MEDICAL POLICY	Oxygen Therapy and Home Equipment	
Effective Date: 8/1/2019	Section: DME	Policy No.: 300
Lauf Son 8/1/2019	Technology Assessment Committee Approved Date: 7/07 Medical Policy Committee Approved Date: 8/95; 10/97; 9/98; 7/99; 8/00; 9/01; 10/02; 2/03; 3/04; 3/05; 3/07; 3/08; 3/10; 8/10; 5/11; 4/13; 9/13; 10/14; 10/15; 1/16; 3/17; 3/18; 12/18; 5/19	
Medical Officer Date		

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

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

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

<u>Note:</u> 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^{1,2}
- Local Coverage Determination (LCD) L33797: Oxygen and Oxygen Equipment²
- Local Coverage Article (LCA) A52514: Oxygen and Oxygen Equipment³

COVERAGE CRITERIA

I. Home oxygen therapy and oxygen equipment may be considered **medically necessary and covered** if the following conditions are met:

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- 1. The treating physician has determined that the beneficiary has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, **and**
- 2. The beneficiary's blood gas study meets the criteria stated below (Group I. or II. criteria below), **and**
- 3. The qualifying blood gas study* was performed by a physician or by a qualified provider or supplier of laboratory services, **and**
- 4. The qualifying blood gas study* was obtained under the following conditions:
 - a. 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**
 - b. 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
- 5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

In this policy, the term blood gas study refers to either an oximetry test or an arterial blood gas test.

*See the Policy Guideline section below for Testing Specifications regarding a qualifying blood gas study

Group I criteria include any of the following:

- 1. 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**
- 2. 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**
- 3. 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**
- 4. 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.

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Initial coverage for beneficiaries meeting Group I criteria is limited to 12 months or the physicianspecified length of need, whichever is shorter.

See the Policy Guideline section below for additional information regarding:

- **Exercise testing; and
- ***Certification of Medical Necessity (CMN) or recertification

Group II criteria include the presence of

- A. An arterial PO $_2$ 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
- B. Any of the following:
 - 1. Dependent edema suggesting congestive heart failure, or
 - 2. 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**
 - 3. Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for beneficiaries meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter. (Refer to the Certification section*** in the Policy Guideline section below for information on recertification.)

Portable Oxygen Systems

II. A portable oxygen system is covered if the beneficiary is mobile within the home and 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. (See billing guidelines for additional information regarding billing rules)

If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the beneficiary uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed.

Long Term Oxygen Therapy (LTOT) Clinical Trials

Oxygen and oxygen equipment is **covered** for beneficiaries who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and who have an arterial PO 2 from 56 to 65 mm Hg or an oxygen saturation at or above 89 percent. The additional Group 2 coverage criteria do not apply to these beneficiaries.

NON-COVERAGE CRITERIA

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- III. **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**.
- IV. 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:
 - 1. 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.
 - 2. Dyspnea without cor pulmonale or evidence of hypoxemia
 - 3. 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 PO₂ will improve the oxygenation of tissues with impaired circulation.
 - 4. Terminal illnesses that do not affect the respiratory system
- V. 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.
- VI. Topical hyperbaric oxygen chambers (A4575) are considered **not medically necessary and are not covered.**
- VII. Topical oxygen delivery systems (E0446) are considered **not medically necessary and are not covered.**

POLICY GUIDELINES

*Testing Specifications

For purposes of this policy:

- "Blood gas study" shall refer to both arterial blood gas (ABG) studies and pulse oximetry
- "Oximetry" shall refer to routine or "spot" pulse oximetry
- "Overnight oximetry" shall refer to stand-alone pulse oximetry continuously recorded overnight. It does not include oximetry results done as part of other overnight testing such as polysomnography or home sleep testing.

The qualifying blood gas study must be one that complies with the Fiscal Intermediary, Local Carrier, or A/B Medicare Administrative Contractor (MAC) policy on the standards for conducting the test and is covered under Medicare Part A or Part B. This includes a requirement that the test be performed by a provider who is qualified to bill Medicare for the test – i.e., a Part A provider, a laboratory, an Independent Diagnostic Testing Facility (IDTF), or a physician. A supplier is not considered a qualified

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provider or a qualified laboratory for purposes of this policy. Blood gas studies performed by a supplier are not acceptable. In addition, the qualifying blood gas study may not be paid for by any supplier. These prohibitions do not extend to blood gas studies performed by a hospital certified to do such tests.

