

OHCA Guideline

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| Medical Procedure Class: | Home Mechanical Ventilation |
| Initial Implementation Date: | 10/8/2021 |
| Last Review Date: | 10/20/2025 |
| Effective Date: | 1/1/2026 |
| Next Review/Revision Date: | January 2029 |
| Reviewed By | |
| * This document is not a contract, and these guidelines do not reflect or represent every conceivable situation. Although all items contained in these guidelines may be met, this does not reflect or imply any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit. | |
| <input type="checkbox"/> New Criteria | <input checked="" type="checkbox"/> Revision of Existing Criteria |
| Summary | |
| Purpose: | To provide guidelines to assure medical necessity and consistency in the prior authorization process. |
| Definitions | |
| <p>Apnea: The cessation of airflow for at least 10 seconds in adults. Because of children's different physiology and higher baseline respiratory rate, clinically relevant apneas may not last this long. Apneas of three to four seconds duration can be accompanied by oxygen desaturations.</p> <p>Arterial Blood Gas (ABG): A combination of the following respiratory system-related laboratory data from venous blood: pH, PaCO₂, PaO₂, HCO₃, and calculated oxygen saturation. These data can be useful for evaluating oxygen and carbon dioxide gas exchange, respiratory function, hypoxia, and acid/base balance, particularly in patients with asthma, chronic obstructive pulmonary disease, chronic respiratory failure, and many other types of lung disease. (Mean differences between venous and arterial blood gas measurements vary and must be understood when interpreting the results.)</p> <p>Bi-level Positive Airway Pressure (BPAP): bi-level respiratory assist device that provides differing positive airway pressure depending on inspiration and expiration. Ventilation is provided mainly by inspiratory iPAP, whereas expiratory ePAP recruits under-ventilated or collapsed alveoli for gas exchange and allows for the removal of the exhaled gas.</p> <p>Chronic Obstructive Pulmonary Disease (COPD): a chronic inflammatory lung disease that causes obstructed airflow from within the airways of the lungs.</p> <p>Chronic Respiratory Failure: Chronic respiratory failure is a nonspecific medical condition characterized by the inability to maintain normal oxygen (PaO₂ ≥ 60mmHg) and/or carbon dioxide (PaCO₂ ≤ 45mmHg) levels. Many diseases may lead to chronic respiratory failure, including chronic obstructive pulmonary disease (COPD), and thoracic restrictive diseases (TRD) such as kyphoscoliosis, neuromuscular diseases (NMD), and obesity hypoventilation. Chronic respiratory failure may range from mild to severe and may be stable or progressive.</p> <p>Congestive Heart Failure (CHF): a chronic, progressive condition in which the heart muscle is unable to pump enough blood to meet the body's needs for blood and oxygen.</p> | |

Continuous Positive Airway Pressure (CPAP): positive airway pressure used to deliver a constant pressure to the airways that is maintained throughout the respiratory cycle, during both inspiration and expiration.

Emphysema: a condition in which the alveoli at the end of the smallest air passages (bronchioles) of the lungs are destroyed as a result of damaging exposure to cigarette smoke and/or other irritants in the form of gases or particulates.

Home Mechanical Ventilation (HMV): The delivery of pressure-targeted, volume-targeted, and/or preset volume ventilation outside of the hospital setting. Compared to BPAP machines, HMV machines are highly variable in functionality, often with features that include monitoring, rate control, preset volume ventilation, safety, and backup power features. (Some newer BPAP machines may also have certain advanced features.) Current medical research evidence is insufficient to assess the comparative effectiveness of HMV vs. BPAP on patient outcomes. HMV is usually more appropriate in members with a tracheostomy, but in certain situations it may also be used in patients via a noninvasive interface (i.e., a mask). In this guideline, HMV device refers to either invasive interface (i.e., E0465) or non-invasive interface (i.e., E0466).

Hypopnea: An abnormal respiratory event lasting at least 10 seconds associated with at least a 30% reduction in thoracoabdominal movement or airflow as compared to baseline and with at least a 4% decrease in oxygen saturation.

