Ohio Administrative Code

Rule 5160-10-38 DMEPOS: respiratory assist devices.

Effective: August 1, 2025

(A) Terminology.

(1) The following abbreviations are used in this rule:

(a) "AHI" stands for 'apnea-hypopnea index'.

(b) "CAHI" stands for 'central apnea-central hypopnea index'.

(c) "CompSA" stands for 'complex sleep apnea'.

(d) "CSA" stands for 'central sleep apnea'.

(e) "FEV1" stands for 'forced expiratory volume in one second'.

(f) "FIO2" stands for 'fractional concentration of oxygen delivered for inspiration'.

(g) "FVC" stands for 'forced vital capacity'.

(h) "LPM" stands for 'liters per minute'.

(i) "OSA" stands for 'obstructive sleep apnea'.

(j) "PaCO2" stands for 'partial pressure of carbon dioxide'. The measurement can be expressed in millimeters of mercury (mm Hg).

(k) "PAPD" stands for 'positive airway pressure device', "PAPD-W" stands for 'positive airway pressure device with backup rate', and "PAPD-WO" stands for 'positive airway pressure device without backup rate'.

(l) "RAD" stands for 'respiratory assist device', "RAD-W" stands for 'respiratory assist device with backup rate', and "RAD-WO" stands for 'respiratory assist device without backup rate'.

(2) The policy provisions in this rule depend on the following definitions:

(a) Apnea is a breathing disorder characterized by the cessation of airflow for at least ten seconds. Hypopnea is a reduction in airflow of more than thirty per cent.

(i) OSA is the obstruction or collapse, either total or partial, of the airways during sleep.

(ii) CSA is an interruption of breathing caused by a brief lack of communication between the brain and the muscles that control breathing. CSA is characterized by the following symptoms:

(A) An AHI of five or greater with no evidence of diurnal or nocturnal hypoventilation;

(B) A CAHI of five or greater;

(C) Episodes of central apnea and central hypopnea making up more than half of all episodes of apnea and hypopnea; and

(D) The presence of at least one of the following symptoms:

(i) Sleepiness;

(ii) Difficulty initiating or maintaining sleep, frequent waking, or non-restorative sleep;

(iii) Shortness of breath on waking;

(iv) Snoring; or

(v) Witnessed episodes of apnea.

(b) CompSA is a form of CSA characterized by all of the following symptoms:

(i) After resolution of obstructive events, episodes of central apnea and central hypopnea make up more than half of all episodes of apnea and hypopnea;

(ii) When a PAPD-WO is used and episodes of obstructive apnea or hypopnea have been resolved, episodes of central apnea or hypopnea persist or emerge; and

(iii) The CAHI is five or greater.

(c) The severity of apnea is expressed by a numerical index.

(i) AHI is the mean number of episodes per hour of apnea or hypopnea, either obstructive or central, without the use of a PAPD or a RAD, reported by polysomnogram.

(ii) CAHI is the mean number of episodes per hour of central apnea and central hypopnea, reported by polysomnogram. For CSA, the CAHI is determined without the use of a PAPD; for CompSA, the CAHI is determined with the use of a PAPD after resolution of obstructive events.

(iii) Calculation of the AHI or CAHI is normally based on at least two hours of continuous recorded sleep. However, if the threshold number (e.g., ten recorded events in two hours) is reached before the allotted time has elapsed, sleep may be discontinued.

(d) Prescribed FIO2 is the oxygen concentration an individual normally breathes in the absence of testing.

(i) For an individual who normally uses supplemental oxygen, the prescribed FIO2 is the supplemental oxygen concentration, expressed in LPM.

(ii) For an individual who does not normally use supplemental oxygen, the prescribed FIO2 is the oxygen concentration in the surrounding air.

(B) Coverage.

