



CIGNA MEDICAL COVERAGE POLICY

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Subject Ventilator Weaning

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Inhaled Nitric Oxide (INO)
Noninvasive Negative Pressure Ventilators

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Coverage Policy

Many health benefit plans administered by CIGNA contain definitions of medical necessity which permit the plan administrator to compare the cost-effectiveness of alternative services, settings or supplies when determining the least intensive setting.

CIGNA covers mechanical ventilation weaning as medically necessary in the least intensive, clinically appropriate setting. This may include a skilled nursing facility, subacute facility, regional weaning center, long-term acute hospital, step-down unit or respiratory care unit. CIGNA does not consider an intensive care unit level of care to be medically necessary for weaning from mechanical ventilation in the absence of other medical conditions requiring an intensive care unit level of care.

General Background

Mechanical ventilation is a method that uses a device to help patients breathe when they are unable to breathe sufficiently on their own. Mechanical ventilation is indicated as a measure to control ventilation in critically ill patients and as prophylaxis for impending collapse of other physiologic functions. It can be given by using positive or negative pressure. Physiologic indications include respiratory or mechanical insufficiency and ineffective gas exchange. Mechanical ventilation devices provide oxygen and carbon dioxide transport between the environment and the alveolar-pulmonary capillary interface. The desired effect of mechanical ventilation is to maintain appropriate levels of Po₂ and Pco₂ in arterial blood while unloading the ventilatory muscles. Endotracheal intubation is usually performed to facilitate mechanical ventilation (MacIntyre, 2010).

Common modes of mechanical ventilation include (Ferri, 2010):

- Intermittent mandatory ventilation (IMV): allows the patient to breathe spontaneously, and the ventilator delivers a number of machine breaths at a preset rate and volume.
- Assist control ventilation (ACV): allows the patient to breathe at their own rate, and the ventilator senses the inspiratory effort and delivers a preset tidal volume with each patient effort.
- Controlled mechanical ventilation (CMV): does not allow the patient to breathe spontaneously; therefore, the ventilator assumes the respiratory work by delivering a preset volume of gas at a preset rate.
- Synchronized intermittent mandatory ventilation (SIMV): delivers synchronized ventilator breaths with the patient's respiratory efforts (a combination of ACV and IMV).
- Pressure control ventilation (PCV): the inspiratory pressure, respiratory rate, and inspiratory time are determined by ventilator settings.
- Pressure support ventilation (PSV): the patient's inspiratory effort is supported by a set level of inspiratory pressure.
- Inverse ratio ventilation (IRV): the inspiratory to expiratory ratio is prolonged to 1:1 or greater.
- Noninvasive positive pressure ventilation (NPPV): ventilatory support is delivered by using a mechanical ventilator connected to a mouthpiece or mask instead of an endotracheal tube. NPPV is used in patients with chronic respiratory failure caused by neuromuscular disease or thoracic deformities and in patients with idiopathic hypoventilation. It may eliminate the need for tracheostomies.

Ventilator Weaning

Mechanical ventilation is the most common treatment plan in intensive care units (ICU) and is used in approximately 25% of hospital admissions. Prolonged ICU stays and mechanical ventilation may predispose patients to a greater risk of nosocomial infection, pneumonia and death (Dasta, et al., 2005; Cox, et al., 2004). Some of the potential major complications associated with mechanical ventilation include (Ferri, 2010):

- pulmonary barotraumas (e.g., pneumothorax, subcutaneous emphysema, pneumomediastinum), which are generally secondary to high levels of positive end-expiratory pressure (PEEP), excessive tidal volumes, high peak airway pressures, and coexistence of lung disease
- pulmonary thromboemboli, which can be prevented by leg care, antiembolic stockings, and low dose heparin
- gastrointestinal bleeding, which can be prevented with prophylactic treatment
- accumulation of large amount of secretions, which requires frequent respiratory toilet
- arrhythmias, nosocomial infections, laryngotracheal injury, malnutrition, hypophosphatemia, oxygen toxicity, psychosis

