnea, positional apnea, non-compliant with standard CPAP therapy	• Resistance is measured in the patient's breathing delivering the precise pressure required at a given moment avoiding the compromise of fixed pressure delivery system such as CPAP
BiPAP (Bilevel Positive Airway Pressure) or VPAP (Variable Positive Airway Pressure)	• Designed specifically to treat a broad range of conditions, including some that require 24-hour ventilator support including both CSA, OSA or a combination of both • Adapts to the patient's ventilatory needs on a breath-by-breath basis • Automatically calculates a target ventilation (90% of the patient's recent average ventilation) • Automatically adjusts the pressure support	• Treats complex sleep apnea syndrome and CSA • Delivers two levels of air pressure that are set to coincide with the patient's inspiratory and expiratory efforts • Normalizes breathing, completely suppressing CSA and/or Cheyne-Stokes respiration • Improves sleep architecture (the amount of time the patient spends in slow-wave and REM sleep increases) • Enhances quality of life for patients with CSA

The positive airway pressure device consists of three main components, the flow generator that supplies the airflow, the interface or the nasal/face mask, nasal pillow or lip seal mouthpiece and the hose that connects the flow generator to the interface. Positive airway pressure devices have additional optional features that can improve comfort and usage compliance. Some of those features include heated or non-heated humidity, exhalation pressure relief, and a ramp feature that allows the device to gradually rise to the prescribed level of pressure, flexible chinstraps, data logging, automatic altitude adjustment and DC power source versus AC power source.

Diagnosing Apnea

Obstructive Sleep Apnea (OSA) is typically diagnosed by overnight monitoring with polysomnography (PSG).

A diagnosis of OSA is accepted when an adult individual has an apnea-hypopnea index (AHI) greater than 5 and symptoms of excessive daytime sleepiness or unexplained hypertension. An AHI equal to or greater than 15 is typically considered moderate OSA, while an AHI greater than or equal to 30 is considered severe OSA.

The presentation of OSA in children may differ from that of adults. Children frequently exhibit behavioral problems or hyperactivity rather than daytime sleepiness. Obesity is defined as a body mass index greater than the 90th percentile for the weight/height ratio. Although the

definition of severe OSA in children is not well established, an AHI greater than 1.5 is considered abnormal and an AHI of greater than or equal to 10 may be considered severe.

Regulatory Status:

Various PAP devices have been cleared by FDA through the 510(k) process since 1977. Bilevel positive airway pressure devices were first cleared for marketing in 1996. FDA product codes: BZD, MNT.

Medical Policy Statement

Positive pressure airway devices are considered safe, effective and useful therapeutic options for the management of obstructive sleep apnea, central sleep apnea or mixed apnea.

Inclusionary and Exclusionary Guidelines

Inclusions:

Auto-adjusting positive airway pressure (APAP) is considered established for the titration of pressure in adults with clinically significant OSA defined as those who have:

- An AHI, RDI, or Respiratory Event Index (REI) of at least 15 events per hour, OR
- An AHI, RDI, or REI of at least 5 events per hour in a individual with 1 or more signs or symptoms associated with OSA (eg, excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke); OR
- If there is a significant change in weight or change in symptoms suggesting that CPAP should be re-titrated or possibly discontinued.

Continuous Positive Airway Pressure (CPAP) is considered established in adult or pediatric individuals with clinically significant OSA.

Clinically significant OSA in adults is:

- An AHI, RDI, or REI ≥15, OR
- An AHI, RDI, or REI ≥5 in an individual with 1 or more signs or symptoms associated with OSA (e.g., excessive daytime sleepiness, hypertension, cardiovascular heart disease, or stroke).

In pediatric individuals (age 1-17),

- An AHI or RDI ≥5 OR

- An AHI or RDI ≥1.5 in an individual with excessive daytime sleepiness, behavioral problems or hyperactivity.

Bilevel positive airway pressure (BiPAP)/ Variable Positive Airway Pressure (VPAP) or APAP is considered established in both pediatric and adult individuals with clinically significant OSA who have failed a prior trial of CPAP or for whom bilevel positive airway pressure is found to be more effective in the sleep lab.

Central sleep apnea:
- Polysomnogram with more than five central apneas per hour of sleep lasting 10 seconds or longer
- Polysomnogram with the presence of at least 10 central events per hour of sleep in the crescendo-decrescendo pattern

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, because oral appliances have been shown to be less efficacious in individuals with severe OSA than in individuals with mild-to-moderate OSA. Therefore, it is particularly important that individuals with severe OSA 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.

Exclusions:

- Diagnosis of snoring without sleep apnea
- The use of CPAP, BiPAP/VPAP and APAP that do not meet the above criteria is considered investigational for the treatment of OSA.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

A7030	A7031	A7032	A7033	A7034	A7035
A7036	A7037	A7038	A7039	A7046	E0470
E0471	E0472	E0561	E0562	E0601	

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life,

quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to individuals and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Positive Airway Pressure Devices

Positive pressure airway devices are established for the treatment of sleep apnea syndromes. A variety of devices is available to help deliver positive pressure during sleep and help with individual compliance. The literature indicates that most of these devices are relatively free of serious side effects in most individual populations and produce acceptable reductions among outcome parameters, such as the apnea/hypopnea index (AHI).

