NEED AND DURATION OF EMERGENCY PROVISIONS

2. Documents or source relied upon: Centers for Medicare & Medicaid Services (CMS) released “Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19
3. Initial Effective Date: 3/1/2020
5. Termination Date: 12/31/2021
6. Reassessment Date determined at Companies sole discretion: 12/30/2021

POLICY ADDENDUM

COVID-19 Public Health Emergency

On March 30th, 2020, the Centers for Medicare & Medicaid Services (CMS) released “Physicians and Other Clinicians: CMS Flexibilities to Fight COVID-19”, which states:

National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) on Respiratory Related Devices, Oxygen and Oxygen Equipment, Home Infusion Pumps and Home Anticoagulation Therapy: Clinicians now have maximum flexibility in determining patient needs for respiratory related devices and equipment and the flexibility for more patients to manage their treatments at the home. The current NCDs and LCDs that restrict coverage of these devices and services to patients with certain clinical characteristics do not apply during the public health emergency. For example, Medicare will cover non-invasive ventilators, respiratory assist devices and continuous positive airway pressure devices based on the clinician’s assessment of the patient.
Therefore, beginning 3/30/2020, the Medicare Guidelines below do not apply during this public health emergency. During this time, the DME addressed in this medical policy will be covered based on the clinician’s assessment of the patient.

**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:**

All lines of business except Medicare

**BENEFIT APPLICATION**

**Medicaid Members**

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**POLICY CRITERIA**

**Note:** This policy does not address home oxygen therapy and oxygen equipment in patients under 18 years of age.

This policy is based on the following Centers for Medicare & Medicaid guidelines:

- National Coverage Determination (NCD) 240.2: Home Use of Oxygen
- Local Coverage Determination (LCD) L33797: Oxygen and Oxygen Equipment
- Local Coverage Article (LCA) A52514: Oxygen and Oxygen Equipment

**Home Oxygen Therapy**

1. Home oxygen therapy and oxygen equipment for severe lung disease or hypoxia-related symptoms may be considered medically necessary and covered if the following conditions are met (I.A-E):
   A. The treating practitioner has determined that the member has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy; and
B. The member meets the standards of a qualified blood gas study (for definition of qualifying blood gas study, see the Policy Guidelines section), measured through either an oximetry test or an arterial blood gas test; and
C. The qualifying blood gas test was performed by a treating practitioner or by a qualified provider or supplier of laboratory services; and
D. The qualifying blood gas study was obtained under the following conditions:
   1. If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date, or
   2. If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the beneficiary is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease, and
E. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

II. Home oxygen therapy and oxygen equipment for severe lung disease or hypoxia-related symptoms is considered **not medically necessary and not covered** when criterion I above is not met.

**Portable Oxygen Systems**

III. A portable oxygen system may be considered **medically necessary and covered** if the member is mobile within the home and the qualifying blood gas study was performed while at rest (awake) or during exercise.
IV. Portable oxygen is considered **not medically necessary and not covered** if the only qualifying blood gas study was performed during sleep.

**NON-COVERAGE CRITERIA**

V. **Group III** includes beneficiaries with arterial PO₂ levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these beneficiaries there is a rebuttable presumption of non-coverage.

VI. If the coverage conditions specified above are not met, the oxygen therapy will be **denied as not reasonable and necessary**. Oxygen therapy will also be denied as **not reasonable and necessary** if any of the following conditions are present (VI.1-4):

   A. Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood and there are other preferred treatments.
   B. Dyspnea without cor pulmonale or evidence of hypoxemia
C. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO$_2$ will improve the oxygenation of tissues with impaired circulation.

D. Terminal illnesses that do not affect the respiratory system

VII. Emergency or stand-by oxygen systems for members who are not regularly using oxygen are considered **not medically necessary and are not covered** since they are precautionary and not therapeutic in nature.

VIII. Topical hyperbaric oxygen chambers (A4575) are considered **not medically necessary and are not covered**.

IX. Topical oxygen delivery systems (E0446) are considered **not medically necessary and are not covered**.

**POLICY GUIDELINES**

Standards for qualifying blood gas study:

A qualifying blood bag study can be defined in two ways, through Group I or Group II criteria:

**Group I** criteria include any of the following:

- An arterial PO$_2$ at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
- 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, or
- 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, or
- 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.
Initial coverage for beneficiaries meeting Group I criteria is limited to 12 months or the treating practitioner-specified length of need, whichever is shorter.

**Group II** criteria include the presence of:

- An arterial PO2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes, or during exercise (as described under Group I criteria), and any of the following:
  - Dependent edema suggesting congestive heart failure, or
  - Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), or
  - Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for beneficiaries meeting Group II criteria is limited to 3 months or the treating practitioner specified length of need, whichever is shorter.

**BILLING GUIDELINES**

A maximum of 3 months of oxygen may be delivered at any one time.