Ventilator weaning is used to describe the process of gradually removing the patient from the ventilator and restoring spontaneous breathing after a period of mechanical ventilation. This process has also been referred to as discontinuation or liberation from mechanical ventilation. Four modes of discontinuing patients from mechanical ventilation are in general use: trials of spontaneous breathing with or without the addition of continuous positive airway pressure, SIMV, PSV, and NPPV. Although most physicians generally use one of the first three modes alone, some have used them in combination. As a discontinuation mode, the role of NPPV is presently evolving. It is being used as an early extubation and discontinuation technique in intubated patients, as a bridge to avoid reintubation, and to serve a prophylactic role in postoperative patients who are at high risk of respiratory complications. Studies have not consistently shown spontaneous breathing, SIMV, or PSV modes to be superior to the others. A variety of unconventional techniques have been tried for discontinuing mechanical ventilation, including inspiratory resistive training %, mandatory minute-volume ventilation, computerized or automated weaning, and biofeedback. Their roles remain to be defined by controlled prospective studies (Burns, et al., 2009; Byrd, et al., 2010; Irwin and Hubmary, 2008; Scheinhorn, et al., 2001).

Physicians and the ICU respiratory care specialists help patients to wean from ventilatory support when it is determined to be medically appropriate. The team decision to wean or discontinue mechanical ventilation is based on the patient's current illness and past medical history, complete medical assessment, tests of daytime and nighttime breathing efficiency, and ability to breathe without assistance. Long-term mechanical ventilation is for patients whose medical conditions become unstable without mechanical ventilation. While the majority of patients with some conditions can be weaned from mechanical ventilation after a few days to a week in the ICU,

patients with other conditions cannot or should not be taken off the ventilator. In the minority of patients, probably 10% to 20% overall, mechanical ventilation is more difficult to discontinue. This group is largely composed of patients receiving mechanical ventilation for longer than 21 days. Patients with stable chronic medical conditions are more likely to require long-term mechanical ventilation, (e.g., patients with neuromuscular disorders or chest wall deformities). Conditions such as stroke and spinal cord injury damage the nerves that control breathing and make spontaneous breathing impossible for an extended period or for life. Chronic illness that requires recurrent ICU hospitalization may require frequent repeated treatments with mechanical ventilation and repeated attempts to wean from mechanical ventilation. Aggressive removal of ventilatory support is balanced against the risks of premature withdrawal of ventilatory support, including difficulty in re-establishing the artificial airway, compromised gas exchange, and ventilatory muscle fatigue (MacIntyre, 2010; Irwin and Hubmayer, 2008; Moonsie and Davidson, 2005; MacIntyre, et al., 2001; ACCP, 1999).

Data from observational studies has proven that 34–60% of patients who are discharged from the ICU, as being ventilator dependent, can be successfully weaned when they are transferred to units dedicated to ventilator weaning (Scheinhorn, et al., 2001). Various types of facilities may be considered for patients who require ongoing mechanical ventilation. Those patients who leave the ICU but require hospitalization can receive care in a specialized respiratory care unit of the hospital or a general medical/surgical unit in the hospital. For patients with special medical needs who can be discharged from the hospital, care can be given in a subacute care unit of the hospital, a long-term hospital or a rehabilitation hospital. If the patient is capable of independent living, they can be discharged to a skilled nursing facility or home (MacIntyre, et al., 2005a; MacIntyre, et al., 2001; ACCP, 1999).

There is a growing interest in the use of NPPV as a technique to discontinue invasive ventilatory support. NPPV has been primarily used as a method to avoid intubation. The increasing awareness of tube related complications has contributed to the emergence of noninvasive mechanical ventilation through a face mask, nasal mask or mouth seal as a treatment option for some patients with respiratory failure. Although NPPV was being used as a means of discontinuing invasive mechanical ventilation earlier with promising results (e.g., reducing duration of mechanical ventilation, ICU stay, mortality, and nosocomial pneumonia), its role relative to other modes needs to be determined in randomized controlled clinical trials (Irwin and Hubmayr, 2008; Hubmayr and Irwin, 2008; MacIntyre, et al., 2001).

Eskandar et al. (2007) reviewed the causes of weaning failure and an approach to liberating patients from mechanical ventilation. The authors noted that to optimize the chance of successful weaning the following key elements should be corrected:

- determine cause of ventilatory dependence
- rectify correctable problems
 - pulmonary gas exchange
 - fluid balance
 - mental status
 - acid-base status
 - electrolyte disturbance
- consider psychological factors
- optimize posture and provide ambulation

Literature Review

Mechanical Ventilation Weaning Protocols/Parameters: The most favorable discontinuation outcomes are most likely achieved by protocol- directed ventilator management teams that adhere to their protocols. These programs can improve the quality of care of patients on mechanical ventilation and decrease their length of ICU stay especially when the ventilator management program has built into it the active search for, and correction of, medical barriers that allow for the persistence of inspiratory respiratory muscle fatigue or weakness (Irwin and Hubmayr, 2008).