Systematic Reviews

The American Academy of Sleep Medicine (AASM) commissioned a task force (Patil et al, 2019) to conduct an updated systematic review and meta-analysis of studies for the AASM 2019 guidelines on PAP for the treatment of OSA. [1, 2] Meta-analyses of 184 studies indicated that PAP use leads to clinically significant reductions in disease severity (−23 events/hour; 95% confidence interval [CI], −29 to −18 events/hour), both subjective and objective sleepiness, daytime and nighttime blood pressure, and motor vehicle accidents, and improved sleep-related quality of life (QOL). The overall quality of evidence for the outcome of sleepiness was high and the overall quality of evidence for sleep-related QOL and for blood pressure was moderate. The quality of evidence on the effect of PAP on cardiovascular events and mortality was low to moderate, with benefits reported in non-randomized studies but not in RCTs. The task force concluded that the potential benefits of CPAP outweighed the harms in symptomatic individuals. PAP initiation in the home had equivalent effects on individual outcomes compared to in-laboratory titration, and there were no clinically significant differences in individual outcomes with the use of auto-adjusting or bilevel PAP compared with standard continuous PAP. Adherence to PAP was improved with the use of educational, behavioral, troubleshooting, and telemonitoring interventions.

Balk et al (2011) conducted a comparative effectiveness review for the Agency for Healthcare Research and Quality (AHRQ) on the diagnosis and treatment of OSA in adults. The review concluded that the strength of evidence for CPAP for OSA was moderate based on the large magnitude of effect on the intermediate outcomes of the AHI, ESS score, and arousal index, even though there was weak evidence demonstrating an effect of CPAP on clinical outcomes.[3]

In addition, reviewers found moderate evidence that APAP and fixed-pressure CPAP result in similar levels of compliance (hours used per night) and treatment effects for individuals with OSA. There was moderate evidence that CPAP is superior to mandibular advancement devices (MADs) in improving sleep study measures.

Evidence-based guidelines from the AASM concluded that CPAP and APAP devices have similar outcomes in terms of AHI, oxygen saturation, and arousals. [4-7] As indicated in the AHRQ report, increased compliance with APAP devices has not been well-documented in clinical trials. 11,12,13, Thus, the issues associated with APAP are similar to those for bilevel PAP.

Yu et al (2017) conducted a meta-analysis assessing the association between PAP and cardiovascular events and death.[8] They included 10 trials with a total of 7266 individuals with sleep apnea. There were 356 major adverse cardiovascular events and 613 deaths observed during follow-up (range, 6-57 months). The analysis found no significant association of PAP with a composite outcome of acute coronary syndrome events, stroke, or vascular death (relative risk, 0.77; 95% CI, 0.53 to 1.13). Trials were grouped according to adherence to PAP (<4 vs ≥4 hours/day), type of sleep apnea (obstructive vs. central), and type of PAP (CPAP vs. adaptive servo-ventilation). Meta-regression identified no association between PAP with outcomes for different levels of apnea severity, follow-up duration, or adherence to PAP. As reported by McEvoy et al (2016), the largest trial included in the meta-analysis was the Sleep Apnea Cardiovascular Endpoints RCT, which found no benefit of CPAP on the primary composite outcome of death or hospitalization for cardiovascular events in 2717 adults with moderate-to-severe OSA and cardiovascular disease who were followed for a median of 44 months. [9] With a mean duration of adherence to CPAP therapy of 3.3 hours per night, CPAP significantly reduced daytime sleepiness (adjusted difference in ESS score, -2.5; 95% CI, -2.8 to -2.2; p<.001) and improved health-related QOL and mood. Lisan et al (2019) reported 11-year follow-up of a cohort of 392 individuals from the Sleep Heart Health Study who had obesity and severe OSA.[10] For the 81 individuals who were prescribed PAP therapy, the propensity-matched hazard ratio for all-cause mortality was 0.58 (95% CI, 0.35 to 0.96) compared to matched individuals who did not receive a prescription for PAP. Survival curves indicated that the difference in mortality appeared 6 to 7 years after initiation of PAP. Exploratory analysis indicated that PAP might also be associated with a lower risk of cardiovascular mortality.

Randomized Controlled Trials

Monitoring of APAP use by daily transmission to a web-based database and review by a research coordinator has been shown to improve compliance to PAP therapy (191 min/day vs. 105 min/day). [11] For the telemedicine arm of this randomized trial, as reported by Fox et al (2012), the research coordinator reviewed the transmitted data daily and contacted the individual if any of the following were present: mask leak greater than 40 L/min for more than

30% of the night, less than 4 hours of use for 2 consecutive nights, machine-measured AHI of more than 10 events per hour, and 90th percentile of pressure greater than 16 cm H2O. Evaluation by their physician sleep specialist after 3 months of therapy showed a similar modest decrease in AHI for the 2 groups (1.6 for telemedicine vs. 0.7 for controls).

