Clinical Policy: Outpatient Oxygen Use

Reference Number: CP.MP.190
Date of Last Revision: 01/23

Coding Implications
Revision Log

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]

Note: If a medically necessary, lesser cost item exists and will suit the member/enrollee's medical needs, a higher cost item will be denied.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that initial approval of oxygen concentrators and oxygen systems (for indications other than cluster headaches; for stationary oxygen systems for cluster headaches, see section VII) for members/enrollees ≥ 21 years of age are **medically necessary** when meeting all of the following:

A. Physician-documented severe lung disease or hypoxemia-related symptoms that might be expected to improve with oxygen therapy;

B. The blood gas study meets one of the following:

1. Member/enrollee qualifies for Group I by meeting any of the following [8]:
   a. An arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake);
   b. An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least five minutes taken during sleep for a beneficiary who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake;
   c. A decrease in arterial PO2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than five percent from baseline saturation, for at least five 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 PO2 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 PO2 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. Member/enrollee qualifies for Group II by meeting both of the following [8]:
   a. An arterial PO2 of 56 through59 mm Hg or an arterial blood oxygen saturation of 89 percent or less at rest (awake), during sleep for at least five 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" 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 two 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;
F. If the request is for a portable oxygen system, both of the following:
1. The member/enrollee is mobile within the home or community;
2. The qualifying blood gas study 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).

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 years of age (including medically fragile members/enrollees and those covered under EPSDT) are **medically necessary** when meeting all of the following:
A. Physician-documented severe lung disease or hypoxemia-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 PaO_2 levels below 80 mm Hg;
2. Baseline oxygen saturations below 92%;
3. Significant percentage of time spent with SpO_2<92% due to validated desaturations;
C. If request is for a portable oxygen system, member/enrollee is mobile within the home or community.

III. It is the policy of health plans affiliated with Centene Corporation that reauthorization of oxygen concentrators and oxygen systems for members/enrollees ≥ 21 years of age are **medically necessary** when meeting the following:[1]

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 criteria section I), and two 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 three months with PO2 56 through59 or O2 sat 89%), a repeat ABG or oximetry must be obtained within 30 days of recertification date;

B. If the request is for a portable oxygen system, both of the following:
   1. The member/enrollee is mobile within the home or community;
   2. The qualifying blood gas study 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).

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 years of age (including medically fragile members/enrollees and those covered by EPSDT) are medically necessary when meeting all 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/enrollee 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 resolve or is expected to worsen, as documented in an explanatory letter of medical necessity (LOMN);

C. If request is for a portable oxygen system, member/enrollee is mobile within the home or community.

V. It is the policy of health plans affiliated with Centene Corporation® that oxygen concentrators **are not medically necessary** for the following indications:[1]
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.

VI. It is the policy of health plans affiliated with Centene Corporation® that stationary gaseous oxygen systems (i.e. cylinder of liquid or gaseous oxygen) and related delivery equipment for the treatment of cluster headaches are **medically necessary** when meeting the following:
A. Diagnosis of cluster headache as evidenced by both of the following;
1. At least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated;
2. The headaches are accompanied by at least one of the following:
a. Ipsilateral conjunctival injection and/or lacrimation;
b. Ipsilateral nasal congestion and/or rhinorrhea;
c. Ipsilateral eyelid edema;
d. Ipsilateral forehead and facial sweating;
e. Ipsilateral miosis and/or ptosis;
f. A sense of restlessness or agitation.

