



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Pulse Oximetry for Home Use**

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- Obstructive Sleep Apnea Diagnosis and Treatment Services
- Oxygen for Home Use

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

Coverage for home pulse oximeters is subject to the terms, conditions and limitations of the applicable benefit plan's Durable Medical Equipment (DME) benefit and schedule of copayments. Please refer to the applicable benefit plan document to determine benefit availability and the terms, conditions and limitations of coverage. Under many benefit plans, coverage for DME is limited to the lowest-cost alternative.

If coverage for home pulse oximeters is available, the following conditions of coverage apply.

CIGNA covers pulse oximetry or use of a pulse oximetry device in the home as medically necessary for EITHER of the following when the associated criteria are met:

- intermittent or short-term pulse oximetry for EITHER of the following indications
 - gauging the need for supplemental oxygen in an individual with chronic lung disease, severe cardiopulmonary disease or neuromuscular disease involving muscles of respiration
 - periodic evaluation of oxygen saturation level in an individual on long-term medically necessary oxygen therapy
- continuous or long-term pulse oximetry to monitor supplemental oxygen use for ANY of the following indications:
 - mechanical ventilation
 - infant with chronic lung disease (e.g., bronchopulmonary dysplasia)

- premature infant on active therapy for apnea

CIGNA does not cover continuous home pulse oximetry or use of a pulse oximetry device in the home to monitor a stable respiratory condition because it is not medically necessary.

CIGNA does not cover continuous home pulse oximetry or use of a pulse oximetry device in the home for screening or diagnostic test for sleep apnea because it is considered experimental, investigational or unproven. -

General Background

Pulse oximetry is a non-invasive method of measuring and monitoring arterial blood oxygenation with the use of an oximeter. Pulse oximetry is used in a variety of settings, including hospitals, clinics, physician offices and homes. Continuous pulse oximetry is used routinely in certain facility settings such as operating rooms, recovery rooms, intensive care units and other settings where detection of hypoxemia is important. In many situations, it has replaced the use of arterial blood gas analysis to diagnose hypoxemia.

Intermittent or short-term pulse oximetry readings are routinely used in the home for patients on long-term oxygen therapy. It is part of the assessment used in determining the initial need for oxygen therapy. The need for ongoing oxygen should be assessed via pulse oximetry performed by the attending physician or an independent respiratory practitioner three months after initiation of home oxygen. Pulse oximetry is also performed for patients on long-term oxygen therapy when there is a change in their medical condition, to determine the appropriate oxygen settings. For patients on long-term oxygen therapy, an oximetric measurement is performed periodically to determine if the therapeutic goals are being met.

Oxygen therapy and pulse oximetry are often used in the home management of infants and children with chronic lung disease (e.g., bronchopulmonary dysplasia [BPD]). The American Thoracic Society (ATS), in the Statement on Care of the Child with Chronic Lung Disease of Infancy and Childhood, note that an oximeter in the home has the advantage of providing the caretaker with useful information. This can be particularly true during times of illness when the home oximetry reports may help determine whether the supplemental oxygen flow rate or concentration should be increased, or whether the child needs to be further evaluated in the office or emergency room (Allen, et al., 2003; Thoracic Society of Australia and New Zealand, et al., 2008). The ATS statement also notes that oxygen saturation measurements are utilized for this condition during the process of weaning from supplemental oxygen.

Ambulatory oximetry monitoring has been proposed as a tool for identifying candidates for long-term oxygen therapy for patients with chronic obstructive pulmonary disease (COPD). The standard method of determining oxygen requirements in these patients is based on a standard oximetric measurement. The ATS/European Respiratory Society (ERS) have noted that arterial blood gas assessment is the preferred method to determine oxygen need because it includes acid-base information (Celli, et al., 2004). The ATS/ERS statement notes that arterial oxygen saturation as measured by pulse oximetry is adequate for trending. Fussell et al. (2003) performed a prospective cohort study with 20 patients with COPD for the purpose of comparing the standard method with ambulatory oximetry monitoring. The authors noted that the study supports the hypothesis that there is a poor relationship between results of conventional methods and results from continuous ambulatory oximetry, but that additional studies are needed to determine if the prescription of oxygen based on continuous ambulatory oximetry can result in a higher percent of time in the desired oxygen saturation range.

Gay (2004) reviewed the literature regarding COPD and sleep and noted that “that there is no universal agreement as to how and when COPD patients should be evaluated for nocturnal hypoxemia, because it is controversial what level of nocturnal hypoxemia merits treatment, who should be treated, and how aggressively to follow it.” The author notes that while the decision for oxygen therapy is usually made during an office visit, home overnight oximetry before and after selection of nocturnal oxygen flow rates should usually be done for optimal management.