Cohort Studies

An improvement in postoperative outcomes with CPAP was suggested by Mutter et al (2014) in a matched comparison of individuals with OSA who had been diagnosed prior to surgery (2640 surgeries), those not diagnosed until up to 5 years after surgery (1571 surgeries), and 16277 surgeries for individuals without a diagnosis of OSA over 21 years of available data.[12] In multivariate analysis, the risk of respiratory complications was increased for both diagnosed and undiagnosed OSA individuals compared with controls (odds ratio, 2.08; p<.001). The risk of cardiovascular complications, primarily cardiac arrest and shock, was higher in OSA individuals not diagnosed until after surgery (relative risk, 2.20; 95% CI, 1.16 to 4.17; p=.02), but not in those diagnosed prior to surgery (relative risk, 0.75; 95% CI, 0.43 to 1.28; p=.29); the difference between groups was statistically significant (p=.009). There was a significant trend toward a higher risk with increasing OSA severity. Study limitations included the inability to determine whether CPAP was used perioperatively, and, because body mass index could not be determined, potential confounding from the close association between obesity and OSA.

Subsection Summary: Positive Airway Pressure Devices

PAP devices are accepted therapies for OSA. Studies have suggested that both CPAP and APAP are associated with improvements in sleep architecture. Although PAP has been associated with an improvement in intermediate outcomes in multiple studies, it has not been shown to improve hard cardiovascular outcomes. Interpretation of this finding is limited by the duration of follow-up (from 6 to 57 months) and mean CPAP use (<4 hours per night in the largest studies). Eleven-year follow-up of obese individuals with severe OSA from the Sleep Heart Health Study found a reduction in all-cause mortality with PAP use which appeared after 6 to 7 years.

SUMMARY OF EVIDENCE

For individuals who have OSA who receive PAP devices, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, and quality of life. Conventional medical management of OSA includes weight loss, avoidance of stimulants, body position adjustment, oral appliances, and use of CPAP during sleep. A diagnostic sleep study may be followed by a trial of APAP to evaluate efficacy and adjust pressure. APA or bilevel PAA may also be indicated if the individual is intolerant of CPAP. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2010 Input
In response to requests, the BCBSA received input from 1 physician specialty society and 6 academic medical centers (8 reviewers) for their 2010 policy update. The input focused on the sensors required for unattended home sleep studies and on diagnosis and treatment of OSA in children. In general, the reviewers supported the requirement that home monitors measure 4 parameters, including respiratory effort, airflow, and oxygen saturation, and that their use be restricted to adults. Some exceptions were noted for specific situations. The update included recommendations from reviewers regarding indications that are specific to pediatric individuals.

2009 Input
In response to requests, the BCBSA received input from 5 physician specialty societies (6 reviewers) and 3 academic medical centers while their policy was under review in 2009. Professional society guidelines and position statements were also reviewed. In general, the input supported the use of PSG, portable sleep monitoring tests, multiple sleep latency test, and CPAP for adults as described in the policy. The update included the reviewer's recommendations for clarifications and modifications to the policy statements.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will begiven to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine
The American Academy of Sleep Medicine (AASM) also issued guidelines in 2009 on the evaluation, management, and long-term care of adults with OSA. [13] The levels of recommendation are "standard"(generally accepted individual-care strategy, with a high degree of certainty; level 1 to 2 evidence), "guideline"(moderate degree of clinical certainty; level 2 to 3 evidence), or "option" (uncertain clinical use; insufficient or inconclusive evidence).

Treatment with positive airway pressure (PAP)
- CPAP is indicated for individuals with moderate to severe OSA (Standard) and mild OSA (Option).
- Bilevel PAP can be considered in CPAP-intolerant individuals (Consensus).
- Autotitrating positive airway pressure (APAP) can be considered in CPAP-intolerant individuals(Consensus).

The AASM (2019) also published a clinical practice guideline on the treatment of OSA with PAP that was based on a systematic review of the evidence. [1, 2] "A STRONG (ie, "We recommend…") recommendation is one that clinicians should follow under most circumstances. A CONDITIONAL recommendation (ie, "We suggest…")
reflects a lower degree of certainty regarding the outcome and appropriateness of the individual-care strategy for all individuals."

The AASM provided strong recommendations for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with excessive sleepiness.
- That PAP therapy be initiated at home using APAP or in-laboratory PAP titration in adults with no significant morbidities.
- Use of CPAP or APAP for ongoing treatment of OSA.
- That clinicians provide educational interventions with the initiation of PAP.

The AASM provided conditional recommendations (suggest) for the following use of PAP therapy in adults:

- Use of PAP to treat OSA in adults with impaired sleep-related quality of life (QOL).
- Use of PAP to treat OSA in adults with comorbid hypertension.
- Use CPAP or APAP over Bilevel PAP in the routine treatment of OSA.
- That behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy.
- That clinicians use telemonitoring during the initial period of PAP therapy.

American Heart Association
In 2021, the American Heart Association (AHA) published a scientific statement on OSA and cardiovascular disease. [14] The treatment options for OSA and eligibility for their use are described in the statement and briefly summarized below:

- CPAP: "The Centers for Medicare & Medicaid Services cover CPAP on the basis of an AHI or REI ≥15events per hour or AHI (or REI) ≥5 with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented comorbidities (ie, hypertension, ischemic heart disease, or history of stroke)."
- APAP: "Same as CPAP."
- Bilevel PAP: "Individuals intolerant of CPAP pressure or who require additional ventilatory support."

