



Guidelines for Medical Necessity Determination for Oxygen Therapy

These Guidelines for Medical Necessity Determination (Guidelines) identify the clinical information that MassHealth needs to determine medical necessity for oxygen therapy. These Guidelines are based on generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs.

Providers should consult MassHealth regulations at [130 CMR 427.000: Oxygen and Respiratory Therapy Equipment](#) and [130 CMR 450.000: Administrative and Billing Regulations; Subchapter 6 of the Oxygen and Respiratory Therapy Equipment Manual](#); and the [MassHealth Durable Medical Equipment and Oxygen Payment and Coverage Guideline Tool](#) for information about coverage, limitations, service conditions, and prior authorization (PA) requirements.

Links to the regulations, the tool, and PA form referenced below can be found in Appendix B at the end of these Guidelines.

Providers serving members enrolled in a MassHealth-contracted accountable care partnership plan (ACPP), managed care organization (MCO), integrated care organization (ICO), Senior Care Options (SCO) plan, or Program of All-inclusive Care for the Elderly (PACE) should refer to the ACPP's, MCO's, ICO's, SCO's, or PACE's medical policies, respectively, for covered services.

MassHealth requires PA for oxygen therapy. MassHealth reviews requests for PA on the basis of medical necessity. If MassHealth approves the request, payment is still subject to all general conditions of MassHealth, including member eligibility, other insurance, and program restrictions.

SECTION I. GENERAL INFORMATION

1

Oxygen therapy is used to maintain oxygenation and alveolar ventilation. Oxygen has been used as a first-line treatment for patients in respiratory distress or in hypoxemic respiratory failure. Acute hypoxemic respiratory failure can be caused by multiple disease progressions, such as acute respiratory distress syndrome (ARDS), underlying heart or lung disease, and pneumonia. To measure adequate oxygenation, PaO_2 and SaO_2 may be measured. Hypoxemia is defined as a reduction of PaO_2 . Hypoxia is defined as a failure of oxygenation at the tissue level. Oxygenation is generally considered adequate if an individual's PaO_2 is $>60\text{mmHg}$ or SaO_2 is $\geq 90\%$. In conditions such as chronic obstructive pulmonary disease (COPD), oxygen delivery needs to be closely monitored and can cause more harm than good in certain clinical applications. At high concentrations, the result of excess oxygen therapy can lead to hypercapnia and is associated with an increased risk of death. Hyperoxia or higher than normal PaO_2 can cause oxygen toxicity or oxygen poisoning and should be avoided as well; as such, care should be taken to avoid the overuse of oxygen therapy. Of note, recent evidence suggests that pulse oximetry may be falsely elevated in patients of color. Our guidelines accept either blood gas or pulse-oximetry measurements to demonstrate medical necessity of oxygen therapy. Racial and ethnic disparities in supplemental oxygen administration associated with inconsistent pulse oximeter performance should be considered for anyone who has SaO_2 between 88% and 92%, particularly for

patients of color. Providers using pulse oximetry may consider performing a blood gas if patients meet the clinical guidelines, but do not demonstrate the required pulse oximetry reading. Intranasal or subcutaneous triptans and oxygen therapy is considered a first-line treatment for cluster headaches. Cluster headache is a trigeminal autonomic cephalalgia affecting 0.1%–0.4% of the population in an approximate 5:1 male to female ratio. The peak age of onset is between 25 and 50 years of age. Approximately 90% of cluster headache patients have episodic cluster headaches, with headache-free periods between attacks, and 10% have chronic cluster headaches, each of which is further defined below. Cluster attacks are severely painful and debilitating, with unilateral pain lasting 15–180 minutes, and occurring at varying frequencies from once every other day up to eight times per day. The minimum period of episodic cluster headaches is seven days, but cycles of these headaches can last months. Episodic headaches are separated from chronic cluster headaches by headache-free periods of at least three months between headache cycles. Due to the fast onset and potential high frequency of these attacks, acute therapies for relief are limited.

SECTION II. CLINICAL GUIDELINES

A. CLINICAL COVERAGE

MassHealth bases its determination of medical necessity for oxygen therapy on clinical data including, but not limited to, indicators that would affect the relative risks and benefits of the procedure or equipment (if appropriate, including post-operative recovery). Home oxygen therapy is considered medically necessary only if *all* the following conditions are met:

1. **THE TREATING CLINICIAN HAS DETERMINED THAT THE MEMBER** has severe lung disease, hypoxia-related symptoms, or cluster headache that might be expected to improve with oxygen therapy.
 - a. Severe lung disease includes, but is not limited to:
 - i. chronic obstructive pulmonary disease;
 - ii. diffuse interstitial lung disease, known or unknown etiology;
 - iii. cystic fibrosis;
 - iv. bronchiectasis;
 - v. widespread pulmonary neoplasm; or
 - vi. pediatric broncho-pulmonary dysplasia (BPD).
 - b. Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy include, but are not limited to:
 - i. pulmonary hypertension;
 - ii. obstructive sleep apnea;
 - iii. recurring congestive heart failure due to chronic cor pulmonale;
 - iv. erythrocytosis;
 - v. impairment of the cognitive process;

- vi. nocturnal restlessness;
 - vii. pulmonary insufficiency or prematurity (PIP); or
 - viii. tracheomalacia.
- c. Other diagnoses of hypoxia-related symptoms or findings with qualifying lab values that usually resolve with limited, or short-term (generally less than one month), oxygen therapy include, but are not limited to:
- i. asthma;
 - ii. bronchitis;
 - iii. croup; or
 - iv. pneumonia.
- d. Cluster headache (CH), or previously used terms, such as ciliary neuralgia, erythromelalgia of the head, erythroprosopalgia of Bing, hemicrania angiotoparalytica, hemicrania neuralgiformis chronica, histaminic cephalalgia, Horton's headache, Harris-Horton's disease, migrainous neuralgia (of Harris), petrosal neuralgia (of Gardner), Sluder's neuralgia, sphenopalatine neuralgia, or vidian neuralgia, meets the diagnostic criteria used by the International Classification of Headache Disorders (3rd Edition) to form a definitive diagnosis of CH.
- i. CH is defined as:
 - A. at least five attacks fulfilling criteria B-D below;
 - B. severe or very severe unilateral orbital, supraorbital, and/or temporal, lasting 15-180 minutes, when untreated;
 - C. either or both of the following:
 - 1. At least one of the following symptoms or signs, ipsilateral to the headache:
 - a. conjunctival infection and/or lacrimation;
 - b. nasal congestion and/or rhinorrhea;
 - c. eyelid oedema;
 - d. forehead and facial sweating; or
 - e. miosis and/or ptosis;
 - 2. A sense of restlessness or agitation;
 - D. occurring with frequency between one every other day or up to eight per day; or
 - E. not-better-accounted-for by another ICHD-3 diagnosis.
 - ii. Episodic cluster headache is defined as:
 - A. attacks fulfilling criteria for cluster headache and occurring in bouts (cluster periods);
 - B. at least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of ≥ 3 months; and
 - C. cluster periods usually lasting between two weeks and three months.
 - iii. Chronic cluster headache is defined as:

- A. attacks fulfilling criteria for cluster headache in Section II.A.1.d.i, above, and criterion B below;
- B. occurring without a remission period, or with remission lasting <3 months, for at least one year; and
- C. may be arising de novo (previously referred to as primary chronic cluster headache) or evolving from episodic cluster headache (previously secondary chronic cluster headache).

2. QUALIFYING FINDINGS

Blood gas or pulse oximetry values must be obtained on room air unless medically contraindicated. Home oxygen must be prescribed by an ordering practitioner (physician) or a non-physician practitioner (nurse practitioner, physician assistant, or clinical nurse specialist). The prescription must specify the diagnosis, the oxygen flow rate, and frequency/duration of therapy.

For oxygen being prescribed for an inpatient hospital stay, the reported test must be collected closest to, but no earlier than, two days before the hospital discharge date. For oxygen being prescribed in an outpatient setting for chronic conditions, the reported test must be performed while the member is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease. Tests should be performed within 90 days of a new or renewal order. See Appendix A for oxygen delivery systems and coding.

a. CONTINUOUS OXYGEN.

Symptoms must include:

- i. an arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air, or;
- ii. an arterial PO₂ 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 PO₂ 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 PO₂ more than 10 mm Hg, or 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) or;
- iii. an arterial PO₂ at 56–59 *mm Hg or arterial blood oxygen saturation of 89% if there is evidence of:
 - A. dependent edema suggesting congestive heart failure; or
 - B. 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
 - C. erythrocythemia with a hematocrit greater than 56%.

b. NON-CONTINUOUS SUPPLEMENTAL OXYGEN.

The number of hours per day and oxygen flow rate must meet one or both of the following criteria:

- i. an arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg; or
- ii. an arterial oxygen saturation at or above 89%, during the day while at rest.
 - A. In this case, supplemental oxygen is provided for use during exercise if there is evidence that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air; or
 - B. during sleep:
 1. PaO₂ less than or equal to 55 mm Hg or oxygen saturation less than or equal to 88 % for at least five minutes; or
 2. a decrease in PaO₂ of more than 10 mm Hg; or
 3. a decrease in arterial oxygen saturation more than five percent from baseline saturation, for at least five minutes taken during sleep associated with symptoms from listed conditions in Section II.A.1.b, c, or d.

c. CLUSTER HEADACHES.