In a Cochrane systematic review and meta-analysis, Blackwood et al. (2011) investigated the effects of weaning protocols on the total duration of mechanical ventilation, mortality, adverse events, quality of life, weaning duration, and length of stay in the intensive care unit and hospital. They included randomized and quasi-randomized controlled trials of weaning from mechanical ventilation with and without protocols in critically ill adults. Eleven trials that included 1971 patients met the inclusion criteria. The authors reported that there is evidence of a reduction in the duration of mechanical ventilation, weaning, and stay in the intensive care unit when standardized weaning protocols are used, but there is significant heterogeneity among studies and an insufficient number of studies to investigate the source of this heterogeneity. Some studies suggest that organizational context could influence outcomes, but this could not be evaluated as it was outside the scope of the review.

Tanios et al. (2006) conducted a multicenter, randomized controlled trial to determine the effect of including a weaning predictor (i.e., frequency-tidal volume ratio) in a weaning protocol. Three hundred and four patients were randomized to two groups. All adult patients were eligible once mechanically ventilated for ≥ 24 hours. One group (n=151) had the frequency-tidal volume ratio measured, but it was not used in the decision to wean. The other group (n=153) had the frequency-tidal volume ratio measured and was used with a threshold of 105 breaths/min/L. The mean duration for weaning time was shorter in the group where the weaning predictor was not used. There was no difference between the two groups with regard to the extubation failure, in hospital mortality rate, tracheostomy, or unexplained extubation. The authors' state one possible role for weaning predictors is in the evaluation of patients intolerant of SBT with a goal of identifying reversible causes of weaning failure.

In a controlled trial, Krishnan et al. (2004) reported that adults requiring mechanical ventilation for > 24 hours showed no difference in duration of mechanical ventilation, ICU stay, need for reinstitution of mechanical ventilation, or hospital mortality in the group treated with a nursing/respiratory therapist-driven protocol compared with those in whom weaning was managed off protocol by the supervising physician. This study was conducted in a closed, intensivist-run ICU with high levels of staffing with a routine management template that was used daily to encourage the staff to address weaning issues every day.

Vitacca et al. (2001) conducted a multicenter, randomized controlled study in three long-term weaning units to evaluate which protocol, PSV or SBT, is more effective in weaning patients with chronic obstructive pulmonary disease (COPD) requiring mechanical ventilation for more than 15 days. Fifty-two patients were randomly assigned to PSV or SBT. The authors report no significant difference in weaning success rate, mortality rate, duration of ventilatory assistance, long-term weaning unit, or hospital stay in the PSV and SBT groups. The authors reported that the application of a well-defined protocol, independent of the mode used, may result in better patient outcomes than uncontrolled clinical practice.

In 2000, the Agency for Healthcare Research and Quality (AHRQ) published an evidence-based report on issues related to weaning patients from mechanical ventilation (Cook, et al., 2000). The key questions in the investigation included: when should weaning be initiated; what criteria should be used to initiate the weaning process; what are the most effective methods of weaning from mechanical ventilation; what are the optimal roles of nonphysician health care professionals in facilitating safe and expeditious weaning; and what is the value of clinical practice algorithms and computers in expediting weaning. The investigators included all studies of adult and pediatric patients who were mechanically ventilated and had either endotracheal tube or tracheostomy tube. They excluded studies of highly specific populations and studies in neonates. The settings included ICUs, intermediate care units, step down units, and post-anesthetic recovery rooms. Home ventilation for children and adults and chronic ventilator settings were excluded. The investigators included any ventilation or weaning strategy. Also included were predictors of weaning and/or extubation success and predictors of duration of mechanical ventilation in cardiac surgery and COPD patients. They included all clinical outcomes and excluded studies that only reported physiologic outcomes. The authors reported the following findings:

