Clinical Policy: Oxygen Use and Concentrators

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Oxygen therapy is the administration of oxygen at concentrations greater than that in ambient air (20.9%) with the intent of treating or preventing the symptoms and manifestations of hypoxemia.¹

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation® that initial approval of oxygen concentrators and stationary oxygen systems (for indications other than cluster headaches; for stationary oxygen systems for cluster headaches, see section VII) for members/enrollees ≥ 21 are medically necessary when meeting all of the following:
   A. Physician-documented severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy;
   B. The blood gas study meets one of the following:
      1. For Group I, any of the following:
         a. An arterial PO 2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake);
         b. An arterial PO 2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a beneficiary who demonstrates an arterial PO 2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake;
         c. A decrease in arterial PO 2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, for at least 5 minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and [nocturnal restlessness or insomnia]) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia;
         d. An arterial PO 2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO 2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air;
      2. For Group II, both of the following:
         a. An arterial PO2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent or less at rest (awake), during sleep for at least 5 minutes, or during exercise (as described under Group I criteria);
         b. Any of the following:
            i. Dependent edema suggesting congestive heart failure;
            ii. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P"
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pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF);

iii. Erythrocythemia with a hematocrit greater than 56 percent;

C. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services;

D. The qualifying blood gas study was obtained under one of the following conditions:
   1. Performed during an inpatient hospital stay and the reported test was the one obtained closest to, but no earlier than 2 days prior to, the hospital discharge date;
   2. Not performed during an inpatient hospital stay, and the reported test was performed while the beneficiary was in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease;

E. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

II. It is the policy of health plans affiliated with Centene Corporation that initial approval of oxygen concentrators and other oxygen delivery systems for members/enrollees < 21 of age (including medically fragile members/enrollees and those covered under EPSDT) are medically necessary when meeting both of the following:

A. Physician-documented severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, including but not limited to the following:
   1. Chronic lung disease of prematurity;
   2. Cystic fibrosis;
   3. Acute pulmonary/respiratory disease with persistent type I (hypoxic) respiratory failure, as a means to facilitate earlier discharge to home, when deemed safe;
   4. Bronchopulmonary dysplasia (BPD) with type I respiratory failure;
   5. Agenesis, hypoplasia, dysplasia of the lung;
   6. Chronic cardiopulmonary disease (cor pulmonale);
   7. P pulmonale (right atrial enlargement) on EKG;
   8. Any of the diagnostic causes of chronic hypoxemia due to alveolar hypoventilation, ventilation-perfusion mismatching, intracardiac or intrapulmonary shunting, or impaired alveolar-capillary diffusion.

B. Laboratory results of oximetry, polysomnography or arterial blood gases demonstrate one of the following:
   1. Baseline PaO2 levels below 80 mm HG;
   2. Baseline oxygen saturations below 92%;
   3. Significant percentage of time spent with SpO2<92% due to validated desaturations.

III. It is the policy of health plans affiliated with Centene Corporation that reauthorization of oxygen concentrators and stationary oxygen systems for members ≥ 21 are medically necessary when meeting the following:

A. Evaluation by the treating physician within 90 days prior to the date of recertification, and one of the following:
   1. Chronic hypoxemia is not expected to improve or is expected to worsen, as documented in an explanatory letter of medical necessity (LOMN);
   2. Treatment is for nocturnal hypoxemia in a member/enrollee who qualifies for Group I (as defined in section I), and 2 oxygen requests have already been authorized;
3. A new arterial blood gas (ABG) or pulse oximetry result documents that member/enrollees still meets the criteria in section I above (initial approval criteria), and one of the following:
   a. For Group 1 (as defined in section I), the measurement is obtained within 90 days of the recertification date, and by the physician or designee, or by an independent diagnostic testing facility (IDTF). O2 levels obtained by DME providers do not qualify. Home oxygen companies are permitted to coordinate with an IDTF for the purpose of obtaining needed overnight oximetry saturation testing;
   b. For Group 2 (as defined in section I; rare cases where initial certification was for 3 months with PO2 56-59 or O2 sat 89%), a repeat ABG or oximetry must be obtained within 30 days of recertification date.

IV. It is the policy of health plans affiliated with Centene Corporation that reauthorization of oxygen concentrators and other supplemental oxygen delivery systems for members/enrollees < 21 of age (including medically fragile members/enrollees and those covered by EPSDT) are medically necessary when meeting both of the following:
A. Evaluation by the treating physician within 30 days prior to the date of recertification;
B. One of the following:
   1. A new recorded (overnight recommended) pulse oximetry tracing, sleep study report, or blood gas result documents that the member still meets the initial authorization criteria in Section II above, and the measurement meets both of the following:
      a. Obtained within 30 days of the recertification date;
      b. Obtained by the physician or designee, or by an independent diagnostic testing facility (IDTF). DME companies are prohibited from obtaining the O2 levels unless they are also home oxygen providers. Home oxygen companies are permitted to coordinate with an IDTF for the purpose of obtaining needed overnight oximetry saturation testing;
   2. Chronic hypoxemia is not expected to improve or is expected to worsen, as documented in an explanatory letter of medical necessity (LOMN).

V. It is the policy of health plans affiliated with Centene Corporation that portable oxygen systems for members/enrollees ≥ 21 are medically necessary when meeting all of the following:
A. Criteria in section I. is met;
B. The member/enrollee is mobile within the home;
C. The qualifying blood gas study for the approved stationary concentrator was performed while at rest (awake) or during exercise. (If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not reasonable and necessary).

