

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline

WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

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Harmony Behavioral Health, Inc.

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WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Continuous Positive Airway Pressure (CPAP) for Treatment of Obstructive Sleep Apnea in Adults

Guideline Number: HS-008

Original Effective Date: 12/6/2007

Revision Date: 4/22/2009

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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.

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DISCLAIMER

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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.

CLINICAL COVERAGE GUIDELINE

Continuous Positive Airway Pressure (CPAP) is considered medically necessary if ALL of the following criteria are met:

- 1) There is a clinical evaluation through an attended polysomnography (PSG) in a sleep laboratory ordered by the treating physician; **AND**,
- 2) The member is educated on the use of the CPAP by the provider of the device prior to use;

AND,

- 3) The results of the PSG indicate an AHI or RDI greater than or equal to 15 events per hour; **OR**,
- 4) 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.

State-Specific Criteria

Florida

Medicaid may reimburse for a CPAP device when there is documentation in the medical record to indicate:

- A diagnosis of moderate or severe OSA; **AND**,
- The device is prescribed for six months or less*.

*Medicaid may approve a renewal request in cases that are certified by the attending physician that CPAP is effective and the recipient is compliant.

The following information must be documented in the recipient's record:

- That the recipient has at least thirty episodes of OSA, each lasting a minimum of ten seconds, during six to seven hours of recorded sleep; **AND**,
- Surgery is a likely alternative; **AND**,
- A sleep study was conducted that indicates oxygen saturation on room air, with a saturation level at 88% or below, for more than 5% of total sleep; **AND**,
- A second sleep study was conducted that indicates an oxygen saturation increase of 15%, or more, was experienced by using a CPAP device, and a decrease in the number of airway obstruction per hour; **AND**,
- Any correctable causes of the recipient's sleep apnea have been considered along with an explanation whether these factors are being treated; **AND**,
- If there are no corrective causes or if all correctable causes have been resolved; **AND**,
- Whether the recipient is symptomatic or asymptomatic, and identify what impairments are present secondary to the sleep apnea.

Georgia

CPAP is considered medically necessary for Medicaid members in Georgia if **ALL** of the following criteria are met:

- There is a diagnosis of obstructive sleep apnea; **AND**,
- AHI is equal to or greater than 30; **OR**,
- AHI is equal to or greater than 15 and equal to or less than 30 with documented symptoms of two or more of the following from the first set and one or more of the following from the second set:
 - Excessive daytime sleepiness, impaired cognition, mood disorders or insomnia;
 - Documented hypertension, ischemic heart disease, or history of stroke
- A complete polysomnography sleep evaluation of 6 to 8 hours documenting the above criteria must be submitted. A split night study may be considered. The AHI is based on a minimum of 3 hours of sleep recorded by the polysomnography; **AND**,
- The polysomnography must be performed no more than six months from the date the prior authorization is received and must be performed in a facility based sleep study laboratory and not in the home or in a mobile facility; **AND**,
- Documentation from the provider and/or physician that the member is cooperative and motivated; **AND**,
- Set-up, teaching, home visits and associated professional services must be performed by a credentialed respiratory therapist or a certified sleep technologist; **AND**,
- Approval will be for a ten month rental to capped purchase. Providers must check compliancy during the ten months and maintain the documentation in their records. If a member is documented as non-compliant, that member may be warned. If non-compliance continues, the provider must retrieve the device and not bill for the remaining months.

Ohio

A request for CPAP must contain ALL of the following information:

- 1) A statement of medical necessity from the consumer's attending prescriber indicating:
 - a. Diagnosis of OSA; **AND**,
 - b. Surgery is a likely alternative; **AND**,
- 2) Sleep study reports from both a diagnostic and a titration sleep study (these may be performed as two separate studies or consecutively as a split study) conforming to the following:
 - a. The sleep studies must be performed in an attended, facility-based sleep study laboratory which is eligible for reimbursement for the study, and not in a home or in a mobile facility. A DME supplier may not perform the study; **AND**,
 - b. During at least two hours of recorded sleep for the diagnostic study:
 - The AHI is equal to or greater than 15 events per hour; **OR**,
 - The AHI is from 5 to 14 events with documented symptoms stated previously.
 - c. The titration study of at least three hours duration shows efficacy of the CPAP system by decreasing the number of airway obstructions per hour and:
 - Shows a percentage increase in oxygen saturation of at least fifteen%; **OR**,
 - Shows an increase in oxygen saturation to 89% or greater; **OR**,
 - At the discretion of the department, shows other clinical improvement.
 - d. If oxygen is needed in addition to CPAP, documentation of effectiveness must be shown by the sleep study.
- 3) A statement from the attending prescriber documenting any correctable causes of the consumer's sleep apnea which are present, and whether or not they are being treated or have been abolished. It must be specified if none exist; **AND**,
- 4) A statement from the attending prescriber indicating whether the consumer is symptomatic or asymptomatic and what impairments secondary to sleep apnea are present; **AND**,
- 5) A statement from the attending prescriber certifying that the consumer is using the device regularly as prescriber.

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.

Coverage with Evidence Development

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?

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 patient 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.

CODING

Related CPT® Code

94660 Continuous positive airway pressure ventilation (CPAP), initiation and management

ICD-9-CM Procedure Codes

No applicable codes.

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

Covered ICD-9-Diagnosis Code

327.23 Obstructive sleep apnea

REFERENCES

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2. Hayes Directory. Sleep Apnea Treatment, Devices-ARCHIVED: 2006. September 16, 1999.
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4. American Academy of Sleep Medicine Report. Practice Parameters for the Use of Continuous and Bilevel Positive Airway Pressure Devices to Treat Adult Patients with Sleep-Related Breathing Disorders. Kushida et al, 2006.
5. UnitedHealthcare Technology Assessment. Continuous Positive Airway Pressure (CPAP) and Bi-Level Positive Airway Pressure (BPAP) for Treatment of Obstructive Sleep Apnea. May 15, 2008.
6. Florida Medicaid DME/Medical Supply Services Coverage and Limitations Handbook. 2-53. July, 2001.
7. Georgia Durable Medical Equipment Services Manual. VIII-12-14. Revised April, 2008.
8. Ohio Durable Medical Equipment Handbook. Promulgated Under 119.03, Statutory Authority 5111.02> Effective Date: January 1, 2008.