MEDICAL POLICY	**Temporary Policy Emergency Provisions for:** **Home Oxygen Equipment and Supplies (Medicare Only)**
Effective Date: 7/1/2022  7/1/2022 Medical Officer Date	Medical Policy #292 Medical Policy Committee Approved Date: 3/2021;12/2021; 3/2022; 6/2022

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

NEED AND DURATION OF EMERGENCY PROVISIONS

1. **Need for the temporary Provisions: COVID-19 public health emergency**
2. **Documents or source relied upon:**
    a. Rural Crosswalk: CMS Flexibilities to Fight COVID-19: https://www.cms.gov/files/document/omh-rural-crosswalk-5-21-21.pdf
    b. Noridian Article CMS Issues Interim Final Rules with Comment (CMS-1744-IFC & CMS-5531-IFC) – COVID-19 Public Health Emergency – Revised; *[Last updated 07/14/2021]*
    c. CMS Final Rule: CMS-5531-IFC for *Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program*
    d. CMS Final Rule: CMS-1744-IFC for *Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*
    e. CMS COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing document *[Last updated 11/17/2021]*
3. **Initial Effective Date: 3/1/2020**
4. **Re-review dates: 5/27/2020; 7/22/2020; 9/23/2020; 11/30/2020; 2/3/2021; 3/31/2021; 6/1/2021; 12/8/2021; 7/20/2022; 10/4/2022**
5. **Termination Date: 12/31/2022**
6. **Reassessment Date determined at Companies sole discretion: 12/30/2022, or sooner if regulations or clinical practice guidelines change.**

POLICY ADDENDUM

COVID-19 Public Health Emergency

Since March 2020, Medicare has released various final rules on the CMS response to the COVID-19 public health emergency (PHE). Some of these final rules apply to enforcement of certain requirements for select durable medical equipment (DME) and supplies (e.g., face-to-face or in-person encounters or provider specialty requirements when required by NCD/LCD, etc.).

> *"For the duration of this PHE for the COVID-19 PHE, it is in the best interest of patients, health care professionals and suppliers to limit face-to-face encounters and avoid exposure of vulnerable Medicare beneficiaries to COVID-19. Therefore, on an interim basis, we are finalizing that to the extent an NCD or LCD (including policy articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the COVID-19 PHE."*[1]

Thus, telehealth (telemedicine) visits would satisfy any face-to-face or in-person requirements when noted in an NCD, LCD, or LCA.

> *"Effective for claims with dates of service on or after March 1, 2020 and for the duration of this COVID-19 PHE, clinical indications for coverage found in respiratory, infusion pump, and therapeutic continuous glucose monitor NCDs or LCDs will not be enforced. These NCDs and LCDs include:*
>
> - ***Home Oxygen (NCD 240.2)***
> - *Infusion Pumps (NCD 280.14)*
> - *Continuous Positive Airway Pressure for Obstructive Sleep Apnea (NCD 240.4)*
> - *Intrapulmonary Percussive Ventilator (NCD 240.5)*
> - *Durable Medical Equipment Reference List (NCD 280.1) – Only clinical indications for ventilators are not enforced*
> - ***Oxygen and Oxygen Equipment (L33797)***
> - *Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea (L33718)*
> - *Oral Appliances for the Treatment of Obstructive Sleep Apnea (L33611)*
> - *Respiratory Assist Devices (L33800)*
> - *Mechanical In-exsufflation Devices (L33795)*
> - *High Frequency Chest Wall Oscillation (L33785)*
> - *Nebulizers (L33370)*
> - *Suction Pumps (L33612) – Only clinical indications for respiratory suction pumps (E0600) are not enforced*
> - *Glucose Monitors (L33822) – Only clinical indications for Therapeutic Continuous Glucose Monitors (CGM) are not enforced*
> - *External Infusion Pumps (L33794)"*[1]

Treating practitioners and suppliers must still:

- Provide a standard written order (SWO) for all items.
- Ensure that the items or services are reasonable and necessary;
- Continue documenting the medical necessity for all services and the medical record must be sufficient to support payment for the services billed (i.e., the services were actually provided, were provided at the level billed, and were medically necessary);
- Make documentation available, upon request.[1]

MEDICAL POLICY	**Temporary Policy Emergency Provisions for:** **Home Oxygen Equipment and Supplies (Medicare Only)**

While prior authorization and review will not be required for the items addressed by this medical policy, the CMS-5531-IFC clarifies that the lack of enforcement of certain elements of NCDs and LCDs does **not** mean medical necessity requirements for items and services are waived during this PHE. This final rule serves to *"remind physicians, practitioners and suppliers that most items and services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Part A or Part B of Title XVIII. Physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed…"*

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
Home Use of Oxygen and Oxygen Equipment – General Coverage Guidance	For **general medical necessity criteria** for oxygen, as well as variable factors that may affect blood gas values: • National Coverage Determination (NCD) for Home Use of Oxygen (240.2) The LCD below supplements this NCD, providing the same coverage criteria, as well as providing further clarifying details.
Home Oxygen and Oxygen Equipment – Supplemental Information – Initial Provision	***IMPORTANT NOTE:*** *Effective September 27, 2021, Medicare updated their oxygen criteria and the above NCD. As of this policy update, the LCD below has **not** yet been updated, which means it may conflict with the NCD, specifically regarding coverage of oxygen for acute conditions and the requirement of testing being performed with the patient in a "chronic stable state." For acute conditions, the above NCD criteria take precedent.*

	Supplemental information, including clarifications regarding criteria, coding, and documentation requirements and oxygen accessories: • Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797) *See "Policy Guidelines" below*
Travel Oxygen Equipment and Spare Tanks	For **travel situations**, such as short-term travel (i.e., days or weeks) or for temporary relocation (e.g., snowbird) outside of the supplier's service area): Noridian web page for Travel Oxygen For **spare tanks**: NCD for Durable Medical Equipment Reference List (280.1)
Replacement of Oxygen Equipment (Excludes Accessories)	• LCD: Oxygen and Oxygen Equipment (L33797) *(See the "Certification" section to determine if repeat blood gas studies are needed for a specific situation)* • LCA: Oxygen and Oxygen Equipment- Policy Article (A52514) *(See the "Reasonable Useful Lifetime (RUL) section for replacement of equipment when a member has both stationary and portable oxygen equipment)* **Note:** The reasonable useful lifetime (RUL) for oxygen equipment is 5 years. When the end date of the RUL occurs, a member may elect to obtain replacement equipment; however, the replacement must still be medically reasonable and necessary. It is important to advise the member that if the elect to obtain replacement equipment, their financial liability may increase due to the 36-month rental period starting over. *See "Policy Guidelines" below*

POLICY GUIDELINES

Initial Provision of Oxygen Equipment

Initial requests for oxygen therapy must be based on the results of a clinical test, such as the measurement of the partial pressure of oxygen (PO2) in arterial blood or the measurement of arterial oxygen saturation obtained by ear or pulse oximetry. Testing must be ordered and evaluated by the treating practitioner and performed under their supervision or when performed by a qualified provider or supplier of laboratory services. Note that a durable medical equipment (DME) supplier is **not** considered a qualified provider or supplier of laboratory services in this context, but blood gas testing conducted by a hospital certified to do such tests **is** considered a qualified provider in this context.

Continued Use

Diagnosis alone does not guarantee continued coverage of oxygen equipment. There must be documentation of continued medical need for the oxygen and related supplies.

Replacement of Oxygen Equipment

The reasonable useful lifetime (RUL) for oxygen equipment is 5 years. Replacement of this equipment ***prior to*** the 5-year RUL is eligible for coverage only in select situations (e.g., lost, stolen, irreparably damaged). Replacement when the 5-year RUL **ends** may be eligible for coverage when medically indicated (i.e., the member continues to use and benefit from the device).

