Continuous Positive Airway Pressure (CPAP) for Adults (≥ 18 Years)

Policy Number: HS-008

Original Effective Date: 12/6/2007


APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.
BACKGROUND

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 is measured by polysomnography (PSG) in a facility-based sleep study laboratory. 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.¹

Coverage with Evidence Development ¹,²,³

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 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, 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.

POSITION STATEMENT

Applicable To:
- Medicaid
- Medicare

Note: Applicable to adults ≥ 18 years old. For CPAP for pediatric members, refer to HS 099 Pediatric CPAP for the Treatment of Obstructive Sleep Apnea.

CPAP is considered medically necessary if ALL of the following criteria are met:

1. Member has a diagnosis of one or more of the following:
   - Obstructive sleep apnea (OSA)
   - Central or complex sleep apnea
   - Neuromuscular condition
   - Chronic obstructive pulmonary disease (COPD)
   - Thoracic expansion limited or restrictive lung disease
   - Hypoventilation syndrome

   AND,

2. There is a clinical evaluation through an attended polysomnography (PSG) in a sleep laboratory ordered by the treating physician; AND,

3. The member is educated on the use of the CPAP by the provider of the device prior to use;

   AND,

4. The results of the PSG indicate an AHI or RDI greater than or equal to 15 events per hour; OR,
   The results of the PSG indicate an AHI or RDI greater than or equal to 5 events and less than or equal to 14 events per hour with documented symptoms of ONE of the following:
   - Excessive daytime sleepiness; OR,
- Impaired cognition; OR,
- Mood disorders or insomnia; OR,
- Documented hypertension; OR,
- Ischemic heart disease; OR,
- History of stroke.

Note: Coverage of CPAP is initially limited to a 12-week period to identify members diagnosed with OSA who benefit from CPAP. CPAP is subsequently covered only for those members diagnosed with OSA who benefit from CPAP during the 12-week period. **

Florida

Other items pertaining to coverage include:
- Medicaid will reimburse for only one respiratory assist device per recipient, per month.
- Medicaid will only reimburse for CPAP or BIPAP supplies for recipient-owned devices.
- All supplies needed to safely and effectively operate rented CPAP devices, including tubing and masks, are included in the provider’s scheduled monthly rental fee. Claiming separate reimbursement for supplies used with a rented CPAP device rented by Medicaid is not permitted.
- Heated or non-heated humidifiers prescribed for use with the covered CPAP device is not integral to the CPAP device itself and is not a covered benefit.

CODING

Covered CPT® Code
94660 Continuous positive airway pressure ventilation (CPAP), initiation and management

Covered HCPCS Codes
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
A7039 Filter, non-disposable, used with positive airway pressure device
A7044 Oral interface used with positive airway pressure device, each
E0601 Continuous airway pressure (CPAP) device

ICD-9-CM Procedure Codes
93.90 CPAP – Continuous positive airway pressure

Draft ICD-10-PCS (Inpatient Only)
Refer to the following ICD-10-PCS tables for specific code assignment based on physician documentation.

NOTE: Per ICD-10-PCS Coding Guidelines, "ICD-10-PCS codes are composed of seven characters. Each character is an axis of classification that specifies information about the procedure performed. Within a defined code range, a character specifies the same type of information in that axis of classification. One of 34 possible values can be assigned to each axis of classification in the seven-character code".

5A0 Extracorporeal Assistance and Performance, Physiological Systems, Assistance
Covered ICD-9-Diagnosis Code
327.23 Obstructive sleep apnea
327.26 Sleep related hypoventilation/hypoxemia in conditions classifiable elsewhere
327.27 Central sleep apnea in conditions classified elsewhere
358.9 Other specified myoneural disorders
496 Chronic Obstructive pulmonary disease (COPD)
518.89 Restrictive Lung Disease

Covered Draft ICD-10-CM Diagnosis Codes
G47.31 Primary central sleep apnea
G47.33 Obstructive sleep apnea (adult)(pediatric)
G47.36 Sleep related hypoventilation in conditions classified elsewhere
G47.37 Central sleep apnea in conditions classified elsewhere
G70.9 Myoneural disorder, unspecified
J44.9 Chronic obstructive pulmonary disease, unspecified
J98.4 Other disorders of lung


REFERENCES


MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>7/11/2015, 8/7/2014</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>8/1/2013</td>
<td>Approved by MPC. Incorporated diagnoses required for coverage. Name revised to be more broad as additional diagnoses were included (previously only Obstructive Sleep Apnea was included).</td>
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<tr>
<td>6/6/2013</td>
<td>Approved by MPC. No changes.</td>
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<tr>
<td>6/7/2012</td>
<td>Approved by MPC. Added statement to refer to CCG after InterQual criteria is reviewed for market specific criteria.</td>
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<tr>
<td>12/1/2011</td>
<td>New template design approved by MPC.</td>
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<tr>
<td>7/18/2011</td>
<td>Approved by MPC. Added (&gt;18 years) to define age of adult. Deleted sections related to GA and OH.</td>
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