- Research suggests that the best answer to when to start weaning is to develop a protocol implemented by nurses and respiratory therapists that begins testing for the opportunity to reduce support soon after intubation and reduces support at every opportunity.
- Differences in clinicians' intuitive threshold for reduction in discontinuation of ventilatory support have a greater impact on failure of SBT or on reintubation than do modes of weaning.
- For step-wise reductions in mechanical support, pressure support mode or daily T-piece trials may be superior to IMV

- For trials of unassisted breathing, low levels of pressure support may be beneficial.
- There may be substantial benefits to early extubation and institution of NPPV for patients who are alert, cooperative, and ready to breathe without an artificial airway.
- Following cardiac surgery, early extubation is achieved with a variety of anesthetic interventions and ICU protocols; however, the corresponding reduction in ICU stay is generally small, and the impact on complications, though rare, remains unclear.
- While steroids can reduce postextubation stridor in children, their impact on reintubation in children and adults remains unclear.
- Predictors of weaning and extubation success have no predictive power. In general, weaning predictors were probably found to perform poorly because physicians had already considered the results when they selected their patients for study.
- The role of computerized weaning protocols has not been established.

Mechanical Ventilation Weaning in Acute Care Hospitals versus Alternative Settings: In a multicenter observational study, Scheinhorn et al. (2007) characterized the population of ventilator-dependent patients admitted to long-term care hospitals (LTCHs) with weaning programs, and reported treatments, complications, weaning outcome, discharge disposition, and survival in these patients. The study included twenty-three National Association of Long Term Hospital member LTCHs. Eight of the 19 facilities offered multiple levels of care (i.e., long-term acute, acute rehabilitation, subacute, and skilled nursing), although all conducted weaning activities at the long-term acute care level of care. A total of 1419 patients were enrolled in the study. The patients included consecutive ventilator-dependent patients admitted over a one-year period with a median age of 71.8 years (range, 18–97.7 years). The following patients were excluded from the study: patients admitted specifically for end-of-life care or terminal weaning, or for home ventilator training; patients receiving long-term ventilation admitted for treatment of an intercurrent medical problem; not a weaning candidate, as documented by the physician on admission; prior inclusion in the study; and age < 18 years. The pre-morbid location and functional status for the majority of the patients was at home where they were largely independent and able to perform daily activities and self-care before their ICU stay. Nearly 60% of the patients were smokers with a heavy smoking history. The patients included consecutive ventilator-dependent patients admitted over a one-year period, with a median age of 71.8 years (range, 18–97.7 years). Most of the patients had prolonged and aggressive ICU interventions prior to admission to the LTCH. The patients averaged 6.9 procedures and treatments during the LTCH hospitalization; median length of stay was 40 days (range, 1–365 days). Seven of the 10 most frequent complications treated at the LTCH were infections; congestive heart failure and diabetes mellitus were the most common comorbidities requiring treatment. Outcomes of weaning attempts, scored at LTCH discharge, were 54.1% weaned, 20.9% ventilator-dependent, and 25.0% deceased. Median time to wean (n=766) was 15 days (range, 7–30 days). Discharge disposition included 28.8% to home, 49.2% to rehabilitation and extended care facilities, and 19.5% to short-stay acute hospitals. Nearly one third of patients were known to be alive 12 months after admission to the LTCH. The authors reported that patients admitted to LTCHs for weaning attempts were elderly, with acute-on-chronic diseases, and continued to require considerable medical interventions and treatments. Furthermore, more than half of ventilator dependent survivors of catastrophic illness transferred from the ICU were successfully weaned from prolonged mechanical ventilation in the setting of an LTCH.

In a retrospective chart review, Seneff et al. (2000) compared the six-month mortality rate of chronically ventilated patients treated either exclusively in a traditional acute care hospital or transferred during hospitalization to a long-term acute care facility. The authors reported that patients undergoing prolonged ventilation have high hospital and six-month mortality rates, and six-month outcomes are not significantly different for those transferred to long-term acute care facilities. Acute care hospitals can reduce the amount of uncompensated care by earlier transfer of appropriate patients to a long-term acute care facility.

In a review of post-ICU weaning from prolonged mechanical ventilation, it was reported that the data from observational studies has proven that 34–60% of patients who are discharged from the ICU as being ventilator-dependent can be successfully weaned when they are transferred to units dedicated to ventilator weaning. Success is likely to fall within a three-month time frame (Scheinhorn, et al., 2001).

