OXYGEN USE AND O2 CONCENTRATORS

HS-088

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.

Oxygen Use and O2 Concentrators

Policy Number: HS-088

Original Effective Date: 3/2/2009


Clinical Coverage Guideline
BACKGROUND

Home oxygen therapy is used to treat and prevent symptoms and manifestations of hypoxemia. Home oxygen may be indicated for patients with severe lung disease such as chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, or widespread pulmonary neoplasm.

Stationary oxygen systems include gaseous oxygen cylinders, liquid oxygen systems and oxygen concentrators.

- **Oxygen gas cylinders**: Oxygen gas is stored under pressure in tanks or cylinders. Large H cylinders weigh approximately 200 pounds and provide continuous oxygen at two liters per minute for 2.5 days.
- **Liquid oxygen**: Oxygen is stored in a reservoir as a very cold liquid that converts to gas when released from the tank. Liquid oxygen is more expensive than compressed gas but takes up less space and can be more easily transferred to a portable tank. A typical liquid oxygen system weighs approximately 120 pounds and provides continuous oxygen at two liters per minute for 8.9 days. Certain liquid oxygen systems can provide oxygen at the same rate for 30 days or more.
- **Oxygen concentrator**: An oxygen concentrator is an electric device that extracts oxygen from ambient air and delivers oxygen at 85% or greater at concentrations of up to four liters per minute. A back-up oxygen cylinder is used in the event of a power failure for patients on continuous oxygen using concentrators.
- **Portable oxygen concentrator**: A portable oxygen concentrator is a small, lightweight (< 10 lbs.) battery charged device.

Additional measurements of arterial blood gas tensions and/or saturations by invasive or noninvasive methods may be indicated whenever there is a change in clinical status that may be cardiopulmonary related. Once the need for long-term oxygen therapy (LTOT) has been documented, repeat arterial blood gases or oxygen saturation measurements are unnecessary other than to follow the course of the disease, to assess changes in clinical status, or to facilitate changes in the oxygen prescription.

POSITION STATEMENT

**Applicable To:**

- Medicaid
- Medicare

**Exclusions**

Oxygen therapy **may be considered NOT medically necessary** for members with ONE of the following conditions:

- Angina pectoris in the absence of hypoxemia; OR;
- Breathlessness without cor pulmonale or evidence of hypoxemia; OR,
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities; OR,
- Terminal illnesses that do not affect the lungs

Coverage is not applicable for individuals traveling outside of the United States borders and territories (CMS, 2012).

**Coverage**

Oxygen therapy **may be considered medically necessary** for members with ONE of the following conditions:

- Emphysema, chronic bronchitis, and bronchiectasis; OR
• Chronic interstitial pneumonia; OR
• Chronic interstitial pulmonary infiltrate-type pulmonary disease such as pulmonary fibrosis from extensive tuberculosis, eosinophilia, granuloma, idiopathic fibrosis, and pneumoconiosis; OR
• Pulmonary hypertension; OR
• Secondary polycythemia; OR
• Terminal lung cancer; OR
• Severe lung disease such as COPD, diffuse interstitial lung disease, cystic fibrosis bronchiectasis, or widespread pulmonary neoplasm; OR,
• Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy (e.g., pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache).

Oxygen therapy may be considered medically necessary for members < 21 years of age with ONE of the following conditions:

• Bronchopulmonary dysplasia (BPD); OR
• Cystic fibrosis; OR
• Pulmonary fibrosis; OR
• Pulmonary insufficiency of prematurity (PIP); OR
• Tracheomalacia; OR
• Chronic lung disease; OR
• Agenesis, hypoplasia, dysplasia of the lung; OR
• Chronic cardiopulmonary disease (cor pulmonale); OR
• “P” pulmonale on EKG; OR
• Erythrocytosis (familial polycythemia, hereditary elliptocytosis, or polycythemia/secondary); OR
• Other diagnoses, based upon medical necessity.

In addition, for members < 21 years of age laboratory results of oximetry or arterial blood gases must show:

• The pO2 levels at or below 65mm Hg; OR
• Oxygen saturation at or below 90 percent.

NOTE: Criteria for arterial blood gases or oximetry do not apply for recipients under 21 years of age.