The statement also notes the following with regards to treatment:
"All individuals with OSA should be considered for treatment, including behavioral modifications and weight loss as indicated. Continuous positive airway pressure should be offered to individuals with severe OSA, whereas oral appliances can be considered for those with mild to moderate OSA or for continuous positive airway pressure–intolerant individuals. Follow-up sleep testing should be performed to assess the effectiveness of treatment."

Government Regulations
National:
NCD – 240.4 – Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea, 8/4/2008.

Nationally Covered Indications

Effective for claims with dates of service on and after March 13, 2008, the Centers for Medicare & Medicaid Services (CMS) determines that CPAP therapy when used in adult patients with OSA is considered reasonable and necessary under the following situations:

1. The use of CPAP is covered under Medicare when used in adult patients with OSA. Coverage of CPAP is initially limited to a 12-week period to identify beneficiaries diagnosed with OSA as subsequently described who benefit from CPAP. CPAP is subsequently covered only for those beneficiaries diagnosed with OSA who benefit from CPAP during this 12-week period.
2. The provider of CPAP must conduct education of the beneficiary prior to the use of the CPAP device to ensure that the beneficiary has been educated in the proper use of the device. A caregiver, for example a family member, may be compensatory, if consistently available in the beneficiary's home and willing and able to safely operate the CPAP device.
3. A positive diagnosis of OSA for the coverage of CPAP must include a clinical evaluation and a positive:
   a. attended PSG performed in a sleep laboratory; or
   b. unattended HST with a Type II home sleep monitoring device; or
   c. unattended HST with a Type III home sleep monitoring device; or
   d. unattended HST with a Type IV home sleep monitoring device that measures at least 3 channels.
4. The sleep test must have been previously ordered by the beneficiary’s treating physician and furnished under appropriate physician supervision.
5. An initial 12-week period of CPAP is covered in adult patients with OSA if either of the following criterion using the AHI or RDI are met:
   a. AHI or RDI greater than or equal to 15 events per hour, or
   b. AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.
6. The AHI or RDI is calculated on the average number of events of per hour. If the AHI or RDI is calculated based on less than 2 hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing must be at a minimum the number of events that would have been required in a 2-hour period.
7. 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 thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% oxygen desaturation.
8. Coverage with Evidence Development (CED): Medicare provides the following limited coverage for CPAP in adult beneficiaries who do not qualify for CPAP coverage based on criteria 1-7 above. A clinical study seeking Medicare payment for CPAP provided to a beneficiary who is an enrolled subject in that study must address one or more of the following questions
   a. In Medicare-aged subjects with clinically identified risk factors for OSA, how does the diagnostic accuracy of a clinical trial of CPAP compare with PSG and Type II, III & IV HST in identifying subjects with OSA who will respond to CPAP?
   b. In Medicare-aged subjects with clinically identified risk factors for OSA who have not undergone confirmatory testing with PSG or Type II, III & IV HST, does CPAP cause clinically meaningful harm?

   The study must meet the following additional standards:

c. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
d. The research study is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
e. The research study does not unjustifiably duplicate existing studies.
f. The research study design is appropriate to answer the research question being asked in the study.
g. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
h. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is Food and Drug Administration-regulated, it also must be in compliance with 21 CFR Parts 50 and 56.
i. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
j. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
k. The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the disease or condition being studied is life-threatening as defined in 21 CFR § 312.81(a) and the individual has no other viable treatment options.
l. The clinical research study is registered on the ClinicalTrials.gov Web site by the principal sponsor/investigator prior to the enrollment of the first study subject.
m. The research study protocol specifies the method and timing of public release of all pre-specified outcomes to be measured, including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned for publication in a peer-reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors. However, a full report of the outcomes must be made public no later than 3 years after the end of data collection.
n. The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria affect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
o. The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability, or Medicaid eligibility.

Nationally Non-covered Indications
Effective for claims with dates of services on and after March 13, 2008, other diagnostic tests for the diagnosis of OSA, other than those noted above for prescribing CPAP, are not sufficient.

Local:

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.

- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

- Refer to the Supplier Manual for additional information on documentation requirements.

- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

DEFINITIONS:

Apnea is defined as the cessation of airflow for at least 10 seconds.

Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a 4% decrease in oxygen saturation.

The apnea-hypopnea index (AHI) is defined as the average number of episodes of apnea and hypopnea per hour of sleep without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the calculation of the AHI. Sleep time can only be measured in a Type I (facility based polysomnogram) or Type II sleep study (see descriptions below).

The respiratory disturbance index (RDI) is defined as the average number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. For purposes of this policy, respiratory effort related arousals (RERAs) are not included in the

calculation of the RDI. The RDI is reported in Type III, Type IV, and Other home sleep studies.

If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach ≥30 events without symptoms or ≥10 events with symptoms).

INITIAL COVERAGE:

In this policy, the term PAP (positive airway pressure) device will refer to both a single-level continuous positive airway pressure device (E0601) and a bi-level respiratory assist device without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

I. An E0601 device is covered for the treatment of obstructive sleep apnea (OSA) if criteria A – C are met:
   - A. The beneficiary has a face-to-face clinical evaluation by the treating practitioner prior to the sleep test to assess the beneficiary for obstructive sleep apnea.
   - B. The beneficiary has a sleep test (as defined below) that meets either of the following criteria (1 or 2):
     1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (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 or equal to 14 events per hour with a minimum of 10 events and documentation of:
        - a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
        - b. Hypertension, ischemic heart disease, or history of stroke.
   - C. The beneficiary and/or their caregiver has received instruction from the supplier of the device in the proper use and care of the equipment.