Supplemental oxygen for cluster headaches is indicated if the member meets the criteria for cluster headaches as outlined above in Section II.A.1.d. Prescriptions for oxygen therapy may be reordered as needed when a member enters a cycle of cluster headaches. Portable oxygen tanks may be considered to enable mobility and participation in work or activities of daily living outside the home.

d. PEDIATRIC PATIENTS (UNDER 21 YEARS OF AGE).

Supplemental oxygen for pediatric patients is indicated if the member has:

- i. PO₂ levels at or below 65 mmHg; or
- ii. Oxygen saturation at or below 90%.

B. NONCOVERAGE

MassHealth does not consider oxygen therapy to be medically necessary under certain circumstances. Examples of such circumstances include, but are not limited to, the following.

1. Terminal illnesses that do not affect the respiratory system
2. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia
3. Angina pectoris in the absence of hypoxemia
4. Breathlessness without cor pulmonale or evidence of hypoxemia
5. Headaches other than criteria listed in Section II.A.1.d

6. Prophylactic home oxygen to reduce transfusion-related adverse events in pregnant members with sickle cell disease
7. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep
8. Oxygen that is required on a Pro re nata (PRN) basis for members living in skilled nursing facilities
9. Headaches not meeting the ICHD-3 criteria for cluster headache as described above in Section II.A.1.d

C. AUTHORIZATION OF OXYGEN

Oxygen will be authorized for **12 months** for members who are determined to be in a **chronic stable state** and for whom oxygen has been determined to be medically necessary for long-term use.

Oxygen will be authorized for **less than six months** for members who demonstrate conditions that are acute in nature, are anticipated to resolve, and for whom oxygen has been determined to be medically necessary for short-term use. (See Section II.A.1.d.)

SECTION III. SUBMITTING CLINICAL DOCUMENTATION

3

- A. Requests for PA for oxygen therapy must be accompanied by clinical documentation that supports the medical necessity for oxygen therapy, as described below, and must be submitted to MassHealth in accordance with 130 CMR 427.409. As part of the PA request, the provider of oxygen therapy must obtain a written prescription signed by the member's prescribing provider. The prescription must meet the requirements at 130 CMR 427.408. Any additional clinical documentation supporting medical necessity must be submitted with the PA request.

Oxygen therapy providers must submit all information related to a PA request through the Long-Term Services and Supports Management System (LTMS) unless the provider has a currently approved electronic claims waiver or the PA request is for 1) prescription drugs, regardless of where they are dispensed or how they are billed; or 2) non-drug products dispensed at a pharmacy and billed through either the Pharmacy Online Processing System (POPS) or the Medicaid Management Information System (See [All Provider Bulletin 369](#)). Providers with any questions about LTMS access may direct them to the MassHealth LTSS Provider Service Center at (844) 368-5184; email: support@masshealthltss.com.

When submitting PA requests for Community Case Management (CCM) members, all information related to the request should be submitted using the Provider Online Service Center (POSC) unless the provider has a currently approved electronic claims waiver or the PA request is for 1) prescription drugs, regardless of where they are dispensed or how they are billed; or 2) non-drug products dispensed at a pharmacy and billed through either the Pharmacy Online Processing System (POPS) or the Medicaid Management Information System (See [All Provider Bulletin 369](#)). Providers with any questions about POSC access may direct them to MassHealth Customer Service at (800) 841-2900, TDD/TTY: 711.

B. Documentation of medical necessity must include all the following:

1. the primary diagnosis name and ICD-CM code specific to the medical condition causing the oxygen distress for which oxygen products are requested (as indicated in Section II.A.1);
2. secondary diagnosis name and ICD-CM code specific to the comorbid conditions, if applicable;
3. documentation of clinical signs and symptoms of respiratory distress to include documented lab values or an arterial oxygen saturation (as indicated in Section II.A.2.);
4. the recommended liter flow and hours needed per day;
5. if requesting portable oxygen, documentation that the member's activities take them beyond the functional limits of the stationary system;
6. additional clinical documentation supporting medical necessity, which may include, but is not limited to, a letter of medical necessity, treatment notes, overnight oximetry study, and sleep study;
7. for cluster headaches:
 - i. provider documentation criteria fulfilling the ICHD-3 definition of cluster headache as defined above in Section II.A.1.d.; and
 - ii. provider documentation of the frequency of attacks, duration of a cycle of attacks, and number of cycles the member has had in the past. Or, if this is a new diagnosis, please describe the current duration of the cycle if the member is not in cycle.

