

Durable Medical Equipment (DME): Respiratory Devices

MPM 4.3

Disclaimer

Refer to the member's specific benefit plan and *Schedule of Benefits* to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in these criteria.

Description

Durable Medical Equipment (DME) is equipment which:

- Can withstand repeated use
- Is primarily and customarily used to serve a medical purpose
- Generally is not useful to a person in the absence of illness or injury
- Is appropriate for use in a patient's home, at school or at work¹

DME can be rented or purchased, depending on the length of time the member will need the equipment, or if there must be frequent and substantial servicing in order to avoid risk to the patient's health. The decision whether to rent or purchase DME is made by Presbyterian Health Plan (PHP).

Other related medical policies:

- Durable Medical Equipment (DME): Diabetic Equipment, MPM 4.4
- Durable Medical Equipment (DME): Miscellaneous, MPM 4.5
- Durable Medical Equipment (DME): Orthotics and Prosthetics, MPM 4.6
- Durable Medical Equipment (DME): Rehabilitation and Mobility Devices, MPM 4.2
- Durable Medical Equipment (DME) for State Coverage Insurance (SCI), MPM 4.7

This Medical Policy includes the following items:

- Apnea monitors
- Oxygen (includes travel oxygen)
- Oxygen for cluster headaches
- Pulse oximeter
- Respiratory assist devices (CPAP and BiPAP)

Coverage Determination

Durable Medical Equipment (DME) listed in PHP's Prior Authorization/Benefit Certification Guide requires Prior Authorization/Benefit Certification. Log on to Pres Online to submit a request:

<https://ds.phs.org/preslogin/index.jsp>.

- **Items that do not require Prior Authorization/Benefit Certification are subject to retrospective review, and are only covered for the indications listed.**
- **All Durable Medical Equipment is subject to the limitations and exclusions of the member's specific benefit plan.**

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Items classified in DME may not be covered in every instance. Coverage is subject to the following:

- The equipment must be necessary and reasonable for the treatment of an illness or injury, or to improve the functioning of a body part.⁶
- The patient's diagnosis justifies that the equipment or supply being requested is medically necessary.
- The practitioner's documentation must include the patient's diagnosis, the reason equipment is required and the practitioner's estimate of the duration of its need.

Criteria for Respiratory Devices

1. Apnea monitors are usually considered medically necessary until the infant has been episode free for 6 weeks to 3 months. **Prior Authorization/Benefit Certification is not required; claims are subject to retrospective review and are only covered for the indications listed. One of the following criteria must be met for coverage of apnea monitors:**

A. For infants with documented apnea **and one** of the following:

- Prematurity (< 37 weeks gestation), **or**
- Required mechanical ventilation or oxygen due to chronic lung disease, **or**
- Apparent Life Threatening Event (ALTE) signs such as choking, color change, lethargy or decrease in muscle tone, **or**
- Bradycardia (less than 80 beats per minute).

OR

B. Known risk factors for life threatening apnea such as a sibling who died of SIDS. In this case, a monitor would be medically necessary until one month older than the age at which the sibling died.^{5,6}

OR

C. Airway compromise or conditions affecting respiratory control such as tracheostomies, CPAP or mechanical ventilation, or neurological disorders.

2. Oxygen:

Oxygen is covered when medically necessary for use in the home. PHP follows Centers for Medicare and Medicaid Services (CMS) DME MAC guidelines in the coverage of oxygen. **Prior Authorization/Benefit Certification is not required; claims are subject to retrospective review and are only covered for the indications listed.** Cigna DME MAC Local Coverage Determination L11446 can be accessed on the Internet at:

[http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=140&name=CIGNA%20Government%20Services%20\(18003,%20DME%20MAC\)&letter_range=4&retired=&sort=titlea&num_on_page=10&page_num=1](http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=140&name=CIGNA%20Government%20Services%20(18003,%20DME%20MAC)&letter_range=4&retired=&sort=titlea&num_on_page=10&page_num=1)

If a member plans to travel and needs oxygen while away from home,

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PHP will cover the oxygen if it is arranged for and billed by a participating practitioner/provider. The member should check with their DME supplier to see if this service is available. Oxygen provided by a non-participating practitioner/provider is not a covered benefit.^{10,11}

3. Oxygen for cluster type migraine headaches. Prior Authorization/Benefit Certification is not required; claims are subject to retrospective review and are only covered for the indications listed.

Oxygen therapy is indicated for acute treatment of cluster headaches, with the following requirements:

- Use non-rebreather mask.
- Administer 100% oxygen at flow rate of 7 L to 10 L/minutes for no more than 15 to 20 minutes in an upright position, and then stop.
- Appropriate equipment required, including oxygen tank.^{4,9}
- For Medicare members, coverage is available for those enrolled in a clinical trial approved by CMS and are in compliance with the requirements at IOM 100-3 240.22 for dates of service on or after 01/04/2011. Additional information can be accessed at <https://www.cms.gov/medicare-coverage-database/indexes/ncd-by-chapter-and-section-index.aspx?bc=AqAAAAAAAAAAAA&>.