If a claim for an E0601 is submitted and all of the criteria above have not been met, it will be denied as not reasonable and necessary.

II. An E0470 device is covered for those beneficiaries with OSA who meet criteria A-C above, in addition to criterion D:
   - D. An E0601 has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting.

Ineffective is defined as documented failure to meet therapeutic goals using an E0601 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).

If E0470 is billed for a beneficiary with OSA and criteria A-D are not met, it will be denied as not reasonable and necessary.

A bi-level positive airway pressure device with back-up rate (E0471) is not reasonable and necessary if the primary diagnosis is OSA. If an E0471 is billed with a diagnosis of OSA, it will be denied as not reasonable and necessary.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not require a new initial face-to-face clinical evaluation or a

new sleep test.

If an E0601 device has been used for more than 3 months and the beneficiary is switched to an E0470, a new initial face-to-face clinical evaluation is required, but a new sleep test is not required. A new 3 month trial would begin for use of the E0470.

Coverage, coding and documentation requirements for the use of E0470 and E0471 for diagnoses other than OSA are addressed in the Respiratory Assist Devices (RAD) Local Coverage Determination (LCD) and related Policy Article (PA).

Sleep Tests

Coverage and Payment rules for sleep tests may be found in the LCDs for the applicable Medicare Part A or Part B contractor. There may be differences between those LCDs and the DME MAC LCD. For the purposes of coverage of PAP therapy, the DME MAC coverage, coding and payment rules take precedence.

Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a sleep test (Type I, II, III, IV, Other) that meets the Medicare coverage criteria in effect for the date of service of the claim for the PAP device. The sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or an inpatient hospital-based or home based sleep test (HST) (Types II, III, IV, Other). The test must be ordered by the beneficiary's treating practitioner and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

A Type I sleep test is the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep with practitioner review, interpretation, and report. It is facility-based and must include sleep staging, which is defined to include a 1-4 lead electroencephalogram (EEG), electro-oculogram (EOG), submental electromyogram (EMG) and electrocardiogram (ECG). It must also include at least the following additional parameters of sleep: airflow, respiratory effort, and oxygen saturation by oximetry. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

An HST is performed unattended in the beneficiary's home using a portable monitoring device. A portable monitoring device for conducting an HST must meet one of the following criteria:

A. Type II device – Monitors and records a minimum of seven (7) channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory movement/effort and oxygen saturation; or,
B. Type III device – Monitors and records a minimum of four (4) channels: respiratory movement/effort, airflow, ECG/heart rate and oxygen saturation; or,
C. Type IV device – Monitors and records a minimum of three (3) channels, one of which is airflow; or,
D. Other - Devices that monitor and record a minimum of three (3) channels that include actigraphy, oximetry and peripheral arterial tone and for which there is substantive clinical evidence in the published peer-reviewed medical literature that demonstrates that the results accurately and reliably correspond to an AHI or RDI as defined above. This determination will be made on a device by device basis (See Appendix B for list of approved devices in this category).

For all PAP devices, beneficiaries who undergo an HST must, prior to having the test, receive

instruction on how to properly apply a portable sleep monitoring device. This instruction must be provided by the entity conducting the HST and may not be performed by a DME supplier. Beneficiary instruction may be accomplished by either:

1. Face-to-face demonstration of the portable sleep monitoring device's application and use; or,
2. Video or telephonic instruction, with 24 hour availability of qualified personnel to answer questions or troubleshoot issues with the device.

For all PAP devices the sleep test (Type I - IV, Other) must be interpreted by a practitioner who holds either:

1. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or,
2. Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS) or American Osteopathic Association (AOA); or,
3. Completed residency or fellowship training by an ABMS or AOA member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the practitioner is eligible; or,
4. Active staff membership of a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM), Accreditation Commission for Health Care (ACHC), or The Joint Commission (TJC, formerly the Joint Commission on Accreditation of Healthcare Organizations – JCAHO).

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.

For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:

1. Face-to-face clinical re-evaluation by the treating practitioner with documentation that symptoms of obstructive sleep apnea are improved; and,
2. Objective evidence of adherence to use of the PAP device, reviewed by the treating practitioner.

Adherence to therapy is defined as use of PAP ≥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.

If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not reasonable and necessary.

If the treating practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the beneficiary is benefiting from PAP therapy as defined in criteria 1 and 2 above, continued coverage of the PAP device will commence with the date of that re-evaluation.

Beneficiaries who fail the initial 12 week trial are eligible to re-qualify for a PAP device but must have both:

1. Face-to-face clinical re-evaluation by the treating practitioner to determine the etiology

of the failure to respond to PAP therapy; and,

2. Repeat sleep test in a facility-based setting (Type 1 study).This may be a repeat diagnostic, titration or split-night study.