For members with cluster headaches (CH), only a stationary gaseous oxygen system and related contents are covered for the treatment of cluster headaches for beneficiaries enrolled in a clinical trial approved by CMS which are in compliance with the requirements described in the CMS National Coverage Determination Manual §240.2.2 for dates of service on or after 01/04/2011. This section states, in part:

Only those beneficiaries diagnosed with the condition of cluster headache are eligible for participation in a clinical study. CMS adopts the diagnostic criteria used by the International Headache Society to form a definitive diagnosis of CH. Therefore, the home use of oxygen to treat CH is covered by Medicare only when furnished to Medicare beneficiaries who have had at least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated.*

* Intensity of pain: Degree of pain usually expressed in terms of its functional consequence and scored on a verbal 5-point scale: 0=no pain; 1=mild pain, does not interfere with usual activities; 2=moderate pain, inhibits but does not wholly prevent usual activities; 3=severe pain, prevents all activities; 4=very severe pain. It may also be expressed on a visual analogue scale.

The headaches must be accompanied by at least one of the following findings:

• Ipsilateral conjunctival injection and/or lacrimation; OR
• Ipsilateral nasal congestion and/or rhinorrhea; OR
• Ipsilateral eyelid edema; OR
• Ipsilateral forehead and facial sweating; OR
• Ipsilateral miosis and/or ptosis; OR
• A sense of restlessness or agitation.
Oxygen Therapy **may be considered medically necessary** for members who have a covered condition noted above and fall into ONE of the following blood gas value groups:

- **Group One:** Coverage provided for members with significant hypoxemia evidenced by ANY of the following:
  - An arterial PO\(_2\) at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air; **OR,**
  - An arterial PO\(_2\) at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO\(_2\) at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO\(_2\) more than 10 mmHg, or a decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen would **NOT** be covered in this situation; **OR,**
  - An arterial PO\(_2\) at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a member who demonstrates an arterial PO\(_2\) at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when a member was breathing room air.

- **Group Two:** Except as modified in the note below, coverage is available for members whose arterial PO\(_2\) is 56-59 mmHg or whose arterial blood oxygen saturation is 89%, if there is evidence of:
  - Dependent edema suggesting congestive heart failure; **OR,**
  - Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVFL; **OR,**
  - Erythrocythemia with a hematocrit greater than 56%.

- **Group Three:** Except as modified in the note below, claims from members with arterial PO\(_2\) levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90% must be submitted for medical director review of medical necessity.

NOTE: In reviewing the arterial PO\(_2\) levels and the arterial oxygen saturation percentages specified above, reviewers must take into account variations in oxygen measurements that may result from such factors as the member's age, the altitude level, or the member's decreased oxygen carrying capacity.

**Requests for portable oxygen requires a prescription** from a treating physician or a treating physician's ARNP or physician assistant documenting the need for oxygen including portable, stationary and concentrator type units. The oxygen provider must maintain documentation in the recipient’s record that includes:

- Documentation of medical necessity for oxygen service; **AND**
- The recipient’s treating physician has ordered a specifically-prescribed program of exercise or an activity program for therapeutic purposes; **AND**
- Recommended exercises or activities cannot be accomplished by the use of stationary oxygen service; **AND**
- Use of a portable oxygen system during the activity or exercise results in an improvement in the recipient’s ability to perform the activities and exercises.

Oxygen systems (including concentrators and portable oxygen) are rentals. WellCare will follow Medicare’s thirty-six (36) month rental payment policy. Rental payments from Medicaid will stop at 36 months and will not resume until the five (5) year equipment re-placement occurs. Source: Quest Hawaii, 2011

**Stationary Oxygen Concentrators**

The following types of stationary oxygen services are **a covered benefit:**

- Compressed oxygen system; and
- Liquid oxygen system; and
• Concentrators

Stationary oxygen concentrators are considered medically necessary when members meet the following criteria:

• Concentrators are not to be used unless the member has an ongoing need for oxygen that requires a minimum of two liters of oxygen per minute for a minimum of 22 hours per day.
• Member must have no more than an 88 percent oxygen saturation level on room air. No other method of oxygen administration (tank or liquid) is reimbursable for a member during a month in which an oxygen concentrator is reimbursed for that same member.
• Only one stationary system will be approved (liquid or gaseous); liquid will be approved for high concentration users.

**Portable Oxygen Concentrators**

Portable oxygen concentrators are covered as medically necessary when the medical necessity criteria for home oxygen criteria are met and the individual is active and mobile and frequently exceeds the time constraint inherent in traditional ambulatory oxygen systems. Portable oxygen concentrators requested for solely convenience reasons will not be approved as medically necessary.