Mechanical Ventilation Weaning in Pediatrics: In a multicenter, randomized controlled trial, Randolph et al. (2002) compared a weaning protocol with standard of care (no defined protocol) in infants and children with acute illnesses requiring mechanical ventilation. The authors found that, in contrast to adult patients, the

majority of children were weaned within two days, and the weaning protocol did not influence the duration of mechanical ventilation.

In a review of pediatric ventilation, Turner and Arnold (2007) summarize that mechanical ventilation with pressure limitation and low tidal volumes has become the prevailing practice in pediatric ICUs. Further research is needed regarding the use of high frequency oscillatory ventilation, airway pressure release ventilation, and surfactant to assist pediatric intensivists in the application of these therapies. The authors state that weaning protocols do not appear to be as useful in pediatrics as they are in adults. In the textbook, Miller's Anesthesia, the author reports that weaning from mechanical ventilation requires close clinical observation, frequent assessment of blood gases, and good clinical judgment. The criteria for weaning are ill-defined. It is recommended that weaning from respiratory support should begin when the child has a stable cardiovascular system and is awake and alert. Any major metabolic abnormalities should be resolved. The chest wall and diaphragm must be intact, and the child should be able to generate at least 20 cm H₂O pressure at the airway and move at least 10 m/kg of air with maximal effort. Ventilator rates should be weaned until the arterial blood gases are stable and all residual effects of neuromuscular blocking drugs have disappeared. Weaning can continue as long as the arterial blood gases are in an acceptable range and the child's clinical condition tolerates weaning (Zwass and Gregory, 2009).

Graham and Kirby (2006) reviewed ventilator management protocols in pediatrics. The authors state that, although specific protocols cannot be routinely recommended, a multidisciplinary team approach that incorporates the available literature to determine the best practice is a useful model. Generally, the pediatric population has a shorter weaning duration, which is a possible reason for not adopting routine ventilator management protocols. The authors state that protocols to titrate sedation and for daily assessment of SBTs, are recommended in the pediatric population.

Mechanical Ventilation Weaning after Cardiac Surgery: Nozawa et al. (2005) conducted a prospective, quantitative, comparative study to identify factors involved in the weaning of patients who require long-term (i.e., > 10 days) of mechanical ventilation after cardiac surgery. The study included 52 patients who required a tracheotomy for the management of long-term mechanical ventilation after cardiac surgery with cardiopulmonary bypass. Pre-, intra- and postoperative data from patients who were not successfully weaned after reintubation, and who underwent an elective tracheotomy were compared. Parameters of respiratory mechanics such as respiratory complications, oxygenation, and cardiac, renal, and neurological function were evaluated. Weaning success was defined as the ability of a patient to tolerate 48 hours without pressure or flow support from a mechanical ventilator. A patient was considered to have failed weaning if they died or remained under ventilation for more than eight weeks. Of the 52 patients studied, 25 were successfully weaned, 21 died, and six remained ventilated for more than eight weeks. Parameters of respiratory mechanics and oxygenation (e.g., static airway compliance and airway resistance) did not influence the success or failure of weaning. The authors reported that cardiac dysfunction, the need for dialysis, and pneumonia are determinants for weaning failure in patients undergoing long-term mechanical ventilation after cardiac surgery.

Hawkes et al. (2005) conducted a Cochrane review, with the authors reporting that removal of the endotracheal tube that allows mechanical breathing support after cardiac surgery in adults may safely reduce the stay in the ICU. Historically, adult cardiac surgical patients needed mechanical breathing support overnight after surgery. Results from six controlled trials showed that earlier removal of the tube that ensures open airways and allows mechanical breathing support, within eight hours of skin closure after surgery, reduces ICU length of stay, and possibly hospital length of stay, with no evidence of an increase in the risk of harmful effects or death.

Noninvasive Positive Pressure Ventilation (NPPV) Weaning: Burns et al. (2006) conducted a meta-analysis comparing early extubation with immediate application of NPPV and invasive positive pressure ventilation (IPPV) on mortality, ventilator-associated pneumonia, and the total duration of mechanical ventilation among invasively ventilated adults with respiratory failure. The authors reported finding five studies enrolling 171 patients which indicated that compared to IPPV, noninvasive weaning decreased mortality, ventilator-associated pneumonia, and the total duration of mechanical ventilation. The authors reported that NPPV weaning is a promising approach to achieve liberation in selected patients recovering from acute respiratory failure, but a large randomized clinical trial is needed to confirm the clinical effectiveness of NPPV weaning and to identify the patient population who will benefit most from it.