**Initial 36 Months**

Reimbursement for oxygen equipment is limited to 36 monthly rental payments. Payment for accessories (e.g., cannula, tubing, etc.), delivery, back-up equipment, maintenance, and repairs is included in the rental allowance. Payment for oxygen contents (stationary and/or portable) is included in the allowance for stationary equipment (E0424, E0439, E1390, E1391).

If the member was using portable gaseous or liquid equipment during the 36th rental month of stationary equipment (gaseous, liquid, or concentrator), payment for portable contents begins when the rental period for the stationary equipment ends. If the member began using portable gaseous or liquid equipment after starting on stationary equipment, payment for the portable equipment would continue until the end of the 36-month rental period for that equipment even though payment was also being made for the portable contents.

If the member is using only portable gaseous or liquid equipment and not stationary equipment during months 1 through 36 of the portable equipment rental, payment for portable contents begins when the rental period for the portable equipment begins. If stationary equipment is subsequently added, separate payment for portable contents ends because payment for contents is included in the payment for stationary equipment.
If the member was not using gaseous or liquid equipment (stationary or portable) in the 36th month, but was subsequently switched to gaseous or liquid oxygen based on a physician order, contents may be paid.

If the member has a stationary concentrator, portable liquid equipment, and a stationary liquid tank to fill the portable cylinders, when payment for contents begins, payment will only be made for portable liquid contents.

Payment for stationary equipment is increased for beneficiaries requiring greater than 4 liters per minute (LPM) of oxygen flow and decreased for beneficiaries requiring less than 1 LPM. If a beneficiary qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, payment will be made for the stationary system at the higher allowance, but not for the portable system. In this situation, if both a stationary system and a portable system are billed for the same rental month, the portable oxygen system will be denied as not separately payable.

The supplier who provides oxygen equipment for the first month must continue to provide any necessary oxygen equipment and all related items and services through the 36-month rental period, unless one of the following exceptions is met:

- Beneficiary relocates temporarily or permanently outside of the supplier’s service area
- Beneficiary elects to obtain oxygen from a different supplier
- Individual case exceptions made by CMS or DME MAC
- Item becomes subject to competitive bidding

Providing different oxygen equipment/modalities (e.g., concentrator [stationary or portable], gaseous, liquid, trans-filling equipment) is not permitted unless one of the following requirements is met:

- Supplier replaces the equipment with the same or equivalent item
- Physician orders different equipment
- Beneficiary chooses to receive an upgrade and signs an Advance Beneficiary Notice of Non-coverage (ABN)
- CMS or the DME MAC determines that a change in equipment is warranted

A new 36-month rental period can begin only in the following situations:

- Specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost
- Break-in-need for at least 60 days plus the days remaining in the month of discontinuation and new medical necessity is established (see “BREAK-IN-SERVICE” below)

A new 36-month rental period does not start in the following situations:

- Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
- Providing different equipment based on a physician order or beneficiary request for an upgrade
- Break-in-need less than 60 days plus the days remaining in the month of discontinuation (see “BREAK-IN-SERVICE” below)
- Break-in-billing (see “BREAK-IN-SERVICE” below)
• Changing suppliers

Months 37-60

There is no further payment for oxygen equipment during the 5-year reasonable useful lifetime (RUL) of the equipment after 36 rental payments have been made. If use of portable equipment (E0431, E0433, E0434, E1392, K0738) begins after the use of stationary equipment begins, payment for the portable equipment can continue after payment for the stationary equipment ends until 36 rental payments have been made for the portable equipment.

For information on payment for contents and maintenance, see separate sections below.

The supplier who provided the equipment during the 36th rental month is required to continue to provide the equipment, accessories, contents (if applicable), maintenance, and repair of the oxygen equipment during the 5 year reasonable useful lifetime of the equipment.

Rules for providing different equipment/modalities are the same in months 37-60 as they are in the initial 36 months (see above).

A new 36-month rental period can begin only in the following situation:

• There is a specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost

A new 36-month rental period does not start in the following situations:
• Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
• Providing different equipment based on a physician order or beneficiary request for an upgrade
• Break-in-need (see “BREAK-IN-SERVICE” below)
• Break-in-billing (see “BREAK-IN-SERVICE” below)
• Changing suppliers

Months 61 and after

At any time after the end of the 5-year reasonable useful lifetime for oxygen equipment, the beneficiary may elect to receive new equipment, thus beginning a new 36-month rental period.