4. Pulse oximetry. Prior Authorization/Benefit Certification is not required; claims are subject to retrospective review and are only covered for the indications listed.

An oximeter is a monitor that measures the oxygen saturation of the blood. **Intermittent or short-term pulse oximetry** is routinely used for people on long-term oxygen therapy. PHP follows CMS Trailblazer Health Enterprises guidelines for the use of intermittent pulse oximeter. CMS Trailblazer LCD L26796 can be accessed on the Internet at http://www.cms.gov/mcd/viewlcd.asp?lcd_id=26796&lcd_version=16&basket=lcd%3A26796%3A16%3A%3Cb%3E+Oximetry+Services+%2D+4F%2D69AB%2DR3%3C%2Fb%3E%3AMAC+%2D+Part+A%3ATrailBlazer+Health+Enterprise%7C%7C+LLC+%2804201%29%3A.

In addition to CMS coverage, PHP covers **continuous pulse oximeter** for the following:

- Patients on mechanical ventilation
- Infants or children with bronchopulmonary dysplasia⁷
- Premature infants being treated for apnea⁵

5. Respiratory assist devices (Bi-Level Positive Airway Pressure devices (BiPAP) and Continuous Positive Airway Pressure devices (CPAP)). Prior Authorization/Benefit Certification is not required; claims are subject to retrospective review and are only covered for the indications listed.

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- PHP follows Cigna DME MAC guidelines for the use of CPAP and BiPAP for obstructive sleep apnea. Cigna DME MAC Local Coverage Determination L11518 is entitled “Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea” and can be accessed on the Internet (link on page 4).

DME MAC LCD L11518 contains criteria for CPAP and BiPAP coverage, as well as information on the sleep tests required to qualify for a respiratory assist device, requirements for continuing coverage of CPAP/BiPAP and physician qualifications.

- PHP follows Cigna DME MAC LCD L5023 guidelines for the use of Respiratory Assist Devices for the following diagnoses:
 - Restrictive thoracic disorders (i.e., progressive neuromuscular diseases or severe thoracic cage abnormalities)
 - Severe chronic obstructive pulmonary disease (COPD)
 - Central sleep apnea or complex sleep apnea
 - Hypoventilation syndrome

Both of these LCDs can be accessed at the following Internet link:

[http://www.cms.hhs.gov/mcd/results_index.asp?from='Imrpcontractor'&contractor=140&name=CIGNA%20Government%20Services%20\(18003,%20DME%20MAC\)&letter_range=4&retired=&sort=titlea&num_on_page=10&page_num=1](http://www.cms.hhs.gov/mcd/results_index.asp?from='Imrpcontractor'&contractor=140&name=CIGNA%20Government%20Services%20(18003,%20DME%20MAC)&letter_range=4&retired=&sort=titlea&num_on_page=10&page_num=1).

- Patients placed on a respiratory assistive device while hospitalized may be discharged with a CPAP or BiPAP device, with the understanding that a sleep study must be done within 30 days. Patients diagnosed with restrictive thoracic disorders are not required to have a sleep study.
- The reasonable useful lifetime of a CPAP device is five years. The purchase of a second CPAP device will require certification from the supplier that the current device is no longer useable, and certification from a board certified sleep specialist that the member has a diagnosis of OSA and is being treated for that condition. In accordance with CMS guidelines, if a CPAP device reaches its 5-year expectancy and remains in good working order and meets the beneficiary’s medical needs, it should not automatically be replaced.
- Other references for CPAP: CMS NCD for Continuous Positive Airway Pressure (CPAP Therapy for Obstructive Sleep Apnea (240.4), available on the Internet at http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=240.4&ncd_version=2&basket=ncd%3A240%2E4%3A2%3AContinuous+Positive+Airway+Pressure+%28CPAP%29+Therapy+For+Obstructive+Sleep+Apnea+%28OSA%29.

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CMS NCD for Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1), is available on the Internet at

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=240.4.1&ncd_version=1&basket=ncd%3A240%2E4%2E1%3A1%3ASleep+Testing+for+Obstructive+Sleep+Apnea+%28OSA%29.

Exclusions

1. Oxygen provided by a non-participating practitioner/provider is not a covered benefit.
2. Unattended home sleep monitoring is not covered for any indication other than obstructive sleep apnea (OSA).
3. Comfort and convenience items generally are **not covered** and include but are not limited to:
 - Vaporizers
 - Humidifiers (if not part of respiratory assist devices)
 - Items that are precautionary in nature, such as spare tanks of oxygen in addition to portable backup systems.
4. Upgraded or deluxe items, or duplicate items (i.e., for home, office or car).

See Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for Jurisdiction C, which has additional specific criteria not listed in this Medical Policy.

[http://www.cms.hhs.gov/mcd/results_index.asp?from=Imrpcontractor&contractor=140&name=CIGNA%20Government%20Services%20\(18003,%20ME%20MAC\)&letter_range=4&retired=&sort=title&num_on_page=10&page_num=5](http://www.cms.hhs.gov/mcd/results_index.asp?from=Imrpcontractor&contractor=140&name=CIGNA%20Government%20Services%20(18003,%20ME%20MAC)&letter_range=4&retired=&sort=title&num_on_page=10&page_num=5)

Definitions

Durable Medical Equipment (DME): Items that are reusable and provide support for physical limitations and disabilities, can withstand repeated use, and are used for a medical purpose, in the member's residence (excluding a skilled nursing facility or acute care hospital) under a physician's supervision.

Items requiring frequent and substantial servicing (rental only): Items for which there must be frequent and substantial servicing in order to avoid risk to the patient's health. Examples of these items include ventilators, aspirators, IPPB machines, passive motion exercise devices, etc. Items in this category may be rented for as long as the patient's need continues.

Reasonable Useful Lifetime: In the absence of Medicare Program Instructions, the Reasonable Useful Lifetime can be determined by the member's individual plan, but in no case can it be less than 5 years.

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Computation of the useful lifetime is based on when the equipment was delivered to the member, not the age of the equipment. If the equipment remains in good working order and meets the member's medical needs, it should not be automatically replaced.

Apnea-Hypopnea Index (AHI): The number of episodes of apnea and hypopnea per hour. If the AHI or RDI is calculated based on less than two hours of continuous recorded sleep, the total number of recorded events to calculate the AHI or RDI during sleep testing is at least the number of events that would have been required in a two hour period.³

Respiratory Distress Index (RDI): The average number of respiratory disturbances per hour.³

Diagnostic tests for obstructive sleep apnea:

- Type I: attended, in-facility polysomnogram.
- Type II: portable monitor (used in both attended and unattended setting) with a minimum of 7 channels, monitoring EEG, EOG (electro-oculogram), EMG (electromyogram), EKG-heart rate, airflow, respiratory effort, oxygen saturation. A Type II device monitors sleep staging, so AHI can be calculated.
- Type III: portable monitor (used in both attended and unattended setting) with a minimum of four monitored channels including ventilation or airflow (at least two channels of respiratory movement or respiratory movement and airflow), heart rate or EKG, and oxygen saturation.
- Type IV: portable monitors which measure one, two or three parameters but do not meet all the criteria of a higher level device. Type IV monitors are used in both attended and unattended setting. To meet CMS guidelines, a Type IV portable monitor should measure at least three channels, one of which is airflow.^{3,8,12}
- Another type of sleep testing device, which does not fit into the classifications noted above, measures three or more channels that include actigraphy, oximetry and peripheral arterial tone. This test is also covered by CMS for members who have signs and symptoms of obstructive sleep apnea.^{13,14}

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Coding

The coding listed in this Medical Policy is for reference only. Covered and non-covered DME are within this list. See CMS Local Coverage Determinations (LCDs) for additional coding references.

CPT Codes	Description
94760	Noninvasive ear or pulse oximetry for oxygen saturation; single determination.
94761	Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (e.g., during exercise)
94762	Measure blood oxygen level
95805	Multiple sleep latency test
95807	Sleep study, attended
95808	Polysomnography, 1-3
95810	Polysomnography, 4 or more
95811	Polysomnography w/CPAP

HCPCS Codes	Description
A4556	Electrodes (e.g., apnea monitor), per pair
A4557	Lead wires (e.g., apnea monitor), per pair
A4604	Tubing with integrated heating element for use with positive airway pressure device
A4606	Oxygen probe for use with oximeter device, replacement
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouth piece
A4618	Breathing circuits
A4619	Face tent
A4620	Variable concentration mask
A7027	Combination oral/nasal mask, used with continuous positive pressure device, each
A7028	Oral cushion for combination oral/nasal mask, replacement only, each
A7029	Nasal pillows for combination oral/nasal mask, replacement only, pair
A7030	Full face mask used with positive airway pressure device
A7031	Face mask interface, replacement for full face mask, only, each