Accessories are not subject to the 5-year RUL and replacement of these items may be warranted sooner. Replacement of items that are not irreparably worn or damaged and which continue to provide necessary therapeutic benefit for the member would not be considered medically reasonable or necessary because the replacement serves essentially the same purpose as equipment already available to the beneficiary, even if the minimum 5-year reasonable useful lifetime (RUL) for an item is met.[4,5] Therefore, an individual simply having a particular piece of oxygen equipment for 5-years does not automatically warrant or justify replacement. It must be determined that the existing equipment does not sufficiently meet the clinical and therapeutic needs for the member.

Replacement of oxygen equipment ***prior to*** the 5-year RUL period being reached:

If due to **irreparable *wear***:

- Medicare expects *rented* equipment to remain in good working order for the entire RUL of the equipment. Therefore, if the equipment does not last for the entire 5-year RUL, the supplier must replace the equipment at no charge.
- For *member-owned* equipment, coverage for replacement equipment is not allowed prior to the 5-year RUL for irreparable ***wear*** per Medicare statute.

If due to **change in patient medical condition**:

- Replacement of rented or member-owned equipment may be warranted if:

1. The current item(s) can no longer meet the patient's therapeutic medical needs; **and**
2. It is the least costly option to replace the equipment in order to meet the patient's medical needs (rather than repair or reconfigure with available options).

Replacement of oxygen equipment ***after*** the 5-year RUL period is reached due to irreparable *wear* ***OR replacement at any time*** due to *theft, loss*, or irreparable ***damage***:

- If the 5-year RUL of the equipment is reached, replacement must still be medically reasonable and necessary:
    - The member must be regularly using the equipment as prescribed; and,
    - The equipment continues to provide the needed therapeutic benefit.
        - For irreparably ***worn*** devices, documentation must support the current device no longer meets the therapeutic medical needs of the member and cannot be repaired to a state where it can provide the needed therapeutic benefit (e.g., it is not cost effective to repair the current device).
        - For lost, stolen, or irreparably ***damaged*** devices, documentation of the specific incident of irreparable damage or a written explanation regarding the loss (e.g., details around circumstances of the loss, a police report for stolen items, etc.).

To safeguard member financial liabilities, it is recommended the member be advised of and understands that the provision of a replacement oxygen equipment will result in new member financial liability due to a new 36-month payment period starting again. If it is unknown whether or not the member is aware of this re-initiated financial out-of-pocket, the health plan may attempt to reach the member to confirm this is understood.

Accessories or replacement components of PAP or RAD equipment are not subject to the 5-year RUL and may be replaced prior to the end of the RUL period.

National Coverage Determination (NCD) Changes and Effective vs. Implementation Dates

> "CMS is revising NCD 240.2, Home Use of Oxygen, to expand patient access to oxygen therapy and oxygen equipment in the home, **effective for claims with dates of service on or after September 27, 2021**."[6,7]

The NCD has an *effective* date of September 27, 2021, but it has an *implementation* date of January 3, 2023. Medicare describes the differences in these dates in the Medicare General Information, Eligibility, and Entitlement Manual, Chapter 7 - Contract Administrative Requirements[8]:

> **§50.4.3:** "The effective date is normally a mandated date resulting from legislation or a regulation. In the case of National Coverage Determinations (NCDs), **the effective date is the first day the item** or service that is the subject of the NCD **is covered nationally under the Medicare Program**."
>
> **§50.4.2:** "The implementation date identified in a change request (CR) is the date by which Medicare fee-for-service contractors and shared system maintainers shall apply all changes detailed in the business requirements... It is the date when all necessary updates to infrastructure, business processes and/or supporting technology changes shall be completed and operational in order to execute new/modified policy and procedure."