Oxygen concentrators may be provided if the Liter flow is over .5 L flow. For members that require a higher concentration of oxygen than what is provided by the concentrator, additional units must be indicated by the prescribing provider and not the need for additional devices to obtain the concentration required.

Certain models have been approved for airline travel (e.g., Inogen One, Eclipse, Eclipse 3, EverGo). Providers should advise members to check with their specific airline prior to travel.

**CODING**

CPT® Codes – No applicable codes.

ICD-9-CM Procedure Codes – No applicable codes.

HCPCS Level II © Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4611</td>
<td>Battery, heavy duty; replacement for patient-owned ventilator</td>
</tr>
<tr>
<td>A4612</td>
<td>Battery cables; replacement for patient-owned ventilator</td>
</tr>
<tr>
<td>A4613</td>
<td>Battery charger; replacement for patient-owned ventilator</td>
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<tr>
<td>A4614</td>
<td>Peak expiratory flow rate meter, hand held</td>
</tr>
<tr>
<td>A4615</td>
<td>Cannula, nasal</td>
</tr>
<tr>
<td>A4616</td>
<td>Tubing (oxygen), per foot</td>
</tr>
<tr>
<td>A4617</td>
<td>Mouthpiece</td>
</tr>
<tr>
<td>A4618</td>
<td>Breathing circuits</td>
</tr>
<tr>
<td>A4619</td>
<td>Face tent</td>
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<tr>
<td>A4620</td>
<td>Variable concentration mask</td>
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<tr>
<td>E0424</td>
<td>Stationary compressed gaseous oxygen system, rental;</td>
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<tr>
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<td>includes container, contents, regulator, flow meter, humidifier, nebulizer,</td>
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<td></td>
<td>cannula or mask, and tubing</td>
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<td>E0425</td>
<td>Stationary compressed gas system, purchase;</td>
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<td></td>
<td>includes regulator, flow meter, humidifier, nebulizer, cannula or mask, and</td>
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<tr>
<td></td>
<td>tubing</td>
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<tr>
<td>E0430</td>
<td>Portable gaseous oxygen system, rental;</td>
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<td>includes regulator, flow meter, humidifier, cannula or mask, and tubing</td>
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<td>E0431</td>
<td>Portable gaseous oxygen system, rental;</td>
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<td>includes portable container, regulator, flow meter, humidifier, cannula or</td>
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<td></td>
<td>mask, and tubing</td>
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<tr>
<td>E0433</td>
<td>Portable liquid oxygen system, rental;</td>
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<td></td>
<td>Includes portable containers, regulator, flowmeter, humidifier, cannula or</td>
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<td></td>
<td>mask and tubing, with or without supply reservoir and contents gauge.</td>
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<tr>
<td>E0434</td>
<td>Portable liquid oxygen system, rental;</td>
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<tr>
<td></td>
<td>includes portable container, supply reservoir, humidifier, flow meter,</td>
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<tr>
<td></td>
<td>refill adaptor, contents gauge, cannula or mask, and tubing</td>
</tr>
</tbody>
</table>
**Clinical Coverage Guideline**


### Covered ICD-9-CM Diagnosis Codes

Oxygen therapy **may be considered medically necessary and a covered benefit** for members with one of the conditions noted above and also falls into ONE of the blood gas value groups noted above.

<table>
<thead>
<tr>
<th>Code Range</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>162.2 - 162.9</td>
<td>Malignant neoplasm of bronchus and lung</td>
</tr>
<tr>
<td>165.0 - 165.9</td>
<td>Malignant neoplasm of other and ill-defined sites within the respiratory system &amp; intrathoracic organs</td>
</tr>
<tr>
<td>197.0</td>
<td>Secondary malignant neoplasm of lung</td>
</tr>
<tr>
<td>231.2</td>
<td>Carcinoma in situ of bronchus and lung</td>
</tr>
<tr>
<td>277.00 - 277.09</td>
<td>Cystic fibrosis</td>
</tr>
<tr>
<td>289.0</td>
<td>Polycythemia; secondary, acquired, hypoxemic</td>
</tr>
<tr>
<td>289.6</td>
<td>Polycythemia; familial, benign, erythrocytosis</td>
</tr>
<tr>
<td>289.7</td>
<td>Methemoglobinemia; Hemoglobin M disease (Hb-M disease)</td>
</tr>
<tr>
<td>339.00</td>
<td>Cluster headache syndrome, unspecified</td>
</tr>
<tr>
<td>339.01</td>
<td>Episodic cluster headache</td>
</tr>
<tr>
<td>339.02</td>
<td>Chronic cluster headache</td>
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<tr>
<td>416.0</td>
<td>Pulmonary Hypertension; Primary; Essential, Idiopathic</td>
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<tr>
<td>416.1</td>
<td>Kyphoscoliotic heart disease</td>
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<tr>
<td>416.8</td>
<td>Chronic Pulmonary Hypertension; Secondary</td>
</tr>
<tr>
<td>416.9</td>
<td>Chronic Pulmonary Heart disease; Chronic Cor Pulmonale</td>
</tr>
<tr>
<td>428.0 - 428.43</td>
<td>Congestive heart failure due to 416.9 Chronic Cor Pulmonale</td>
</tr>
</tbody>
</table>