Hypoventilation Syndrome (HS): Also known as Pickwickian Syndrome, is a condition in which severely overweight people fail to breathe rapidly or deeply enough, resulting in low blood oxygen levels and/or high blood carbon dioxide (CO₂) levels.

Hypoxemia: abnormally low concentration of oxygen in the blood.

Medical Necessity: Services provided within the scope of the Oklahoma Medicaid Program shall meet medical necessity criteria. Requests by medical services providers for services in and of itself shall not constitute medical necessity. The Oklahoma Health Care Authority shall serve as the final authority pertaining to all determination of medical necessity. Medical necessity is established through consideration of the following standards:

- 1) Services must be medical in nature and must be consistent with accepted health care practice standards and guidelines for the prevention, diagnosis, or treatment of symptoms of illness, disease or disability.
- 2) Documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the client's need for the service.
- 3) Treatment of the client's condition, disease or injury must be based on reasonable and predictable health outcomes.
- 4) Services must be necessary to alleviate a medical condition and must be required for reasons other than convenience for the client, family, or medical provider.
- 5) Services must be delivered in the most cost-effective manner and most appropriate setting; and
- 6) Services must be appropriate for the client's age and health status and developed for the client to achieve, maintain, or promote functional capacity. OAC 317: 30-3-1-1 (f) (2).

Noninvasive ventilation (NIV): The administration of ventilatory support without using an invasive artificial airway (endotracheal tube or tracheostomy tube). This is not specific to Home Mechanical Ventilation (HMV) and may refer to any positive airway pressure (PAP), including continuous positive airway pressure (CPAP) and Bi-Level Positive Airway Pressure (BPAP) therapy.

Obstructive Sleep Apnea Syndrome (OSA): Along with upper airway resistance syndrome (UARS), is an increase in respiratory effort due to breathing against relative or absolute airway obstruction resulting in more negative intrathoracic pressure and decreased or absent air flow.

Polysomnography (Polysomnogram) (PSG): The process of using a polygraph to make a continuous record during sleep of multiple physiological variables, such as breathing, heart rate, and muscle activity. Polysomnography is distinguished from sleep studies by the inclusion of sleep staging. It may be performed as either a whole night study for diagnosis only or as a split night study to diagnose and initially evaluate treatment.

Pulmonary function Tests (PFT): a/k/a Respiratory function tests (RFTs) or lung function tests are non-invasive diagnostic tests which provide feedback regarding the function of the lungs. Through the assessment of lung volumes, rates of flow, capacities, and gas exchange, RFTs provide useful information in diagnosing lung disorders.

Positive airway pressure (PAP): In this guideline, the term PAP will refer to both a single level continuous positive airway pressure device, or CPAP, (E0601) and a bi-level respiratory assist device or BPAP, without back-up rate (E0470) when it is used in the treatment of obstructive sleep apnea.

Qualified Medical Professional: A medical doctor (MD), osteopathic doctor (DO), physician's assistant (PA), certified nurse practitioner (CNP), or an advanced practice registered nurse (APRN) who is currently contracted with Sooner Care.

Respiratory disturbance index (RDI): In adults, the number of apneas plus hypopneas per hour of recording without the use of a positive airway pressure device. If the AHI or RDI for an adult is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2-hour period (i.e., must reach > 30 events without symptoms or > 10 events with symptoms).

Restrictive Thoracic Disorders: A group of thoracic deformities that result in inefficient coupling between the respiratory muscles and the thoracic cage, usually characterized by a restrictive defect and share the potential to cause long-term hypercapnic respiratory failure.

Venous Blood Gas (VPG): A combination of the following respiratory system-related laboratory data from venous blood: pH, PvCO₂, PvO₂, and HCO₃. These data can be useful for evaluating oxygen and carbon dioxide gas exchange, respiratory function (but not blood oxygen saturation or hypoxia), and acid/base balance, particularly in patients with asthma, chronic obstructive pulmonary disease, chronic respiratory failure, and many other types of lung disease. (Mean differences between venous and arterial blood gas measurements vary and must be understood when interpreting the results).

