Current Effective Date: 8/7/25
Status: Approved
Reviewed by Medical Policy Subcommittee: 5/3/18, 5/5/22, 12/19/24, 8/7/25
Reviewed Dates: 1/16/18, 3/4/22, 12/2/24, 6/10/25

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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Continuous Positive Airway Pressure (CPAP) Policy

Indication/Usage:

Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

Medical Indications for Authorization Commercial Members

SummaCare considers CPAP with pressure relief technology, autoPAP (APAP), and APAP with pressure relief technology medically necessary DME for members with a positive facility-based NPSG or with a positive home sleep test including Type II, III, IV(A) or Watch-PAT devices, as defined by *either* of the following criteria:

1. An 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 any one episode of oxygen desaturation (i.e., oxygen saturation of less than 70 %).

3. 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:

    a. Face-to-face clinical reevaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; **and**

    b. 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.

Medicare Members

CMS NCD 240.6 Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA)

Item/Service Description

A. General

Continuous Positive Airway Pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep, which occurs in obstructive sleep apnea (OSA).

The apnea hypopnea index (AHI) is equal to the average number of episodes of apnea and hypopnea per hour. The respiratory disturbance index (RDI) is equal to the average number of respiratory disturbances per hour.

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.

The AHI and/or RDI may be measured by polysomnography (PSG) in a facility-based sleep study laboratory, or by a Type II home sleep test (HST) monitor, a Type III HST monitor, or a Type IV HST monitor measuring at least 3 channels.

Indications and Limitations of Coverage

B. 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?
    c. The study must meet the following additional standards:

d. The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
e. 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.
f. The research study does not unjustifiably duplicate existing studies.
g. The research study design is appropriate to answer the research question being asked in the study.
h. The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
i. 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.
j. All aspects of the research study are conducted according to the appropriate standards of scientific integrity.
k. The research study has a written protocol that clearly addresses, or incorporates by reference, the Medicare standards.
l. 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 patient has no other viable treatment options.
m. 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.
n. 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.
o. 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.
p. 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.

C. 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 for the coverage of CPAP.

HCPCS Codes

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

Limitations

SummaCare considers CPAP experimental and investigational for all other indications.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

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