The qualifying blood gas study may be performed while the beneficiary is on oxygen as long as the reported blood gas values meet the Group I or Group II criteria.

When both arterial blood gas (ABG) and oximetry tests have been performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), the ABG result will be used to determine if the coverage criteria were met. If an ABG test done at rest and awake is non-qualifying, but either an exercise or sleep oximetry test on the same day is qualifying, the exercise or oximetry test result will determine coverage.

All oxygen qualification testing must be performed in-person by a physician or other medical professional qualified to conduct oximetry testing. With the exception of overnight oximetry (see below), unsupervised or remotely supervised home testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment.

Overnight Oximetry Studies:

Overnight sleep oximetry may be performed in a facility or at home. For home overnight oximetry studies, the oximeter provided to the beneficiary must be tamper-proof and must have the capability to download data that allows documentation of the duration of oxygen desaturation below a specified value.

For all the overnight oximetry criteria described above, the 5 minutes does not have to be continuous. Baseline saturation is defined as the mean saturation level during the duration of the test. For purposes of meeting criterion 3 described in Group I above there must be a minimum of 2 hours test time recorded for sleep oximetry. The result must reach a qualifying test value otherwise the Group III presumption of non-coverage applies.

Home overnight oximetry is limited solely to stand-alone overnight pulse oximetry performed in the beneficiary's home under the conditions specified below. Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered to be eligible under this provision to be used for qualification for reimbursement of home oxygen and oxygen equipment even if the testing was performed in compliance with the requirements of this section.

Beneficiaries may self-administer home based overnight oximetry tests under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility (IDTF). A DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology to a beneficiary's home under the following circumstances:

- 1. The beneficiary's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed.
- 2. The test is performed under the direction and/or instruction of a Medicare-approved IDTF.

 Because it is the beneficiary who self-administers this test, the IDTF must provide clear written

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instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise. The DME supplier may not create this written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test.

3. The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF which is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no case may the DME supplier access or manipulate the test results in any form.

The IDTF must send the test results to the physician. The IDTF may send the test results to the supplier if the supplier is currently providing or has an order to provide oxygen or other respiratory services to the beneficiary or if the beneficiary has signed a release permitting the supplier to receive the report.

Oximetry test results obtained through a similar process as described for home overnight oximetry (see above) while the beneficiary is awake, either at rest or with exercise, may not be used for purposes of qualifying the beneficiary for home oxygen therapy.

Overnight oximetry does not include oximetry obtained during polysomnography or other sleep testing for sleep apnea, regardless of the location the testing was performed. See below for information on sleep testing that may be used to qualify for oxygen coverage.

Obstructive Sleep Apnea (OSA), Polysomnography and Home Sleep Tests:

Some beneficiaries may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Coverage Indications, Limitations and/or Medical Necessity for both the Oxygen and Oxygen Equipment and any other applicable additional medical policy must be met. Consequently, in addition to this Oxygen LCD, suppliers should refer to any additional PAP-related medical policy for additional coverage, coding and documentation requirements.

Coverage of home oxygen therapy requires that the beneficiary be tested in the "chronic stable state." Chronic stable state is a requirement of the National Coverage Determination (CMS Internet-only Manual, Pub. 100-03, Section 240.2) and is one of the key criteria when determining coverage of home oxygen therapy. The NCD defines chronic stable state as "...not during a period of an acute illness or an exacerbation of their underlying disease." Based on this NCD definition, all co-existing diseases or conditions that can cause hypoxia must be treated and the beneficiary must be in a chronic stable state before oxygen therapy is considered eligible for payment. In addition, the beneficiary must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. In the case of OSA, it is required that the OSA be appropriately and sufficiently treated such that the beneficiary is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy.

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For beneficiaries with OSA, this means that the OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy.

