TO BE RESCINDED

5160-10-22 **Volume ventilators, positive and negative pressure ventilators, continuous positive airway pressure (CPAP), alternating positive airway pressure (APAP), and intermittent positive pressure ventilation (IPPV).**

(A) Any provider billing for ventilatory support services (including volume ventilators, positive and negative pressure ventilators, CPAP, APAP and IPPV) shall have on staff or under contract a licensed respiratory care professional (LRCP) available on a twenty-four-hour basis, seven days a week to provide respiratory care, technical support and clinical ventilator services.

(B) Mechanical ventilator services are covered for consumers residing in a personal residence, a nursing facility (NF), or an intermediate care facility for the mentally retarded (ICF-MR). The monthly rental fee includes reimbursement for the use of a mechanical ventilator, all service and maintenance, related ventilator supplies and equipment listed in paragraph (B)(6)(a) of this rule, and the LRCP services listed in paragraph (B)(6)(b) of this rule. For a pressure ventilator used as an alternative to a volume ventilator, noninvasive applications are covered when a tracheostomy is not medically necessary.

(1) Ventilator definitions

(a) "Invasive mechanical ventilator." An invasive application requires the ventilator be interfaced directly with the consumer via an artificial airway (e.g., tracheostomy tube). Invasive mechanical ventilators (volume and/or pressure) are life support devices designed specifically for invasive mechanical ventilation applications and must accommodate direct current (DC) backup power supply and include disconnect, high pressure, low pressure and power loss alarms.

(b) "Non-invasive mechanical ventilator." Non-invasive mechanical ventilators (volume, or positive or negative pressure) may be used as an alternative to invasive mechanical ventilator services for consumers with appropriate medical necessity and when the consumer's attending prescriber has deemed a tracheostomy not medically necessary.

(2) Mechanical ventilator coverage criteria

(a) To be considered for coverage, consumers must require periodic or continuous mechanical ventilation (volume, or positive or negative pressure). A consumer must demonstrate appropriate medical necessity supporting the need for mechanical ventilatory support as treatment for

respiratory insufficiency and/or respiratory failure resulting from one or more of the following conditions:

(i) Chronic respiratory failure

(ii) Spinal cord injury

(iii) Neuromuscular diseases

(iv) Chronic pulmonary disorders

(v) Other neurological disorders and thoracic restrictive diseases

(3) Medical necessity for pressure support ventilator with volume control is the same as above and also includes the following supportive information:

(a) Statement from the prescriber that the consumer has tried unsuccessfully to be managed with a volume ventilator, and

(b) Statement from the prescriber that the advanced technology offered by this pressure ventilator is required for the safe and appropriate management of the .consumer

(4) Invasive mechanical ventilator services, with backup rate feature, do not require prior authorization for the first three months of use by any particular consumer. Other ventilator services may be prior authorized for up to six months at the time of initial prior authorization. Consumers with chronic nonreversible respiratory insufficiency and/or failure may receive lifetime authorization for rental or purchase at the discretion of the department. All requests for prior authorization of ventilator services must include a fully completed "Certificate of Medical Necessity/Prescription Mechanical Ventilators" form JFS 01902, rev. 06/2007 (appendix to this rule) within thirty days prior to the first date of service being requested. The certification of medical necessity, must include:

(a) Medical history (not required if request is for continuation of services),

(b) Diagnosis and degree of impairment,

(c) Degree of ventilatory support required (e.g., continuous, nocturnal only),

(d) Ventilator settings/parameters including mode and type of ventilator ordered at time of prior authorization request,

(e) List of other respiratory equipment in use,

(f) Documentation that recipient is being weaned (if applicable),

(g) Documentation of initial LRCP services described in (B)(6)(b) of this rule, when performed before prior authorization request, and

(h) Documentation (e.g., copy of a recent checksheet) that a LRCP routinely checks or changes ventilator settings in compliance with prescriber ordered parameters or protocol (not applicable to initial prior authorization request).

(5) Any change in the type of equipment provided, other than invasive mechanical ventilators with backup rate feature used with invasive interface, will require a new prior authorization request with supporting documentation as described in paragraph (B)(4) of this rule.

(6) The monthly rental payment for ventilator services includes reimbursement for the following equipment and supplies and respiratory services:

(a) Equipment and supplies

(i) Mechanical ventilator and accessories, including inlet ventilator filters,

(ii) Humidifier bacteria filters,

(iii) Humidifier tubing (ventilator to humidifier),

(iv) Heated humidifiers,

(v) Permanent or reusable consumer circuits (disposable consumer circuits are billable only to NFs and ICFs-MR), and

(vi) Related accessory and supply items including tracheostomy flex tubes, and peep valves.

(b) Licensed respiratory care professional (LRCP) services

(i) Home evaluation (prior to discharge), and home equipment set-up.

(ii) In-home training of the caregiver(s) (e.g. ventilator operation, tracheostomy care, cleaning/sterilization techniques).

(iii) LRCP visits to include multiple visits in the first week of service and subsequent visits no less frequent than once per month for the first six months, then not less than every sixty days thereafter,

at a frequency determined by the LRCP, in consultation with the consumer's prescriber, to be appropriate to the consumer's condition.