VI. It is the policy of health plans affiliated with Centene Corporation® that oxygen concentrators are not medically necessary for the following indications:
A. Angina pectoris in the absence of hypoxemia;
B. Breathlessness without cor pulmonale or evidence of hypoxemia;
C. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities;
D. Shortness of breath or dyspnea in a pediatric patient without evidence of hypoxemia.
VII. It is the policy of health plans affiliated with Centene Corporation® that stationary gaseous oxygen systems and related contents for the treatment of cluster headaches members/enrollees ≥ 21 are medically necessary when meeting the following:
A. Diagnosis of cluster headache;
B. Enrolled in a clinical trial approved by CMS and which is in compliance with the requirements described in the CMS National Coverage Determination Manual §240.2.2 for dates of service on or after 01/04/2011.7;
C. At least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated;
D. The headaches are accompanied by at least one of the following:
   1. Ipsilateral conjunctival injection and/or lacrimation;
   2. Ipsilateral nasal congestion and/or rhinorrhea;
   3. Ipsilateral eyelid edema;
   4. Ipsilateral forehead and facial sweating;
   5. Ipsilateral miosis and/or ptosis;
   6. A sense of restlessness or agitation.

Background
According to the American Association for Respiratory Care (AARC) long-term oxygen therapy (LTOT) in the home or alternate site health care facility is normally indicated for the treatment of hypoxemia. LTOT has been shown to have a significant positive impact on hypoxemic patients with chronic obstructive pulmonary disease (COPD).¹

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0424</td>
<td>Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
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<tr>
<td>E0425</td>
<td>Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
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<tr>
<td>E0430</td>
<td>Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
</tr>
<tr>
<td>E0431</td>
<td>Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
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<th>HCPCS Codes</th>
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<tr>
<td>E0433</td>
<td>Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or 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; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing</td>
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<tr>
<td>E0435</td>
<td>Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, and tubing</td>
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<tr>
<td>E0439</td>
<td>Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, &amp; tubing</td>
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<tr>
<td>E0440</td>
<td>Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
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<tr>
<td>E0441</td>
<td>Stationary oxygen contents, gaseous, 1 month's supply = 1 unit</td>
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<tr>
<td>E0442</td>
<td>Stationary oxygen contents, liquid, 1 month's supply = 1 unit</td>
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<tr>
<td>E0443</td>
<td>Portable oxygen contents, gaseous, 1 month's supply = 1 unit</td>
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<tr>
<td>E0444</td>
<td>Portable oxygen contents, liquid, 1 month's supply = 1 unit</td>
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<tr>
<td>E0445</td>
<td>Oximeter device for measuring blood oxygen levels noninvasively</td>
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<tr>
<td>E1390</td>
<td>Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate</td>
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<tr>
<td>E1391</td>
<td>Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each</td>
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<tr>
<td>E1392</td>
<td>Portable oxygen concentrator, rental</td>
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<tr>
<td>E1405</td>
<td>Oxygen and water vapor enriching system with heated delivery</td>
</tr>
<tr>
<td>E1406</td>
<td>Oxygen and water vapor enriching system without heated delivery</td>
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<tr>
<td>K0738</td>
<td>Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
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<tr>
<td>S8120</td>
<td>Oxygen contents, gaseous, 1 unit equals 1 cubic foot</td>
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<tr>
<td>S8121</td>
<td>Oxygen contents, liquid, 1 unit equals 1 pound</td>
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**ICD-10-CM Diagnosis Codes that Support Coverage Criteria**

+ Indicates a code(s) requiring an additional character

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**Reviews, Revisions, and Approvals**

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<tr>
<td>Policy developed</td>
<td>05/20</td>
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<td>Noted in reauthorization criteria for Group 1 that nocturnal hypoxemia doesn’t have to have a qualifying ABG or pulse ox after the first two approvals. Added that a DME company cannot provide the reauthorization pulse ox test, but an independent diagnostic testing facility (IDTF) can, and</td>
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Reviews, Revisions, and Approvals | Date | Approval Date
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a home oxygen company can coordinate with an IDTF to do so also. Added criteria for portable oxygen systems in IV. |  |  
In sections I and III, clarified that the criteria applies to stationary oxygen systems as well as portable oxygen systems. In section II: specified that the diagnosis list is not all-inclusive, and that there be a cause of severe lung disease or hypoxia; edited diagnosis list; added polysomnography as a qualifying lab results option. Specified that reauthorization criteria in section III applies to adults. Added reauthorization criteria for age <21 years in section IV. Portable oxygen systems: Added that criteria in section I. must be met and specified that portable oxygen system criteria applies to adults. Added “shortness of breath or dyspnea in a pediatric patient without evidence of hypoxemia” to the list of not medically necessary indications for oxygen concentrators. Removed accessory codes. Replaced “members” with “members/enrollees” in all instances. | 09/20 | 09/20  
Clarified in I.2.a. that the oxygen saturation should be 89% or less, instead of 89%. | 10/20 |  
For reauthorization of oxygen concentrators and stationary oxygen systems in adults in section III, added an option for a letter of medical necessity documenting a chronic condition not expected to improve or expected to worsen, when provided in addition to a physician evaluation within 90 days. Clarified that both the Group 1 re-auth criteria in section III.A.2.a need to be met. Restructured section III with minor rewording. Specified that section I. applies to oxygen concentrators and stationary oxygen systems for indications other than cluster headaches, and referred to section VII for stationary oxygen systems for cluster headaches. Specified in section VII that the criteria for cluster headaches applies to those ≥ 21 years. | 11/20 | 11/20

References

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and
accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.
Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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