If an E0601 device is tried and found ineffective during the initial facility-based titration or home trial, substitution of an E0470 does not change the length of the trial unless there is less than 30 days remaining in the trial period. If more than 30 days remain in the trial period, the clinical re-evaluation would still occur between the 31st and 91st day following the initiation of an E0601 and objective documentation of adherence on the E0470 would need to occur prior to the 91st day following initiation of the E0601. If less than 30 days remain in the trial period, the clinical re-evaluation and objective documentation of adherence must occur before the 120th day following the initiation of the E0601.

If an E0601 device was used for more than 3 months and the beneficiary was then switched to an E0470, the clinical re-evaluation must occur between the 31st and 91st day following the initiation of the E0470. There would also need to be documentation of adherence to therapy during the 3 month trial with the E0470.

If there is discontinuation of usage of a PAP device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

For a PAP device dispensed prior to November 1, 2008, if the initial Medicare coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the device will continue to be covered for dates of service on or after November 1, 2008 as long as the beneficiary continues to use the device.

CONCURRENT USE OF OXYGEN WITH PAP THERAPY

Some beneficiaries may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Coverage Indications, Limitations and/or Medical Necessity for both Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. Consequently, in addition to this LCD, suppliers should refer to the Oxygen and Oxygen Equipment LCD and related Policy Article for additional coverage, coding and documentation requirements.

Coverage of home oxygen therapy requires that the beneficiary be tested in the “chronic stable state.” Chronic stable state is a requirement of the National Coverage Determination (CMS Internet-only Manual, Pub. 100-03, Section 240.2) and is one of the key criteria when determining coverage of home oxygen therapy. The NCD defines chronic stable state as “…not during a period of an acute illness or an exacerbation of their underlying disease.” Based on this NCD definition, all co-existing diseases or conditions that can cause hypoxia must be treated and the beneficiary must be in a chronic stable state before oxygen therapy is considered eligible for payment. In addition, the beneficiary must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy (see Oxygen LCD for additional information). For beneficiaries with OSA to be considered in the chronic, stable state, OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. This must be demonstrated before oxygen saturation results are considered qualifying for oxygen

therapy.

For beneficiaries with OSA, a qualifying oxygen saturation test for the purposes of determining Medicare home oxygen reimbursement may only occur during a titration polysomnographic study (either split-night or stand-alone). The titration PSG is one in which all of the following criteria are met:

1. The titration is conducted over a minimum of two (2) hours; and,
2. During titration:
   A. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or,
   B. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; and,
3. Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; and,
4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for 5 minutes total (which need not be continuous).

If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the beneficiary is considered to be in the “chronic stable state.” To be eligible for Medicare coverage and payment for home oxygen therapy for concurrent use with PAP therapy, in addition to being in the chronic stable state, the beneficiary must meet all other coverage requirements for oxygen therapy.

Suppliers should refer to the Oxygen and Oxygen Equipment LCD and related Policy Article for additional coverage, coding and documentation requirements.

REPLACEMENT:

This section applies to PAP devices initially provided and covered while the beneficiary was in Medicare fee-for-service (FFS).
If a PAP device is replaced during the 5 year reasonable useful lifetime (RUL) because of loss, theft, or irreparable damage due to a specific incident, there is no requirement for a new clinical evaluation, sleep test, or trial period.

If a PAP device is replaced following the 5 year RUL, there must be a face-to-face evaluation by their treating practitioner that documents that the beneficiary continues to use and benefit from the PAP device. There is no requirement for a new sleep test or trial period.

BENEFICIARIES ENTERING MEDICARE:

For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement PAP device and/or accessories, both of the following coverage requirements must be met:

1. Sleep test – There must be documentation that the beneficiary had a sleep test, prior to FFS Medicare enrollment, that meets the Medicare AHI/RDI coverage criteria in effect at the time that the beneficiary seeks Medicare coverage of a replacement PAP device and/or accessories; and,

2. Clinical Evaluation – Following enrollment in FFS Medicare, the beneficiary must have a face-to-face evaluation by their treating practitioner who documents in the beneficiary's medical record that:
    a. The beneficiary has a diagnosis of obstructive sleep apnea; and,
    b. The beneficiary continues to use the PAP device.

If either criteria 1 or 2 above are not met, the claim will be denied as not reasonable and necessary.

In these situations, there is no requirement for a clinical re-evaluation or for objective documentation of adherence to use of the device.

ACCESSORIES:

Accessories used with a PAP device are covered when the coverage criteria for the device are met. If the coverage criteria are not met, the accessories will be denied as not reasonable and necessary.

The following table represents the usual maximum amount of accessories expected to be reasonable and necessary:

A4604	1 per 3 months
A7027	1 per 3 months
A7028	2 per 1 month
A7029	2 per 1 month
A7030	1 per 3 months
A7031	1 per 1 month
A7032	2 per 1 month
A7033	2 per 1 month
A7034	1 per 3 months
A7035	1 per 6 months
A7036	1 per 6 months
A7037	1 per 3 months
A7038	2 per 1 month
A7039	1 per 6 months
A7046	1 per 6 months

Quantities of supplies greater than those described in the policy as the usual maximum amounts will be denied as not reasonable and necessary.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must also obtain a DWO before submitting a claim for any associated options, accessories, and/or supplies that are separately billed. In this scenario, if the supplier bills for associated options, accessories, and/or supplies without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

A WOPD (if applicable) must be received by the supplier before a DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a completed WOPD, the claim shall be statutorily denied. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4604, A7027-A7046) that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the prescribing practitioner that any changed or atypical utilization is warranted.