In reviewing the MLN article (MM12607) and Change Request 12607, when it was updated on May 23, 2022, only the *implementation* date was revised. However, the *effective* date remained unchanged. Therefore, the expanded coverage in the NCD is effective and the NCD will take precedent over the LCD.

BILLING GUIDELINES

General

See associated local coverage article (LCA) for related coding and billing guidance:

- LCA: Oxygen and Oxygen Equipment- Policy Article (A52514)

Rental vs. Purchase

Many home oxygen equipment items are eligible for **rental** only. Purchased oxygen equipment is statutorily non-covered. *(LCA A52514 and Medicare Claims Processing Manual, Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies [DMEPOS], §30.6 – Oxygen and Oxygen Equipment)*

Per Medicare guidelines, no payment is made for oxygen during months 37-60 of the rental period. However, equipment is not eligible for replacement until at least 5-years have passed **AND** replacement is warranted for a clinically indicated device (e.g., the member still uses and benefits from the equipment and their current equipment is not functional or is not functioning at a level sufficient for clinical benefit).

Multi-Function Home Ventilation Systems

If a member is on a multi-function home ventilation system (HCPCS E0467), no separate reimbursement is made for oxygen equipment. *(LCA A52514)*

CPT/HCPCS CODES

Medicare Only	
No Prior Authorization Required	
Group 1 Codes	
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
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 non-invasively
E0447	Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 liters per minute (lpm)
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
Group 2 Codes: Accessories	
A4606	Oxygen probe for use with oximeter device, replacement
A4608	Transtracheal oxygen catheter, each
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouth piece
A4619	Face tent
A4620	Variable concentration mask
A7525	Tracheostomy mask, each
A9900	Miscellaneous DME supply, accessory, and/or service component of another hcpcs code
E0455	Oxygen tent, excluding croup or pediatric tents

E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1352	Oxygen accessory, flow regulator capable of positive inspiratory pressure
E1353	Regulator
E1354	Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each
E1355	Stand/rack
E1356	Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each
E1357	Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each
E1358	Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each
Not Covered	
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously

considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

REFERENCES

1. Noridian web page for the Joint DME MAC Article, *CMS Issues Interim Final Rules with Comment (CMS-1744-IFC & CMS-5531-IFC) – COVID-19 Public Health Emergency – Revised*; Last updated 07/14/2021; Available at: https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2020/cms-issues-interim-final-rules-with-comment-cms-1744-ifc-cms-5531-ifc-covid-19-public-health-emergency-revised3 [Last cited 12/08/2021]
2. Noridian Home Oxygen Initial Qualification Testing Documentation Check List (DCL); Last Updated 07/2021; Available at: https://med.noridianmedicare.com/documents/2230703/17635061/Home%20Oxygen%20Initial%20Qualification%20Testing%20DCL
3. Noridian Oxygen and Oxygen Equipment web page; Last Updated: 10/26/2018; Available at: https://med.noridianmedicare.com/web/jddme/topics/payment-categories/oxygen
4. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health, §110.2 - Repairs, Maintenance, Replacement, and Delivery, C. Replacement; Last Updated: 07/06/2015; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf [Last cited 02/08/2022]
5. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health, §110.1 - Definition of Durable Medical Equipment; Last Updated: 11/08/2021; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf [Last cited 02/08/2022]
6. MLN Matters Number: MM12607, *Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache)*; Last Updated: May 23, 2022; Available at: https://www.cms.gov/files/document/mm12607-revisions-national-coverage-determination-ncd-2402-home-use-oxygen-and-24022-home-oxygen-use.pdf
7. Change Request 12607, Transmittal 11429; Dated: May 23, 2022; Available at: https://www.cms.gov/files/document/r11429ncd.pdf
8. General Information, Eligibility, and Entitlement Manual, Chapter 7 - Contract Administrative Requirements; Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ge101c07.pdf