*S- Codes are NON COVERED FOR MEDICARE – Refer to HCPCS Level II Temporary National Codes*
491.20 COPD – Chronic Obstructive Bronchitis without exacerbation; Emphysema with chronic bronchitis
491.21 COPD – Chronic Obstructive Bronchitis with acute exacerbation; decompensated
493.21-493.22 Chronic Obstructive Asthma with COPD; with status asthmaticus; or with acute exacerbation
494.0 Bronchiectasis without acute exacerbation
494.1 Bronchiectasis with acute exacerbation
496 Chronic airway / lung obstruction; COPD not elsewhere classified
515 Post-inflammatory pulmonary fibrosis;
516.31 Interstitial Pulmonary Fibrosis; diffuse, idiopathic
516.4 Lymphangioleiomyomatosis
516.5 Adult pulmonary Langerhans cell histiocytosis
516.61-516.69 Interstitial lung diseases of childhood
747.83 Primary Pulmonary Hypertension of Newborn; Persistent fetal circulation
748.61 Congenital bronchiectasis
770.7 Chronic Respiratory Disease arising in the perinatal period; BPD - Bronchopulmonary Dysplasia
V70.7 Examination of participant in clinical trial (when trial is for cluster headaches)

Covered 2015 ICD-10 Diagnosis Codes – This list is not all inclusive.
C34.00 - C34.92 Malignant Neoplasm of Bronchus and Lung
C39.0 - C39.9 Malignant neoplasm of other and ill-defined sites in the respiratory system
C78.00 - C78.02 Secondary malignant neoplasm of lung
C78.30 - C78.39 Secondary malignant neoplasm of other and unspecified respiratory organs
D02.20 - D02.22 Carcinoma in situ of bronchus and lung
D74.0 - D74.9 Methemoglobinemia
D75.0 Familial erythrocytosis
D75.1 Polycythemia, secondary
E84.0-E84.9 Cystic fibrosis
G44.001 – G44.009 Cluster headaches syndrome, unspecified
G44.011 – G44.019 Episodic cluster headache
G44.021 – G44.029 Chronic cluster headache
I11.0 Hypertensive heart disease with heart failure
I27.0 - I27.2 Other pulmonary heart disease
I27.81 Cor pulmonale (chronic)
I27.89 Other specified pulmonary heart disease
I27.9 Pulmonary heart disease, unspecified
I50.1 - I50.9 Heart failure
J44.0 - J44.9 Chronic obstructive pulmonary disease
J47.0 - J47.9 Bronchiectasis
J84.10 Pulmonary fibrosis, unspecified
J84.112 Idiopathic pulmonary fibrosis
J84.81 - J84.9 Other specified interstitial pulmonary diseases
P27.0 - P27.9 Chronic respiratory disease originating in the perinatal period
P29.0 Neonatal cardiac failure
P29.3 Persistent fetal circulation
Q33.4 Congenital bronchiectasis
Z00.6 Encounter for examination for normal comparison and control in clinical research program (when program is for cluster headaches)


REFERENCES

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>12/3/2015</td>
<td>• Approved by MPC. Coding update only.</td>
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<tr>
<td>10/2/2014, 10/3/2013</td>
<td>• Approved by MPC. No changes.</td>
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<tr>
<td>11/1/2012</td>
<td>• Approved by MPC. Tabled from 9/6/2012, 10/4/2012. Added information on concentrators, including portable devices. Revised name to reflect coverage.</td>
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<td>3/1/2012</td>
<td>• Approved by MPC. No changes.</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>3/31/2011</td>
<td>• Approved by MPC.</td>
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