An oximeter is a small lightweight device that attaches to a finger, toe, or earlobe, and two wavelengths of light are directed through the body tissue. The pulsating arterial blood in the tissue absorbs some of the light, causing

small variation in detected light. A detector then measures the absorption and provides a measurement of arterial oxygen saturation. This provides a simple, noninvasive technique for measuring arterial oxygen saturation. Available pulse oximeters that may be used in the home include but are not limited to:

- DigiOx finger pulse oximeter (GF Health Products, Inc, Atlanta, GA)
- Drive Fingertip Pulse Oximeter 18710 (Drive Medical, Port Washington, NY)
- OxiMax™ N-65™ Handheld Pulse Oximeter (Nellcor Puritan Bennett LLC, Boulder, CO)

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) classifies an oximeter as a class II device. They are identified as a device used to transmit radiation as known wavelength(s) through blood and to measure the blood oxygen saturation based on the amount of reflected or scattered radiation.

Pulse Oximetry Use in Sleep Apnea Testing

Pulse oximetry is part of the testing performed during polysomnography or sleep study. It has been proposed to use pulse oximetry as a screening tool to identify patients with suspected diagnosis of obstructive sleep apnea (OSA). This use is not supported in the medical literature, and polysomnography (PSG) remains the accepted standard diagnostic test for the investigation of suspected OSA.

Literature Review for Pulse Oximetry Use in Sleep Apnea Testing: Whitelaw et al. (2005) reported a clinical randomized controlled trial to predict which patients have symptoms of OSA that will improve on treatment. The accuracy with which clinicians make this prediction using PSG compared to oximeter-based home monitoring was measured. Patients referred to a sleep center with suspicion of symptomatic OSA were randomized to have PSG or home monitoring. Patients with comorbidity or physiologic consequences of sleep apnea were excluded. Sleep specialists estimated the likelihood of success of treatment as greater than 50% (predicted success) or less than 50% (predicted failure) on the basis of clinical data and test results. All patients were treated for four weeks with autoadjusting continuous positive airway pressure. Success was defined as an increase greater than 1.0 in Sleep Apnea Quality of Life Index. Correct prediction rates were compared. Two hundred eighty-eight patients were enrolled. Initial patient characteristics, compliance, and improvement in quality of life at four weeks were not different in the two groups. The correct prediction rate was 0.61 with PSG and 0.64 with home monitoring (not significant). The authors conclude that the ability of physicians to predict the outcome of continuous positive airway treatment in individual patients is not significantly better with PSG than with home oximeter-based monitoring. The authors note that limitations of the study include: the four-week measurement does not necessarily predict long-term improvement and that only one treatment was attempted.

Kirk et al. (2003) conducted a prospective cohort study to measure the accuracy and reliability of a portable home oximetry monitor with automated analysis for the diagnosis of OSA in children. Fifty-eight consecutive, otherwise healthy children ages four to 18 years were included in the study. All subjects underwent two nights of monitoring in the home with an oximetry based monitor. A third night of monitoring was performed with computerized laboratory polysomnography. It was noted that the polysomnographic apnea-hypopnea (AHI) correlated poorly with the portable monitor-based desaturation index (DI). The sensitivity and specificity of the monitor for the identification of moderate sleep apnea was noted to 67% and 60%, respectively.

Professional Societies/Organizations for Pulse Oximetry Use in Sleep Apnea Testing: The American Academy of Pediatrics (AAP), Subcommittee on Obstructive Sleep Apnea Syndrome, notes that overnight pulse oximetry could provide an accurate screen for OSA, insofar as a positive result may be a good predictor of an abnormal PSG result. Their technical report notes that seven studies were found that reported on pulse oximetry in children suspected of having OSAS. Only one of these studies compared pulse oximetry to PSG; therefore, the findings of the one study would need to be replicated (Schechter, 2002).

The American Academy of Sleep Medicine (AASM) published updated practice parameters for the indications for polysomnography and related procedures in 2005. The practice parameters note that ambulatory overnight oximetry is a type four portable monitor; the utility of ambulatory oximetry varies depending on equipment, analysis methods and patient population; and routine use of these devices is not recommended (Kushida, et al., 2005).

Summary

Home pulse oximetry is a safe, noninvasive method of measuring oxygen saturation levels. Home pulse oximetry and use of a pulse oximeter in the home is a standard of care when used in the management of

patients with respiratory disorders who are on long-term oxygen therapy. The medical literature does not indicate that home pulse oximetry is effective for the screening or diagnosis of sleep disorders or necessary for the care of patients with stable respiratory disease.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®* Codes	Description
94760	Noninvasive ear or pulse oximetry for oxygen saturation; single determination
94761	Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (eg, during exercise)
94762	Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)

HCPCS Codes	Description
A4606	Oxygen probe for use with oximeter device, replacement
E0445	Oximeter device for measuring blood oxygen levels non-invasively

ICD-9-CM Diagnosis Codes	Description
416.0 - 416.9	Chronic pulmonary heart disease
492.0 - 492.8	Emphysema
518.83	Chronic respiratory failure
748.61	Other anomalies of lung, congenital bronchiectasis
770.7	Chronic respiratory disease arising in the perinatal period
770.81	Other respiratory problems after birth, primary apnea of newborn
V46.11	Dependence on respirator, status
V46.2	Supplemental oxygen

Experimental/Investigational/Unproven/Not Covered:

ICD-9-CM Diagnosis Codes	Description
327.23	Obstructive sleep apnea (adult) (pediatric)
780.50 - 780.59	Sleep disturbances

*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	6/15/2007	0376	Pulse Oximetry for Home Use

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