A Cochrane Review (Ram, et al., 2004) concluded NPPV should be considered early in the course of respiratory failure and before severe acidosis ensues, as a means of reducing the likelihood of endotracheal intubation, treatment failure and mortality. Data from good quality randomized controlled trials show benefit of NPPV as first-line intervention as an adjunct therapy to usual medical care in all suitable patients for the management of respiratory failure secondary to an acute exacerbation of COPD. Fourteen studies were included in the review. NPPV resulted in decreased mortality, decreased need for intubation, reduction in treatment failure, rapid improvement within the first hour in pH, P_{aCO_2} and respiratory rate. In addition, complications associated with treatment and length of hospital stay was reduced in the NPPV group.

Ram et al. (2005) conducted a Cochrane review to determine the efficacy of NPPV in adults with severe acute asthma in comparison to usual medical care with respect to mortality, tracheal intubation, changes in blood gases and hospital length of stay. The authors reported the application of NPPV in patients suffering from status asthmaticus, despite promising preliminary results, still remains controversial. Large, prospective, randomized controlled trials are needed to determine the role of NPPV in status asthmaticus.

Professional Societies/Organizations

The National Association for Medical Direction of Respiratory Care (NAMDR) published a consensus statement on the management of patients requiring prolonged mechanical ventilation (MacIntyre, et al., 2005a). The authors state that there is no body of evidence to support a set time limit for considering mechanical ventilation support weaning to be futile, nor when weaning attempts should cease. The authors cite the American College of Chest Physicians (ACCP), the Society of Critical Care Medicine, and the American Association for Respiratory Care evidence-based guidelines for weaning and discontinuing ventilatory support, which state that three months is the period of time when most patients who could be weaned had been weaned from mechanical ventilation. NAMDR's recommendations include the following:

- Prolonged mechanical ventilation should be defined as at least 21 consecutive days of mechanical ventilation for six or more hours per day.
- Large prospective studies, especially those in the acute intensive care setting, should be conducted to better understand how to properly define prolonged mechanical ventilation.
- In patients with slowly resolving respiratory insufficiency, successful weaning should be defined as complete liberation from mechanical ventilation for seven consecutive days.
- Identification of factors associated with ventilator dependence (i.e., mechanical, iatrogenic, psychological, and process of care factors; systemic diseases; and long-term hospitalization complications) should focus on those factors that are potentially reversible.
- When continuing the weaning process outside the ICU, the environment should be selected based on the patient's needs and evaluated for effectiveness and safety.
- Transfer from ICU should be considered as soon as tracheostomy is considered.
- Weaning strategies in the post-ICU setting should include nonphysician implemented protocols and daily SBT that progressively increases in duration as the level of ventilatory support decreases.
- Weaning efforts should continue until the medical team and the patient or patient's families agree they should cease; however, the group should have an open discussion if weaning is deemed futile.
- Palliative care services can benefit patients and their families when weaning efforts continue in the post-ICU setting and should be initiated if resources are available.
- Further research is needed to evaluate long-term outcomes in respect to patient selection, care processes, and care settings.

In 1999, the Society of Critical Care Medicine developed guidelines for ICU admission, discharge, and triage. No updates have been made to the 1999 guidelines. The task force recommends that the status of patients admitted to an ICU should be revised continuously to identify patients who may no longer require ICU level of care. Discharge to a lower level of care is appropriate when the patient's physiologic status has stabilized and the need for ICU monitoring and care is no longer necessary, and when the physiological status has deteriorated and active interventions are no longer planned.

The American Academy of Pediatrics and the Society of Critical Care Medicine developed guidelines (1999) for admission and discharge policies for the pediatric ICU. The guidelines recommend that chronically mechanically ventilated patients whose critical illness has been reversed or resolved and who are otherwise stable may be

discharged to a designated patient care unit that routinely manages chronically ventilated patients, when applicable, or to home. No updates have been made to the 1999 guidelines.