Background

Oxygenation is the process of oxygen diffusing passively from the alveolus to the pulmonary capillary, where it binds to hemoglobin in red blood cells or dissolves into the plasma.[2] A low partial pressure of oxygen in the blood is termed hypoxemia. Hypoxemia can have multiple causes including hypoventilation, ventilation-perfusion (V/Q) mismatch, right-to-left shunts, diffusion limitation, and reduced inspired oxygen tension. Common tests to determine if oxygenation is impaired and at risk of being insufficient include arterial oxygen saturation (SaO2), arterial oxygen tension (PaO2), alveolar to arterial (A-a) oxygen gradient, and the PaO2/fraction of inspired oxygen (FiO2) ratio.[2]

Indications for continuous long-term oxygen therapy (LTOT) for those with chronic lung disease include:[3]

- Resting arterial oxygen tension (PaO2) less than or equal to 55 mmHg (7.32 kPa), or a pulse oxygen saturation (SpO2) less than or equal to 88 percent;
- PaO2 less than or equal to 59 mmHg (7.85 kPa), or an SpO2 less than or equal to 89 percent, if there is evidence of cor pulmonale, right heart failure, or erythrocytosis (hematocrit >55 percent);
- PaO2 of 55 mmHg (7.32 kPa) or lower, or an SpO2 of 88 percent or lower, during exercise or sleep.

Prescribed oxygen flow rates may vary throughout the day with activity or sleep or during acute exacerbations of disease. For patients with nocturnal oxygen desaturation, clinical evaluation for sleep-disordered breathing utilizing polysomnography are often appropriate.[3]

The American Association for Respiratory Care
According to the American Association for Respiratory Care LTOT in the home or alternate site health care facility normally is indicated for the treatment of hypoxemia and has been shown to have a significant positive impact on hypoxemic patients with chronic obstructive pulmonary disease (COPD) as well as to reduce hospitalizations and lengths of stay. Laboratory indications for LTOT include documented hypoxemia in adults, children, and infants older than 28 days as evidenced by PaO2 ≤ 55 mm Hg or SaO2 ≤ 88% in subjects breathing room air or PaO2 of 56-59 mm Hg or SaO2 or SpO2 ≤ 89% in association with specific clinical conditions such as cor pulmonale, congestive heart failure, or erythrocythemia with hematocrit > 56). Some patients may not demonstrate a need for oxygen therapy at rest but will be hypoxemic during ambulation, sleep, or exercise. Oxygen therapy is indicated during these specific activities when the SaO2 is demonstrated to fall to ≤ 88%. The initial need for LTOT is determined by measurement of inadequate arterial blood oxygen tensions and/or saturations and/or the presence of clinical indicators. Ongoing evaluation or reassessment 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.[1]

The American Thoracic Society
Per the American Thoracic Society Clinical Practice Guidelines for Home Oxygen Therapy (HOT) in Adults, HOT is recommended for the following:[4]

- For patients with severe resting hypoxemia, the prescription of LTOT to improve survival is supported by historical trials in patients with COPD;
- The expert panel strongly recommends prescribing oxygen for patients with interstitial lung disease (ILD) with severe resting hypoxemia;
- Existing evidence and panel consensus suggest not prescribing LTOT for patients with COPD with moderate resting hypoxemia;
- This review confirmed scarce and inconclusive data to support the prescription of oxygen in patients who have normoxia at rest but desaturate (sometimes markedly) with exertion;
- Emerging evidence suggests that ambulatory oxygen therapy may improve health-related quality of life in patients with ILD in the short term but longer-term data are needed;
- The panel unanimously agreed that liquid oxygen (LOX) should be offered to active patients on high-flow oxygen;
- Finally, the minimal standard of care for all patients receiving home oxygen therapy must include education and training related to their oxygen equipment, oxygen safety, and self-management.