For beneficiaries with OSA, a qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split night or stand-alone). The titration PSG is one in which all of the following criteria are met:

- 1. The titration is conducted over a minimum of two (2) hours; and
- 2. During titration:
 - a. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or
 - b. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; and
- Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; and
- The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for 5 minutes total (which need not be continuous)

If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the beneficiary is considered to be in the "chronic stable state." To be eligible for Medicare coverage and payment for home oxygen therapy for concurrent use with PAP therapy, in addition to being in the chronic stable state, the beneficiary must meet all other coverage requirements for oxygen therapy. Beneficiaries that qualify for oxygen therapy based on testing conducted only during the course of a sleep test are eligible only for reimbursement of stationary equipment.

Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered as eligible to be used for qualification for reimbursement of home oxygen and oxygen equipment (see overnight oximetry section above for additional information).

Claims for oxygen equipment and supplies for beneficiaries who do not meet the coverage requirements for home oxygen therapy will be denied as not reasonable and necessary.

**Exercise Testing

When oxygen is covered based on an oximetry study obtained during exercise, there must be documentation of three (3) oximetry studies in the beneficiary's medical record. (1) Testing at rest without oxygen, (2) testing during exercise without oxygen, and (3) testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia) are required. All 3 tests must be performed within the same testing session. Exercise testing must be performed in-person by a physician or other medical professional qualified to conduct exercise oximetry testing. Unsupervised or remotely supervised home exercise testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment. Only the testing during exercise without

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oxygen is used for qualification and reported on the CMN. The other two results do not have to be routinely submitted but must be available on request.

Oximetry obtained after exercise while resting, sometimes referred to as "recovery" testing, is not part of the three required test elements and is not valid for determining eligibility for oxygen coverage.

***Certification:

An Initial, Recertification, or Revised (Certification of Medical Necessity) CMN must be obtained and submitted in the situations described below. The Initial Date, Recertification Date, and Revised Date specified below refer to the dates reported in Section A of the CMN.

Initial CMN is required:

- 1. With the first claim for home oxygen, (even if the beneficiary was on oxygen prior to Medicare eligibility or oxygen was initially covered by a Medicare HMO).
- During the first 36 months of the rental period, when there has been a change in the
 beneficiary's condition that has caused a break in medical necessity of at least 60 days plus
 whatever days remain in the rental month during which the need for oxygen ended. Refer to the
 Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES for additional
 information.
- 3. When the equipment is replaced because the reasonable useful lifetime of prior equipment has been reached.
- 4. When the equipment is replaced because of irreparable damage, theft, or loss of the originally dispensed equipment.
 - a. Irreparable damage refers to a specific accident or to a natural disaster [e.g., fire, flood]
 - b. Irreparable damage does not refer to wear and tear over time

Testing and Visit Requirements:

Initial CMN for situations 1 and 2

- The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.
 - For situation 1, there is an exception to the 30-day test requirement for beneficiaries who were started on oxygen while enrolled in a Medicare HMO and transition to feefor-service Medicare. For those beneficiaries, the blood gas study does not have to be obtained 30 days prior to the Initial Date, but must be the most recent qualifying test obtained while in the HMO.

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• The beneficiary must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification.

Initial CMN for scenarios 3 and 4 (replacement equipment)

- Repeat blood gas testing is not required. Enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

Recertification CMN is required:

- 5. 12 months after Initial Certification, (i.e., with the thirteenth month's claim) for Group I
- 6. 3 months after Initial Certification, (i.e., with the fourth month's claim) for Group II

Testing and Visit Requirements:

Recertification following initial certification situations 1 and 2

- For beneficiaries initially meeting Group I criteria, the most recent qualifying blood gas study prior to the thirteenth month of therapy must be reported on the Recertification CMN.
- For beneficiaries initially meeting Group II criteria, the most recent blood gas study that was performed between the 61st and 90th day following Initial Certification must be reported on the Recertification CMN. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy but the beneficiary continues to use oxygen and a test is obtained at a later date, if that test meets Group I or II criteria, coverage would resume beginning with the date of that test.
- For beneficiaries initially meeting group I or II criteria, the beneficiary must be seen and reevaluated by the treating physician within 90 days prior to the date of any Recertification. If
 the physician visit is not obtained within the 90-day window but the beneficiary continues to
 use oxygen and the visit is obtained at a later date, coverage would resume beginning with
 the date of that visit.