If the beneficiary elects not to receive new equipment after the end of the 5-year reasonable useful lifetime and if the supplier retains title to the equipment, all elements of the payment policy for months 37-60 remain in effect. There is no separate payment for accessories or repairs. If the beneficiary was using gaseous or liquid oxygen equipment during the 36th rental month, payment can continue to be made for oxygen contents.
If the beneficiary elects not to receive new equipment after the end of the 5-year reasonable useful lifetime and if the supplier transfers title of the equipment to the beneficiary, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

If a beneficiary enters Medicare FFS with beneficiary-owned equipment, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

**Liter Flow Greater Than 4 LPM:**

If basic oxygen coverage criteria have been met, a higher allowance for a stationary system for a flow rate of greater than 4 liters per minute (LPM) will be paid only if a blood gas study performed while the beneficiary is on 4 or more LPM meets Group I or II criteria. If a flow rate greater than 4 LPM is billed and the coverage criterion for the higher allowance is not met, payment will be limited to the standard fee schedule allowance. (Refer to related Policy Article for additional information on payment for greater than 4 LPM oxygen.)

**Miscellaneous:**

Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment. Oxygen rental is billed using the appropriate code for the provided oxygen equipment. Separately billed options, accessories or supply items will be denied as unbundling.

Emergency or stand-by oxygen systems for beneficiaries who are not regularly using oxygen will be denied as not reasonable and necessary since they are precautionary and not therapeutic in nature.

**Refills of Oxygen Contents:**

For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use.

Oxygen contents are reimbursed with a monthly allowance covering all contents necessary for the month. Supply allowances are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

All other supplies, e.g. tubing, masks or cannulas, etc., are included in the monthly rental payment. Supplies that are not separately payable are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

See the Non-Medical Coverage and Payment Rules section of the related Policy Article for additional information about coverage of oxygen contents.
Reasonable Useful Lifetime (RUL):

The reasonable useful lifetime for oxygen equipment is 5 years. The RUL is not based on the chronological age of the equipment. It starts on the initial date of service and runs for 5 years from that date.

CPT/HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business Except Medicare</th>
<th></th>
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<tbody>
<tr>
<td>Not Covered</td>
<td></td>
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<tr>
<td>A4575</td>
<td>Topical hyperbaric oxygen chamber, disposable</td>
</tr>
<tr>
<td>E0446</td>
<td>Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories</td>
</tr>
<tr>
<td></td>
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<tr>
<td>No Prior Authorization Required</td>
<td></td>
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<tr>
<td>Group 1 Codes</td>
<td></td>
</tr>
<tr>
<td>E0424</td>
<td>Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<tr>
<td>E0425</td>
<td>Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>E0435</td>
<td>Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor</td>
</tr>
<tr>
<td>E0439</td>
<td>Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, &amp; tubing</td>
</tr>
<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>
</tr>
<tr>
<td>E0442</td>
<td>Stationary oxygen contents, liquid, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0443</td>
<td>Portable oxygen contents, gaseous, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0444</td>
<td>Portable oxygen contents, liquid, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0445</td>
<td>Oximeter device for measuring blood oxygen levels non-invasively</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Medical Equipment</td>
</tr>
<tr>
<td>------------</td>
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</tr>
<tr>
<td>E0447</td>
<td>Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 liters per minute (lpm)</td>
</tr>
<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>
</tr>
<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>
</tr>
<tr>
<td>E1392</td>
<td>Portable oxygen concentrator, rental</td>
</tr>
<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>
</tr>
<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>
</tr>
</tbody>
</table>

**Group 2 Codes: Accessories**

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Medical Equipment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4606</td>
<td>Oxygen probe for use with oximeter device, replacement</td>
</tr>
<tr>
<td>A4608</td>
<td>Transtracheal oxygen catheter, each</td>
</tr>
<tr>
<td>A4615</td>
<td>Cannula, nasal</td>
</tr>
<tr>
<td>A4616</td>
<td>Tubing (oxygen), per foot</td>
</tr>
<tr>
<td>A4617</td>
<td>Mouth piece</td>
</tr>
<tr>
<td>A4619</td>
<td>Face tent</td>
</tr>
<tr>
<td>A4620</td>
<td>Variable concentration mask</td>
</tr>
<tr>
<td>A7525</td>
<td>Tracheostomy mask, each</td>
</tr>
<tr>
<td>A9900</td>
<td>Miscellaneous dme supply, accessory, and/or service component of another hcpcs code</td>
</tr>
<tr>
<td>E0455</td>
<td>Oxygen tent, excluding croup or pediatric tents</td>
</tr>
<tr>
<td>E0555</td>
<td>Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter</td>
</tr>
<tr>
<td>E0580</td>
<td>Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter</td>
</tr>
<tr>
<td>E1352</td>
<td>Oxygen accessory, flow regulator capable of positive inspiratory pressure</td>
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<tr>
<td>E1353</td>
<td>Regulator</td>
</tr>
<tr>
<td>E1354</td>
<td>Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1355</td>
<td>Stand/rack</td>
</tr>
<tr>
<td>E1356</td>
<td>Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1357</td>
<td>Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1358</td>
<td>Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each</td>
</tr>
</tbody>
</table>
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