The American Thoracic Society Clinical Practice Guidelines for Home Oxygen Therapy in Children states that, despite widespread use of home oxygen therapy (HOT) in children for various lung and pulmonary vascular diseases, there is a striking paucity of data regarding its implementation, efficacy, monitoring, and discontinuation. With limited evidence, the panel provides recommendations based on expert opinion and experiences associated with patient-

important outcomes which will aid clinicians in the management of complex pediatric patients requiring HOT.[5]

HOT for children is recommended for the following situations:[5]

- Cystic fibrosis complicated by severe chronic hypoxemia;
- Cystic fibrosis patients who have both mild chronic hypoxemia and dyspnea on exertion;
- Bronchopulmonary dysplasia complicated by chronic hypoxemia;
- Sleep-disordered breathing complicated by severe nocturnal hypoxemia in those who cannot tolerate positive airway pressure therapy or are awaiting surgical treatment of sleep-disordered breathing;
- Sickle cell disease complicated by severe chronic hypoxemia;
- Pulmonary hypertension without congenital heart disease, complicated by chronic hypoxemia;
- Interstitial lung disease complicated by severe chronic hypoxemia;
- Interstitial lung disease patients who have mild chronic hypoxemia and either dyspnea on exertion or desaturation during sleep or exertion;
- Pulmonary hypertension with congenital heart disease complicated by chronic hypoxemia but not until there has been consultation with a pediatric pulmonologist or cardiologist who has expertise in the management of pulmonary hypertension in this clinical setting, regardless of previous reparative or palliative congenital heart surgery.

Additionally, the expert panel unanimously agreed that optimal implementation of the above HOT recommendations consists of all of the following:[5]

- Oxygen therapy to maintain an oxygen saturation as measured by pulse oximetry in an acceptable range according to age and respiratory condition outlined in the full document;
- Use of oxygen equipment that is of the appropriate size, developmental stage, and flow rate to function properly;
- Oxygen therapy monitoring by pulse oximetry in the home.

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 2022, 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.

HCPCS Codes	Description
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing

HCPCS Codes	Description
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	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
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E0445	Oximeter device for measuring blood oxygen levels noninvasively
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each
E1392	Portable oxygen concentrator, rental
E1405	Oxygen and water vapor enriching system with heated delivery
E1406	Oxygen and water vapor enriching system without heated delivery
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing
S8120	Oxygen contents, gaseous, 1 unit equals 1 cubic foot
S8121	Oxygen contents, liquid, 1 unit equals 1 pound

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	05/20	
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	07/20	07/20

Reviews, Revisions, and Approvals	Revision Date	Approval Date
facility (IDTF) can, and 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
Annual review. References reviewed and updated. Background updated. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Reviewed by specialist.	09/21	09/21
Edited portable oxygen criteria to include option for "mobile within community" in addition to "within the home." Reorganized portable oxygen criteria within sections I and III. Added criteria for portable oxygen systems for pediatrics in sections II and IV.	10/21	10/21
In the over 21 auth and reauth sections regarding the qualifying blood gas study for portable oxygen and concentrators, removed "for the approved stationary concentrator" for clarity.	11/21	
Annual review. References reviewed and updated. Coding Verified.	01/22	01/22
Annual review. Updated title from Oxygen Use and Concentrators to Outpatient Oxygen Use. Added "Note: If a medically necessary, lesser cost item exists and will suit the member/enrollee's medical needs, a higher cost item will be denied." under the Description section. In I.A. updated "hypoxia" to "hypoxemia." Updated statement and included	01/23	01/23

Reviews, Revisions, and Approvals	Revision Date	Approval Date
reference (based on CMS NCD 240.2)[8] to I.B.1. and I.B.2 for clarity. In II.A. updated "hypoxia" to "hypoxemia." In III.A.2. added "criteria" to (as defined in criteria section I) statement for clarity. In IV.B.2. changed Chronic hypoxemia is not expected to "improve" to "resolve." In VI. added "(i.e. cylinder of liquid or gaseous oxygen)" and related "delivery equipment"... for clarity and removed age criteria "≥ 21." Reformatted criteria in VI.A.1. and 2 for clarity. Removed VI.B. "Enrolled in clinical trial.." Minor rewording with no clinical significance. Background updated with no clinical significance. References reviewed and updated. Internal and external specialist reviewed.		

References

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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.

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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.