(iv) Routine maintenance as specified by manufacturer or company protocol and in compliance with industry standards.

(v) Twenty-four-hour on call respiratory therapist services with two-hour response for emergency visits to include equipment servicing, repair or replacement.

(7) Reimbursement for a secondary or back-up mechanical ventilator for a medically necessary mechanical ventilator may be allowed when the consumer meets the following criteria and only when appropriate documentation is provided:

(a) Statement from the prescriber that the consumer cannot maintain spontaneous ventilation for four or more hours, or

(b) Statement from the prescriber that the consumer requires mechanical ventilation during regular mobility (e.g. attends school or outpatient therapy) as prescribed in their plan of care and needs a second ventilator attached to their wheelchair or mobility device, or

(c) Statement from the supervisor of the emergency team(s) responsible for serving the consumer's address that the emergency medical team estimated response time is more than two hours.

(8) When ventilators are provided to medicaid eligible residents of a NF or ICF-MR, reimbursement shall not be provided for more than one back-up ventilator per eight primary ventilators present in the same facility.

(C) Service and maintenance on consumer owned ventilators requires prior authorization and may be billed once per month. The prior authorization request and documentation of medical necessity must include a prescriber prescription for mechanical ventilatory support, consumer diagnosis and degree of impairment. Payment will be authorized only when the department determines that the ventilator is medically necessary.

(D) Sleep therapy

(1) Definitions

(a) "Apnea" is the cessation of airflow for at least ten seconds documented on a polysomnogram.

(b) "Hypopnea" is an abnormal respiratory event lasting at least ten seconds associated with at least a thirty per cent reduction in thoracoabdominal movement or airflow as compared to baseline, and with at least a four per cent decrease in oxygen saturation.

(c) The "apnea-hypopnea index" (AHI) is the average number of episodes of apneas and hypopneas per hour and must be based on a minimum of two hours of recording time without the use of a positive airway pressure device, reported by polysomnogram. The AHI may not be extrapolated or projected.

(2) With prior authorization, payment can be made for a continuous positive airway pressure (CPAP) home system. The CPAP system was designed for consumers with obstructive sleep apnea. Rental for a six-month period or purchase may be authorized only when a trial period has proven to be beneficial. Documentation will be necessary to substantiate ongoing rental or purchase.

(a) A request for prior authorization must contain all of the following information:

(i) A statement of medical necessity from the consumer's attending prescriber indicating:

(a) Diagnosis of obstructive sleep apnea (OSA).

(b) Surgery is a likely alternative.

(ii) Sleep study reports from both a diagnostic and a titration sleep study (these may be performed as two separate studies or consecutively as a split study) conforming to the following:

(a) The sleep studies must be performed in an attended, facility-based sleep study laboratory which is eligible for reimbursement by the department for the study, and not in the home or in a mobile facility. A DME supplier may not perform the study.

(b) During at least two hours of recorded sleep for the diagnostic study,

(i) The AHI is equal to or greater than fifteen events per hour, or

(ii) The AHI is from five to fourteen events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia or hypertension, ischemic heart disease, or history of stroke.

(c) The titration study of at least three hours duration shows efficacy of the CPAP system by decreasing the number of airway obstructions per hour and

(i) Shows a percentage increase in oxygen saturation of at least fifteen per cent (e.g., eighty per cent to ninety-two per cent), or

(ii) Shows an increase in oxygen saturation to eighty-nine per cent or greater, or

(iii) At the discretion of the department, shows other clinical improvement.

(d) If oxygen is needed in addition to CPAP, documentation of effectiveness must be shown by the sleep study.

(iii) A statement from the attending prescriber documenting any correctable causes of the consumer's sleep apnea which are present, (e.g., alcohol, bedtime sedatives/hypnotics, weight) and whether or not they are being treated or have been abolished. It must be specified if none exist.

(iv) A statement from the attending prescriber, indicating whether the consumer is symptomatic or asymptomatic and what impairment(s) secondary to sleep apnea is (are) present. If the consumer is symptomatic, improvement must be documented and significant to be considered for coverage.

(v) A statement from the attending prescriber certifying that the consumer is using the device regularly as prescribed.

(b) If any of the information in paragraph (D)(2)(a) of this rule is missing or provided by the supplier instead of the attending prescriber, prior authorization will be denied. A new request for authorization may be resubmitted with the required information.

(3) When determined medically appropriate based on a facility-based sleep study, a bi-level/alternating positive airway pressure (APAP) system may be prior authorized for obstructive sleep apnea when a fully completed "Certificate of Medical Necessity/Prescription IPPV or APAP in lieu of a Volume Ventilator" form JFS 01903, rev. 6/2007 (appendix to this rule) is provided that demonstrates:

(a) CPAP has been tried and is ineffective.

(b) APAP was titrated during the sleep study, or a one-week trial period using a respiratory support system bi-level/APAP was effective; and

(c) The attending prescriber certifies in writing the effectiveness of the system and that the consumer is using the device regularly as prescribed.

(E) If there is discontinuation of the use of any respiratory assist device at any time, the supplier is expected to ascertain this, and stop billing for the equipment and related accessories and supplies.

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Certification

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