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

Either a non-heated (E0561) or heated (E0562) humidifier is covered when ordered by the treating practitioner for use with a covered PAP (E0470 or E0601) device.

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea - Policy Article (A52467), Original Article Effective Date 10/01/2015, Revision Effective Date 08/08/2021

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES
For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. “reasonable and necessary”).

Positive airway pressure devices are covered under the Durable Medical Equipment benefit [Social Security Act §1861(s)(6)]. In order for a beneficiary’s DME to be eligible for reimbursement, the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

Accessories are separately reimbursable at the time of initial issue and when replaced.

No aspect of a home sleep test, including but not limited to delivery and/or pickup of the device, may be performed by a DME supplier. This prohibition does not extend to the results of studies conducted by hospitals certified to do such tests or to tests conducted in facility-based sleep laboratories.

A liner used in conjunction with a PAP mask is considered comfort/convenience item. There is no additional payment for liners used with a PAP mask. These products should be coded A9270 (Noncovered item or service) in accordance with the Medicare Benefit Policy Manual 100-02 Chapter 15 Section 110.1.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g)

42 CFR 410.38(g) requires a face-to-face evaluation and a specific written order prior to delivery for specified HCPCS codes. CMS provides a list of the specified codes, which is periodically updated, located here.

Claims for the specified items subject to 42 CFR 410.38(g) that do not meet the requirements specified in the LCD-related Standard Documentation Requirements Article will be denied as statutorily noncovered – failed to meet statutory requirements.

If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be

eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

INITIAL EVALUATION

For the initial evaluation, the report would commonly document pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

History

- Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches;
- Duration of symptoms
- Validated sleep hygiene inventory such as the Epworth Sleepiness Scale (see Appendices of related LCD)

Physical Exam

- Focused cardiopulmonary and upper airway system evaluation
- Neck circumference
- Body mass index (BMI)

A dispensing order is not sufficient to provide these items. A Written Order Prior to Delivery (WOPD) is required.

The DMEPOS supplier must have documentation of both the face-to-face visit and the completed WOPD in their file prior to the delivery of these items.

Suppliers are reminded that all Medicare coverage and documentation requirements for DMEPOS also apply. There must be sufficient information included in the medical record to demonstrate that all of the applicable coverage criteria are met. This information must be available upon request.

For beneficiaries changing from an E0601 to E0470 due to ineffective therapy while on E0601 (either during a facility-based titration or in the home setting), the treating practitioner must document that both of the following issues were addressed prior to changing to an E0470 device:

A. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the E0470 device; and,

B. E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601 were tried but failed to:

    1. Adequately control the symptoms of OSA; or,

    2. Improve sleep quality; or,

    3. Reduce the AHI/RDI to acceptable levels.

The re-evaluation must take place within the first 3 months of treatment; however, formal assessment of improvement cannot be documented before the 31st day. The re-evaluation must document both improvement in subjective symptoms of OSA and objective data related to adherence to PAP therapy.

Documentation of adherence to PAP therapy shall be accomplished through direct download or visual inspection of usage data with documentation provided in a written report format to be reviewed by the treating practitioner and included in the beneficiary's medical record. This information does not have to be submitted with the claim but must be available upon request. Many suppliers have created forms which have not been approved by CMS which they send to practitioners and ask them to complete. Even if the practitioner completes this type of form and puts it in his/her chart, this supplier-generated form is not a substitute for the comprehensive medical record as noted above. Suppliers are encouraged to help educate practitioners on the type of information that is needed to document a beneficiary's need for PAP therapy.

Proper use of modifiers is discussed below. Specific modifiers must be used and differ depending on whether or not the requirements outlined in the documentation section have been met.

INITIAL COVERAGE (FIRST THREE MONTHS):

On claims for the first through third months, suppliers must add a KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if all of the criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD ("Initial Coverage") have been met.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:

On the fourth month's claim (and any month thereafter), the supplier must add a KX modifier to codes for PAP equipment (E0470 or E0601) and accessories only if both the "Initial Coverage" criteria and the "Continued Coverage" criteria in the "Coverage Indications, Limitations and/or

Medical Necessity" section of the related LCD have been met.
If the supplier does not obtain information from the practitioner that the beneficiary has demonstrated improvement in their OSA symptoms and is adhering to PAP therapy in time for submission of the fourth or succeeding months' claims, the supplier may still submit the claims, but a KX modifier must not be added.

If the supplier chooses to hold claims for the fourth and succeeding months pending receipt of information from the treating practitioner that the beneficiary received a clinical re-evaluation between the 31st and 91st day, had documented improvement in OSA symptoms and is adhering to PAP therapy, those claims may then be submitted with the KX modifier.

If the supplier chooses to hold claims for the fourth and succeeding month pending receipt of information from the treating practitioner but learns that the beneficiary did not receive a clinical re-evaluation between the 31st and 91st day but rather was re-evaluated at a later date and had documented improvement in OSA symptoms and is adhering to PAP therapy, those claims may then be submitted with the KX modifier but only for dates of service following the date of the clinical re-evaluation.