Recertification following initial situations 3 and 4 (replacement equipment)

- Repeat testing is not required. Enter the most recent qualifying value and test date. This test
 does not have to be within 30 days prior to the Initial Date. It could be the test result
 reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

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Revised CMN is required:

- 7. When the prescribed maximum flow rate changes from one of the following categories to another:
 - a. Less than 1 LPM,
 - b. 1-4 LPM,
 - c. Greater than 4 LPM

If the change is from category (a) or (b) to category (c), a repeat blood gas study with the beneficiary on 4 LPM must be performed.

- 8. When the length of need expires if the physician specified less than lifetime length of need on the most recent CMN
- 9. When a portable oxygen system is added subsequent to Initial Certification of a stationary system
- 10. When a stationary system is added subsequent to Initial Certification of a portable system
- 11. When there is a new treating physician but the oxygen order is the same
- 12. If there is a new supplier and that supplier does not have the prior CMN

Submission of a Revised CMN does not change the Recertification schedule specified above.

If the indication for a Revised CMN are met at the same time that a Recertification CMN is due, file the CMN as a Recertification CMN.

Testing and Visit Requirements:

None of the Revised Certification situations (7-12) require a physician visit.

Revised Certification situations 7 and 8

• The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.

Revised Certification situation 9

• There is no requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the beneficiary is at rest (awake) or during exercise within 30 days prior to the Revised Date.

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Revised Certifications situations 10-12

- No blood gas study is required
- For situations 11 and 12, the revised certification does NOT have to be submitted with the claim.

General:

Beneficiaries do not change group classification going from an initial certification to a recertification based upon changes in blood oxygen testing results. For example: A beneficiary initially qualifies for group II with an 89% oximetry value. At the 3-month retest a result of 87% is obtained. Despite the group I retesting value, the beneficiary remains in group II. There is no reclassification to group I. Further recertification is not required unless:

- A non-qualifying test result is obtained at the time of recertification but the beneficiary later obtains a qualifying test result; or,
- The specified length of need (LON) is reached.

Generally only one recertification is required regardless of group classification unless the LON specified on the recertification CMN is some value other than 99 (indicating lifetime). If other than lifetime is specified the certification will expire when the specified LON time period elapses. A recertification will be required to continue coverage.

Recertification is required to be completed on or prior to the end of the initial certification period. If timely recertification is not completed by the end of the initial certification period, reimbursement ends until the recertification is completed. At such time that the recertification requirements are met, payment will resume at the month in the rental cycle where the rental was stopped due to the expiration of the initial certification. A new, initial rental cycle does not begin when the recertification requirements are met.

A completed and signed Certificate of Medical Necessity (CMN) is required to receive payment for oxygen. Claims submitted without a valid CMN will be denied as not reasonable and necessary.

BILLING GUIDELINES

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

If the member elects not to replace a concentrator or transfilling equipment and if the supplier transfers title to the beneficiary, maintenance and service is statutorily non-covered.

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

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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 Noncoverage (ABN)
- CMS or the DME MAC determines that a change in equipment is warranted

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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 <u>not</u> 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

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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

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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

All Lines	All Lines of Business		
Not Covered			
A4575	Topical hyperbaric oxygen chamber, disposable		
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories		
No Pric	or 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		

Oxygen Therapy and Home Equipment

E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator,
20110	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
20447	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

MEDICAL POLICY Oxygen Therapy and Home Equipment

E1358	Oxygen accessory, dc power adapter for portable concentrator, any type, replacement
	only, each

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.

REFERENCES

- Centers for Medicare & Medicaid Services. (1993). National Coverage Determination (NCD) for Home Use of Oxygen (240.2). <a href="https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=169&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&r=r10&KeyWord=home+use+of+oxygen&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAA&. Accessed 4/17/2019.
- 3. Centers for Medicare & Medicaid Services. (2015). Local Coverage Article: Oxygen and Oxygen Equipment Policy Article (A52514). https://www.cms.gov/medicare-coverage-database/details/article-details/article-details/article-details/article-details.aspx?articleId=52514&ver=28&Date=&DocID=A52514&SearchType=Advanced&bc=JAAAABAAAAA&. Accessed 4/17/2019.