Ventilator: An automatic machine designed to mechanically move breathable air into and out of the lungs, to provide respiration for a patient who is physically unable to breathe or breathing insufficiently. Backup ventilators are not covered as per policy (317:30-5-211.10).

| Description |
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| The delivery of pressure-targeted, volume-targeted, and/or preset volume ventilation outside of the hospital setting. Compared to BPAP machines, HMV machines are highly variable in functionality, often with features that include monitoring, rate control, safety, and backup power features. (Some newer BPAP machines may also have certain advanced features.) Current medical research evidence is insufficient to assess the comparative effectiveness of HMV vs. BPAP on patient outcomes. |

HCPCS Codes Covered Requiring Prior Authorization (PA)

E0465 - Home ventilator, any type, used with invasive interface (e.g., tracheostomy tube)

E0466 - Home ventilator, any type, used with non-invasive interface (e.g., mask, chest shell)

Approval Criteria

I. GENERAL

Documentation submitted to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the clients need for the service in accordance with OAC 317: 30-3-1-1 (f) (2).

Note: Additional information may be requested and considered, such as PFT's and data trends.

II. INDICATIONS IN CHILDREN (<18 years of age) for HMV Prior Authorization

INITIAL E0465 or E0466 device three-month coverage criteria for **Chronic Respiratory Failure (CRF)** in Children (<18 years of age) will require a PA request that provides the pertinent medical records and demonstrates all the following:

- a. The member has a face-to-face clinical evaluation by a qualified, treating medical professional within one (1) month prior to prior authorization (PA) request, during which the member has been assessed for, and diagnosed with, CRF.
- b. The medical records provide clinical evidence supporting the primary diagnosis of CRF.
- c. The member has fully recovered and stabilized from an acute exacerbation or illness and is at baseline respiratory status.
- d. One of the following:
 1. An arterial blood gas PaCO₂ is greater than or equal to 45 mm Hg, done while awake and using prescribed oxygen (\geq 2L/minute), OR
 2. sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing prescribed recommended oxygen (\geq 2L/minute), OR
 3. a neuromuscular disease (only) with either i or ii,
 - i. Maximal Inspiratory Pressure less than 60 cm H₂O, or
 - ii. Forced Vital Capacity less than 50% predicted
- e. The member has failed PAP therapy using E0470 with prescribed oxygen (\geq 2L/minute): PaCO₂ > 52mmHg, AND oxygen saturation < 88% (while awake); OR failed PAP therapy using E0470 with prescribed oxygen (\geq 2L/minute): oxygen saturation < 88% for greater than or equal to a cumulative 5 minutes (while asleep during PSG).
- f. The member and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

III. INDICATIONS IN ADULTS (>18 years of age) for HMV Initial Prior Authorization.

INITIAL E0465 or E0466 device three-month coverage criteria for the treatment of **Restrictive Lung Diseases (RLD) such as Neuromuscular Diseases (e.g., Amyotrophic Lateral Sclerosis (ALS), Spinal Muscular Atrophies, and Muscular Dystrophies), fibrotic lung diseases, and kyphoscoliosis (for Hypoventilation Syndrome see Section VI)**, will require a PA request that provides the pertinent medical records and demonstrates all the following:

- a. The member has a face-to-face, clinical evaluation by a qualified medical professional within one (1) month prior to prior authorization (PA) request, during which the member has been diagnosed with RLD.
- b. The medical records provide clinical evidence supporting the primary diagnosis of RLD.
- c. The member has fully recovered and stabilized from an acute exacerbation or illness and is at baseline respiratory status.
- d. One of the following:
 1. An arterial blood gas PaCO₂, done while awake and breathing prescribed oxygen (at least ≥ 2L/minute) is greater than or equal to 45 mm Hg, OR
 2. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing prescribed recommended oxygen (at least ≥ 2L/minute), OR
 3. a neuromuscular disease (only) with either i or ii,
 - i. Maximal Inspiratory Pressure less than 60 cm H₂O, or
 - ii. Forced Vital Capacity less than 50% predicted
- e. The member has failed PAP therapy using E0470 with prescribed oxygen (≥ 2L/minute): PaCO₂ > 52mmHg, AND oxygen saturation < 88% (while awake); OR failed PAP therapy using E0470 with prescribed oxygen (≥ 2L/minute): oxygen saturation < 88% for greater than or equal to a cumulative 5 minutes (while asleep during PSG).
- f. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

IV. INITIAL E0465 or E0466 device three-month coverage criteria for the treatment of **Chronic Obstructive Pulmonary Disease (COPD) or **Emphysema**** will require a PA request that provides the pertinent medical records and demonstrates **all** the following:

- a. The member has a face-to-face clinical evaluation by a qualified, treating medical professional within one (1) month prior to prior authorization (PA) request, during which the member has been assessed for, and diagnosed with, COPD or Emphysema.
- b. The medical records provide clinical evidence supporting the primary diagnosis of COPD.
- c. The member is at baseline respiratory status, after recovery from acute respiratory illness or exacerbation.
- d. The member has failed PAP therapy using E0470 with prescribed oxygen (≥ 2L/minute): PaCO₂ > 52mmHg, AND oxygen saturation < 88% (while awake); OR failed PAP therapy using E0470 with prescribed oxygen (≥ 2L/minute): oxygen saturation < 88% for greater than or equal to a cumulative 5 minutes (while asleep during PSG).
- e. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

V. INITIAL E0465 or E0466 device three-month coverage criteria for the treatment of **Obstructive Sleep Apnea Syndrome (OSA), **Central Sleep Apnea**, or **Complex Sleep Apnea**** will require a PA request that provides the pertinent medical records and demonstrates **all** the following:

- a. The member has a face-to-face clinical evaluation by a qualified, treating medical professional within one (1) month prior to prior authorization (PA) request, during which the member has been assessed for, and diagnosed with **Sleep Apnea**.
- b. The medical records provide clinical evidence supporting the primary diagnosis of **Sleep Apnea**.
- c. The member has fully recovered and stabilized from an acute exacerbation or illness and is at baseline respiratory status.

- d. The member has failed PAP therapy using E0470 with prescribed oxygen ($\geq 2\text{L/minute}$): $\text{PaCO}_2 > 52\text{mmHg}$, AND oxygen saturation $< 88\%$ (while awake); OR failed PAP therapy using E0470 with prescribed oxygen ($\geq 2\text{L/minute}$): oxygen saturation $< 88\%$ for greater than or equal to a cumulative 5 minutes (while asleep during PSG).
- e. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

VI. INITIAL E0465 or E0466 device three-month coverage criteria for the treatment of **Hypoventilation Syndrome (HS)** will require a PA request that provides the pertinent medical records and demonstrates **all** the following:

- a. The member has a face-to-face clinical evaluation by a qualified medical professional within one (1) month prior to prior authorization (PA) request, during which the member has been diagnosed with HS.
- b. The medical records provide clinical evidence supporting the primary diagnosis of Hypoventilation Syndrome.
- c. The member has fully recovered and stabilized from an acute exacerbation or illness and is at baseline respiratory status.
- d. The member has failed PAP therapy using E0470 with $\text{PaCO}_2 > 52\text{mmHg}$.
- e. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

VII. INITIAL E0465 or E0466 device three-month coverage criteria for the treatment of **Congestive Heart Failure (CHF)** will require a PA request that provides the pertinent medical records and demonstrates **all** the following:

- a. The member has a face-to-face clinical evaluation by a qualified treating medical professional within one (1) month prior to prior authorization (PA) request, during which the member has been assessed for, and diagnosed with, CHF.
- b. The medical records provide clinical evidence supporting the primary diagnosis of CHF.
- c. Echocardiogram results from within the last 12 months are provided with the initial request for E0465 or E0466 device and services.
- d. The member has fully recovered and stabilized from an acute exacerbation or illness and is at baseline respiratory status.
- e. The member has failed PAP therapy using E0470 with prescribed oxygen ($\geq 2\text{L/minute}$): $\text{PaCO}_2 > 52\text{mmHg}$, AND oxygen saturation $< 88\%$ (while awake); OR failed PAP therapy using E0470 with prescribed oxygen ($\geq 2\text{L/minute}$): oxygen saturation $< 88\%$ for greater than or equal to a cumulative 5 minutes (while asleep during PSG).
- f. The patient and/or their caregiver have received instruction from the supplier of the device in the proper use and care of the equipment.

Continuation Criteria

The initial approval for an HMV device, when approved, will be a maximum of three (3) months. A new PA request will be required for continued authorization of an E0465 or E0466 device beyond the initial 3 months of therapy.

- a. Members approved for the initial three months of an E0465 or E0466 device must be re-evaluated to establish the medical necessity of continued use. While the member may need to be evaluated at earlier intervals after HMV therapy is initiated; re-evaluation by the treating

qualified medical professional for a continued PA must be done no sooner than 61 days after initiating therapy.

- b. Medical records must document the persistence of the disease process for which the HMV device has been prescribed, and that the member is compliant with, and benefiting from, its use.
- c. The DME supplier of the device must provide at least 30 consecutive days of device data, beginning no sooner than 31 days after initiating use of the device, showing that the member is utilizing the device an average of 4-hours per 24-hour period. Failure of the beneficiary to be consistently using an E0465 or E0466 device for an average of 4-hours per 24-hour period would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy. This would constitute reason to deny continued coverage as not reasonable and necessary.

Note: Additional information may be requested.

Discontinuation Criteria

- I. If the above criteria are not met, continued coverage of an E0465 or E0466 device and related accessories will be denied as not medically necessary.
- II. If criteria for continued coverage are not met, the device in question, being the property of the State of Oklahoma, must be recovered by the DME provider and provided to the ReUse program.
- III. All other indications for an E0465 or E0466 device not otherwise noted above as covered or non-covered, remain at discretion of Oklahoma Health Care Authority.

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Appendix A:

Oklahoma Sleep Diagnostic Testing Regulation Act

§63-7200.1. Short title.

This act shall be known and may be cited as the “Oklahoma Sleep Diagnostic Testing Regulation Act”.

Added by Laws 2009, c. 360, § 1.

§63-7200.2. Legislative findings.

The Oklahoma Legislature hereby finds that:

1. There is a growing need for sleep diagnostic testing in the diagnosis and treatment of sleep disorders;
2. Sleep diagnostic testing is being performed in Oklahoma; and
3. Oklahoma law does not provide sufficient regulation of sleep diagnostic testing to assure the protection of the public.

Therefore, there is a need to provide legislation to enable the appropriate entities to regulate persons performing sleep diagnostic testing on the citizens of this state.

Added by Laws 2009, c. 360, § 2.

§63-7200.3. Definitions.

As used in the Oklahoma Sleep Diagnostic Testing Regulation Act:

1. "Advanced practice nurse" means a person licensed to practice as an advanced practice nurse by the Oklahoma Board of Nursing pursuant to the Oklahoma Nursing Practice Act;
2. "Interpreting physician" means a physician who provides professional interpretation of data generated by sleep diagnostic tests. An interpreting physician shall be board-certified in sleep medicine by the American Board of Sleep Medicine (ABSM) or the American Board of Medical Specialties or must have completed a one-year sleep medicine fellowship accredited by the Accreditation Council for Graduate Medical Education (ACGME) or received a Certification of Special Qualifications (CSQ) or a Certification of Added Qualifications (CAQ) in Sleep Medicine issued by the American Osteopathic Association;
3. "Physician" means a person licensed to practice:
 - a. allopathic medicine and surgery by the State Board of Medical Licensure and Supervision pursuant to the Oklahoma Allopathic Medical and Surgical Licensure and Supervision Act, or
 - b. osteopathic medicine by the State Board of Osteopathic Examiners pursuant to the Oklahoma Osteopathic Medicine Act;
4. "Physician assistant" means a person licensed to practice as a physician assistant by the State Board of Medical Licensure and Supervision pursuant to the Physician Assistant Act;
5. "Sleep diagnostic test" means any technological recording procedure used for the diagnosis of sleep-related breathing disorders or other disorders of sleep;
6. "Sleep diagnostic testing facility" means a building or place situated in a fixed location or a mobile entity that is used to conduct sleep diagnostic tests and includes sleep disorder centers and laboratories for sleep-related breathing disorders, but does not include a hospital that conducts sleep diagnostic tests for its patients, including sleep diagnostic tests performed under arrangements made by a hospital for its patients whereby the hospital exercises professional responsibility over the arranged services; and
7. "Supervising physician" means a physician responsible for the supervision of the sleep diagnostic testing performed, including, but not limited to, the quality of the testing performed, the proper operation and calibration of the equipment used to perform sleep diagnostic tests and the actions of nonphysician personnel engaged in the performance of the sleep diagnostic testing. A supervising physician shall be board-certified in sleep medicine by the American Board of Sleep Medicine (ABSM) or the American Board of Medical Specialties or shall have completed a one-year sleep medicine fellowship accredited by the Accreditation Council for Graduate Medical Education (ACGME) or received a Certification of Special Qualifications (CSQ) or a Certification of Added Qualifications (CAQ) in Sleep Medicine issued by the American Osteopathic Association.

Added by Laws 2009, c. 360, § 3. Amended by Laws 2010, c. 200, § 1, eff. Nov. 1, 2010.

§63-7200.4. Ordering and furnishing sleep diagnostic tests - Facility standards.

- A. Sleep diagnostic tests shall be ordered by a physician, physician assistant or advance practice nurse.
- B. Sleep diagnostic tests shall be furnished:
 1. By a sleep diagnostic testing facility;
 2. By, or under arrangements made by, a hospital for its patients whereby the hospital exercises professional responsibility over the arranged services; or
 3. In the patient's home.
- C. Sleep diagnostic testing facilities shall meet the following standards:
 1. Sleep diagnostic testing facilities shall be supervised by a supervising physician as defined by this act;
 2. On and after January 1, 2010, sleep diagnostic testing facilities shall be fully or provisionally certified or accredited by the American Academy of Sleep Medicine

- (AASM), the Joint Commission or the Accreditation Commission for Healthcare (ACHC), except that the full or provisional certification or accreditation by AASM, the Joint Commission, or ACHC shall not be required until June 30, 2010, for any sleep diagnostic testing facility that has submitted a complete application for certification or accreditation to AASM, the Joint Commission and/or ACHC on or before December 31, 2009;
3. An interpreting physician shall interpret the data generated by all sleep diagnostic tests conducted at a sleep diagnostic testing facility; and
 4. Nonphysician personnel conducting sleep diagnostic tests shall perform their duties under the direction and supervision of the supervising physician.
- D. Sleep diagnostic tests performed in the patient's home shall be conducted under the supervision of a supervising physician and interpreted by an interpreting physician.

Added by Laws 2009, c. 360, § 4.

§63-7200.5. Violations - Enforcement - Promulgation of rules.

- A. It shall be unlawful for any facility or person to perform sleep diagnostic tests without having first complied with this act or as may otherwise be allowed by applicable law.
- B. The State Department of Health is authorized to enforce the provisions of this act.
- C. The State Board of Health shall promulgate rules and enforcement measures as necessary to implement the provisions of the Oklahoma Sleep Diagnostic Testing Regulation Act.

Added by Laws 2009, c. 360, § 5. Amended by Laws 2010, c. 200, § 2, eff. Nov. 1, 2010.