(1) The default certificate of medical necessity (CMN) form is the ODM 01910, "Certificate of Medical Necessity: Respiratory Assist Devices." The CMN includes the following information:

(a) A diagnosis of a condition for which a RAD is an appropriate treatment, including but not limited to the disorders specified in the following list:

(i) Restrictive thoracic disorders (i.e., neuromuscular diseases or severe thoracic cage abnormalities);

(ii) Severe chronic obstructive pulmonary disease (COPD);

(iii) CSA or CompSA; or

(iv) Hypoventilation syndrome;

(b) The results of a respiratory study; and

(c) An estimated length of need.

(2) For treatment of the following conditions, payment for the indicated type of RAD may be made only if the associated criteria are met:

(a) Restrictive thoracic disorders, RAD:

(i) COPD does not contribute significantly to the individual's pulmonary limitation; and

(ii) One of the following conditions is met:

(A) Arterial blood gas PaCO2, tested while the individual is awake and breathing oxygen at the prescribed FIO2, is forty-five mm Hg or greater;

(B) Sleep oximetry demonstrates that oxygen saturation falls to eighty-eight per cent or less while the individual is breathing oxygen at the prescribed FIO2, or

(C) For a neuromuscular disease, either the maximal inspiratory pressure is less than sixty centimeters of water (cm H20) or the FVC is less than fifty per cent of the predicted volume.

(b) Severe COPD, RAD-WO:

(i) Arterial blood gas PaCO2, tested while the individual is awake and breathing oxygen at the prescribed FIO2, is fifty-two mm Hg or greater;

(ii) Sleep oximetry demonstrates that oxygen saturation falls to eighty-eight per cent or less while the individual is breathing oxygen at the greater of two LPM or the prescribed FIO2; or

(iii) Treatment with a continuous positive airway pressure (CPAP) device has been considered and ruled out, either by sleep testing or by evidence, documented in the medical record, that sleep apnea (OSA, CSA, or CompSA) is the predominant cause of oxygen desaturation.

(c) Severe COPD, RAD-W, at any time after initial use of a RAD-WO:

(i) Arterial blood gas PaCO2, tested while the individual is awake and breathing oxygen at the prescribed FIO2, varies more than seven mm Hg from the reference measurement of fifty-two mm Hg; and

(ii) Oxygen saturation is eighty-eight per cent or less while the individual is using a RAD-WO and the AHI is less than five.

(d) Severe COPD, RAD-W, not sooner than sixty-one days after initial use of a RAD-WO:

(i) Arterial blood gas PaCO2, tested while the individual is awake and breathing oxygen at the prescribed FIO2, remains at fifty-two mm Hg or greater; and

(ii) Oxygen saturation is eighty-eight per cent or less while the individual, using a RAD-WO, is breathing oxygen at the greater of two LPM or the prescribed FIO2.

(e) Central sleep apnea or complex sleep apnea, RAD:

(i) CSA or CompSA has been diagnosed and documented; and

(ii) There is significant improvement of sleep-associated hypoventilation while the individual, using either a RAD-WO or RAD-W adjusted to the settings that will be prescribed for initial use at home, is breathing oxygen at the prescribed FIO2.

(f) Hypoventilation syndrome, RAD-WO:

(i) Arterial blood gas PaCO2, tested while the individual is awake and breathing oxygen at the prescribed FIO2, is forty-five mm Hg or greater;

(ii) The FEV1/FVC ratio is seventy per cent or greater; and

(iii) One of the following conditions is met:

(A) Arterial blood gas PaCO2, tested either while the individual is asleep or immediately upon waking, varies more than seven mm Hg from the reference measurement of forty-five mm Hg; or

(B) Oxygen saturation is eighty-eight per cent or less and the AHI is less than five.

(g) Hypoventilation syndrome, RAD-W:

(i) The individual is using a RAD-WO; and

(ii) The criteria for initial use of a RAD-WO are still met.

(3) When the FEV1/FVC ratio is less than seventy per cent, the criteria for COPD are applied to hypoventilation syndrome.

(4) A need for oxygen is established if a RAD is effective during a respiratory study only when supplemental oxygen is administered simultaneously. That need for oxygen is presumed to last as

long as the need for the RAD, and no further respiratory study is necessary to confirm a continued need for oxygen.

(5) The provider of a RAD cannot perform the qualifying respiratory study.