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HCPCS Codes	Description
A7032	Cushion for use on nasal mask interface, replacement only, each
A7033	Pillow for use on nasal cannula type interface, replacement only, pair
A7034	Nasal interface (mask or cannula type) used with positive airway pressure device, with or without head strap
A7035	Headgear used with positive airway pressure device
A7036	Chinstrap used with positive airway pressure device
A7037	Tubing used with positive airway pressure device
A7038	Filter, disposable, used with positive airway pressure device
A7039	Filter, nondisposable, used with positive airway pressure device
A7044	Oral interface used with positive airway pressure device, each
A7045	Exhalation port with or without swivel used with accessories for positive airway
A7046	Water chamber for humidifier, used with positive airway pressure device, replacement, each
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizers, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizers, 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
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 masks, tubing and refill adaptor
E0439	Stationary liquid oxygen system; rental, includes container, contents, regulator, flowmeter, humidifier, nebulizers, cannula or mask, and tubing
E0440	Stationary liquid oxygen system; purchase, includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned), 1 month's supply = 1 unit

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HCPCS Codes	Description
E0442	Oxygen contents, liquid (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned), 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid (for use only with portable liquid systems when No stationary gas or liquid system is used), 1 month's supply = 1 unit
E0445	Oximeter device for measuring blood oxygen levels non-invasively
E0470	Respiratory assist device, bi-level pressure capability, without back-up rate feature, used without noninvasive interface, e.g., nasal or facial (intermittent assist device with continuous positive airway pressure device)
E0471	Respiratory assist device, bi-level pressure capability, with back-up rate feature, used with noninvasive interface, e.g., nasal or facial (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, non-heated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device
E0618	Apnea Monitor, without recording feature
E0619	Apnea monitor, with recording feature
E1353	Regulator
E1355	Stand/Rack
E1372	Immersion external heater for nebulizer
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
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

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HCPCS Codes	Description
G0398	Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation.
G0399	Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation
G0400	Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing
S8120	Oxygen contents, gaseous, 1 unit equals 1 cubic foot
S8121	Oxygen contents, liquid, 1 unit equals 1 pound

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- References:**
1. New Mexico Human Services Department, Medical Assistance Division Program Policy Manual, Durable Medical Equipment and Medical Supplies, NMAC 8.324.5, December 2004, updated 03-01-11.
 2. Cigna Government Services. Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for Jurisdiction CME MAC Cigna Government Services. Coverage policies may be accessed on the Internet at: [http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=140&name=CIGNA%20Government%20Services%20\(18003.%20DME%20MAC\)&letter_range=4&retired=&sort=title&num_on_page=10&page_num=5](http://www.cms.hhs.gov/mcd/results_index.asp?from='lmrpcontractor'&contractor=140&name=CIGNA%20Government%20Services%20(18003.%20DME%20MAC)&letter_range=4&retired=&sort=title&num_on_page=10&page_num=5).
 3. Centers for Medicare and Medicaid Service. Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2), effective date 03-13-08.
 4. Milliman Care Guidelines®, 14th Edition. Oxygen Therapy, Continuous and Non-Continuous: Home (DME). ACG: A-0343 (AC), Last Update: 02-09-10.
 5. Milliman Care Guidelines®, 14th Edition. Apnea, Apparent Life-Threatening Event. ORG: P-12 (ISC), Last Update: 02-09-10.
 6. Milliman Care Guidelines®, 14th Edition, Apnea, Neonatal (Term Infants), ORG: P-15((ISC). Last Update: 02-09-10.
 7. Milliman Care Guidelines®, 14th Edition Bronchopulmonary Dysplasia (BPD), Readmission. ORG: P-90(ISC). Last Update: 02-09-10.
 8. American Academy of Sleep Medicine. Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. October 2007.
 9. Dynamed. Ipswich (MA): EBSCO Publishing 2010. Cluster Headache. Updated 04-23-10.
 10. Centers for Medicare and Medicaid Services. CIGNA Government Services, DME MAC, Article for Travel Oxygen, A49113. Effective Date: 01-01-09.
 11. Centers for Medicare and Medicaid Services. CIGNA Government Services DME MAC, Article for Oxygen and Oxygen Equipment – Policy Article. Effective Date: 01-01-10.
 12. Centers for Medicare and Medicaid Services. Durable Medical Equipment Reference List, National Coverage Determination 280.1. Effective Date: 05-05-05.
 13. Centers for Medicare and Medicaid Services. Decision Memo for Sleep Testing for Obstructive Sleep Apnea (OSA) (CAG-00405N), effective date 03-03-09.
 14. Centers for Medicare and Medicaid Services. National Coverage Determination 240.4.1, Sleep Testing for Obstructive Sleep Apnea (OSA) (NCD 240.4.1), effective date 03-03-09.

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06-24-09: Annual Review and Revision
08-26-09: Updated with CMS NCD 240.4.1 reference
06-23-10: Annual Review and Revision
08-24-11: Annual Review and Revision

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. This Medical Policy is not a treatment guide and should not be used as such.

For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available on the Internet at:
<http://www.phs.org/phs/healthplans/providers/healthservices/Medical/index.htm>