C. Documentation requirement for members in nursing facilities:

1. the primary diagnosis name and ICD-CM code specific to the medical condition causing the oxygen distress for which oxygen products are requested (as indicated in Section II.A.1 above);
2. the prescription/order written in the member's medical record;
3. one month of documented usage as indicated on the member's treatment sheet; most recent blood gas or pulse oximetry values; and room air pulse oximetry values, unless contraindicated;
4. the recommended liter flow and hours needed per day; and
5. additional clinical documentation supporting medical necessity which may include, but is not limited to, a letter of medical necessity and facility progress/chart notes.

APPENDIX A: CODES AND CODE DESCRIPTIONS

OXYGEN DELIVERY SYSTEMS

A. CONTINUOUS/STATIONARY

The HCPCS codes below should be considered when addressing the member's stationary oxygen needs.

1. Oxygen concentrators, liquid reservoirs, or large cylinders.
2. Medically necessary for members who do not travel beyond the 50-foot tubing radius of the stationary device or for members who exclusively use O₂ during sleep.

HCPCS Code	Modifier	Description
E0424	RR	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing. 1 unit = each, 1 per month, monthly rental
E0439	RR	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing. 1 unit = each, 1 per month, monthly rental
E1390	RR	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate. 1 unit = each, 1 per month, monthly rental
E1391	RR	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate. 1 unit = each, 1 per month, monthly rental

B. PORTABLE TANKS/CYLINDERS

The HCPCS codes below should be considered when addressing the members portable oxygen needs. <10 pounds when filled with oxygen. Designed to be carried by the member, and to last for four hours at a flow equivalent to 2 L/min continuous flow; e.g., liquid refillable units and aluminum or fiber wrapped light-weight cylinders, with or without oxygen conserving devices. Considered medically necessary for members who regularly go beyond the limits of a stationary oxygen delivery system with a 50-foot tubing. Only one portable oxygen system will be approved for long-term use.

HCPCS Code	Modifier	Description
E0431	RR	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing. 1 unit = each, 1 per month, monthly rental
E0434	RR	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing. 1 unit = each, 1 per month, monthly rental
K0738	RR	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing. 1 unit = each, 1 per month, monthly rental. Procedure code K0738 must be used with E1390 .

C. PORTABLE OXYGEN CONCENTRATOR

Portable oxygen concentrators are considered medically necessary as an alternative to portable tanks/cylinders for members who meet both of the following:

1. The member meets criteria for a portable oxygen system (see above); and
2. The member is regularly away from home for durations that exceed the capacity of a portable tank/cylinder.

HCPSC Code	Modifier	Description
E1392	RR	Portable concentrator requirements: capability of delivering 85% or greater oxygen concentration and of operating on either AC or DC (e.g., auto accessory outlet) power. Code E1392 includes the device itself, and integrated battery or beneficiary replacement batteries that are capable of providing at least 2 hours of remote portability at a minimum of 2 LPM equivalency, a battery charger, an AC power adapter, a DC power adapter and carrying bag and/ or cart. Must not weigh more than 20 pounds. Providers may also request code E1390 for members that require continuous oxygen usage. 1 unit = each, 1 per month, monthly rental

APPENDIX B:

LINKS TO REGULATIONS AND THE MASSHEALTH ONLINE TOOL

130 CMR 427.000: Oxygen and Respiratory Therapy Equipment: www.mass.gov/regulations/130-CMR-427000-oxygen-and-respiratory-therapy-equipment

130 CMR 450.000: Administration and Billing Regulations: www.mass.gov/regulations/130-CMR-450000-administrative-and-billing-regulations

MassHealth Durable Medical Equipment and Oxygen Payment and Coverage Guideline Tool: www.mass.gov/info-details/masshealth-payment-and-coverage-guideline-tools#masshealth-durable-medical-equipment-and-oxygen-payment-and-coverage-guideline-tool-Subchapter

MassHealth Oxygen and Respiratory Therapy Equipment PA-1 form: [www.mass.gov/lists/masshealth-provider-forms-used-by-multiple-provider-types#prior-authorization-request-\[pa-1\]-](http://www.mass.gov/lists/masshealth-provider-forms-used-by-multiple-provider-types#prior-authorization-request-[pa-1]-)

APPENDIX C: SELECT REFERENCES

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These Guidelines are based on review of the medical literature and current practice in oxygen therapy. MassHealth reserves the right to review and update the contents of these Guidelines and cited references as new clinical evidence and medical technology emerge.

This document was prepared for medical professionals to assist them in submitting documentation supporting the medical necessity of the proposed treatment, products, or services. Some language used in this communication may be unfamiliar to other readers; in this case, those readers should contact their health care provider for guidance or explanation.

Policy Effective Date: June 7, 2024

Approved by: _____



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