For a PAP device dispensed prior to November 1, 2008, if the initial coverage criteria in effect at the time were met and the criteria for coverage after the first 3 months that were in effect at the time were met, the KX modifier may be added to claim with dates of service on or after November 1, 2008 as long as the beneficiary continues to use the device.

BENEFICIARIES ENTERING MEDICARE:

For beneficiaries who received a PAP device prior to enrollment in fee for service (FFS) Medicare and are seeking Medicare coverage of either rental of the device, a replacement device or accessories, the supplier may add the KX modifier only if both of the criteria listed in the Coverage Indications, Limitations and/or Medical Necessity for Beneficiaries Entering Medicare section of the related LCD have been met.
The supplier may hold claims, pending confirmation that the above requirements are met, and then submit claims with the KX modifier beginning with the date of FFS Medicare enrollment.

CONCURRENT USE OF OXYGEN WITH PAP THERAPY

In the rare instance where beneficiaries require the simultaneous use of home oxygen therapy and a PAP device, documentation by the treating practitioner in the beneficiary's medical record must clearly demonstrate that the requirements for coverage outlined in the PAP LCD Coverage Indications, Limitations and/or Medical Necessity have been met. In addition, the beneficiary's medical record must also clearly demonstrate that the requirements for coverage outlined in the Oxygen and Oxygen Equipment LCD Coverage Indications, Limitations and/or Medical Necessity have been met. This information does not have to be submitted with the claim but must be available upon request.

Suppliers should refer to the Oxygen and Oxygen Equipment LCD and related Policy Article for additional coverage, coding and documentation requirements.

MODIFIERS

GA, GZ, and KX MODIFIERS:

In all of the situations above describing use of the KX modifier, if all of the coverage criteria have not been met, the GA or GZ modifier must be added to a claim line for the PAP equipment and accessories. When there is an expectation of a reasonable and necessary denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a GA, GZ or KX modifier will be rejected as missing information.

MISCELLANEOUS

Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order must include the type(s) of supplies ordered and the approximate quantity to be used per unit of time. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used.

The supplier must enter the diagnosis code for the PAP device on each claim submitted for PAP supplies.

Refer to the Supplier Manual for additional information on documentation requirements.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Actigraphy for Obstructive Sleep Apnea and Sleep Disorders
- Noninvasive Ear or Pulse Oximetry for Oxygen Saturation by Continuous Overnight Monitoring for Sleep Disorders
- Obstructive Sleep Apnea and Snoring - Surgical Treatment
- Diagnosis of Sleep Disorders
- Obstructive Sleep Apnea – Non-surgical Treatment

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17. CGS Administrators, LLC, DME MAC, 17013 - DME MAC, J-B, Local Coverage Determination (LCD): Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718), Original Effective Date 10/1/2015, Revision Effective Date 8/8/2021.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through February 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/02	7/02	7/02	Joint policy established
11/8/04	11/8/04	12/2/04	Routine update; new codes added, policy and summary statement updated, “continuous” and Bi-PAP added to policy title, Medicare statement expanded, criteria altered to reflect Medicare guidelines.
3/1/07	12/28/06	1/10/07	Routine maintenance
3/1/08	12/11/07	3/1/08	Routine maintenance, include pediatric information
5/1/09	2/10/09	2/10/09	Routine maintenance
1/1/10	10/13/09	10/13/09	Routine maintenance; APAP and VPAP Adaptive ServoVentilation added to policy, name changed from Continuous Positive pressure airway Device to Positive Pressure Airway Devices
7/1/11	4/19/11	5/3/11	Routine maintenance
7/1/12	4/10/12	5/18/12	Routine maintenance
11/1/13	8/20/13	9/3/13	Routine maintenance
5/1/15	2/17/15	2/27/15	Routine maintenance Updated literature & references Inclusions updated/revised Coverage Determination updated for Commercial HMO to reflect Medicare guidelines for CPAP adherence
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance Updated local Medicare contractor information and coverage policy
7/1/18	4/17/18	4/17/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
7/1/20	4/14/20		Routine maintenance

7/1/21	4/20/21		Routine maintenance
7/1/22	4/19/22		Routine maintenance Updated language under Inclusion and Exclusion sections to align with BCBSA.
7/1/23	4/18/23		Routine maintenance Vendor: Northwood (ky)
7/1/24	4/16/24		4/16/24: Per 4/18/23 JUMP recommendation, incorporated "Positive Pressure Airway Devices" Jump policy into JUMP policy Obstructive Sleep Apnea – Non-surgical Treatment for 4/16/2024 JUMP. Vendor: Northwood (ky)

Next Review Date: Policy replaced. Refer to JUMP policy, "Obstructive Sleep Apnea-Non-Surgical Treatments"

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: 11/25/97	Revised: 6/28/01
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: POSITIVE PRESSURE AIRWAY DEVICES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Refer to policy criteria. Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy. For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by: 1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and, 2. Objective evidence of adherence to use of the PAP device, reviewed by the treating physician. Adherence to therapy is defined as use of PAP ≥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. If the above criteria are not met, continued coverage of a PAP device and related accessories will be denied as not reasonable and necessary.
BCNA (Medicare Advantage)	See Government Regulations section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.

- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.