Evidence-Based Guidelines for Weaning and Discontinuing Ventilatory Support: The ACCP, the Society of Critical Care Medicine, and the American Association for Respiratory Care formed a task force and published evidence-based recommendations on ventilator management of patients who require ventilation for greater than 24 hours (MacIntyre, et al., 2001). The task force utilized the results from the AHQR evidence-based review of the literature (Cook, et al., 2000), as well as their own literature review to develop their evidence-based guidelines. The task force addressed these issues in their literature review: pathophysiology of ventilator dependence, the criteria for identifying patients who are capable of ventilator discontinuance, ventilator management strategies to maximize discontinuance potential, the role of tracheostomy, and the role of long-term facilities. The criteria that clinicians utilize to decide whether a patient has recovered enough to tolerate discontinuance of ventilator support have not been clearly defined nor prospectively evaluated in randomized controlled trials. Subjective and objective assessment criteria are used as markers of recovery.

The decision to use the following task force criteria recommendations for discontinuation of mechanical ventilation must be individualized. Some patients may not meet all the criteria but are ready for discontinuance of mechanical ventilation. The task force recommends patients should have a formal assessment of discontinuation potential if the following criteria are met:

- search for all causes that are contributing to ventilator dependence for patients requiring mechanical ventilation > 24 hours
- patients receiving mechanical ventilation for respiratory failure should be assessed for discontinuance potential if all of the following criteria are met:
 - evidence of reversal of underlying cause of respiratory failure
 - adequate oxygenation (e.g., $P_{aO_2}/F_{iO_2} > 150\text{--}200$; requiring $PEEP \leq 5\text{--}8$ cm H₂O; $F_{iO_2} \leq 0.4\text{--}0.5$) and pH (e.g., ≥ 7.25)
 - hemodynamic stability as defined by the absence of active myocardial ischemia and clinically important hypotension) (i.e., a condition requiring no vasopressor therapy or therapy with low dose vasopressor therapy such as dopamine or dobutamine < 5 μ /kg/min)
 - capability to initiate an inspiratory effort

The criteria used in weaning/discontinuance studies to determine whether patients receiving high levels of ventilatory support can be considered for discontinuance:

- adequate oxygenation (e.g., $P_{O_2} \geq 60$ mm Hg on $F_{iO_2} \leq 0.4$, $PEEP \leq 5\text{--}10$ cm H₂O, $P_{O_2}/F_{iO_2} \geq 150\text{--}300$)
- stable cardiovascular system (e.g., heart rate ≤ 140 , stable blood pressure, no or minimal vasopressors)
- afebrile
- no significant respiratory acidosis
- adequate Hgb (e.g., $Hgb \geq 8\text{--}10$ g/dL)
- adequate mentation (e.g., arousable, Glasgow coma scale ≥ 13 and no continuous sedative infusions)
- stable metabolic status (e.g., acceptable electrolytes)
- subjective clinical assessments including: resolution of acute disease phase, physician believes discontinuance possible, adequate cough

The task force recommends that formal discontinuance assessments for patients receiving mechanical ventilation should be done during spontaneous breathing rather than when the patient is receiving substantial ventilatory support. A brief period of spontaneous breathing can be used to assess the capability of continuing onto a formal SBT. The SBT is the most direct way to assess a patient's performance without ventilatory support. Multiple studies have found that patients who tolerate SBTs, that are 30–120 minutes in length, were found to have successful discontinuations at least 77% of the time. The criteria used to assess the patient's tolerance during SBTs are the respiratory pattern, adequacy of gas exchange, hemodynamic stability, and subjective comfort.

Several large clinical trials identified objective and subjective criteria to define tolerance or success of an SBT. The criteria include:

- objective measurements indicating success of an SBT:
 - gas exchange acceptability (e.g., $S_{\text{po}_2} \geq 85\text{--}90\%$, $P_{\text{o}_2} \geq 50\text{--}60$ mm Hg, $\text{pH} \geq 7.32$, increase in $P_{\text{aco}_2} \leq 10$ mm Hg)
 - hemodynamic stability (e.g., heart rate $< 120\text{--}140$ beats/min; heart rate not changed $> 20\%$; systolic BP $< 180\text{--}200$ and > 90 mm Hg; BP not changed $> 20\%$, no pressors required)
 - stable ventilatory pattern (e.g., respiratory rate $\leq 30\text{--}35$ breaths/min, respiratory rate not changed $> 50\%$)

- subjective clinical measurements indicating intolerance/failure of an SBT:
 - change in mental status (e.g., somnolence, coma, agitation, anxiety)
 - onset or worsening of discomfort
 - diaphoresis
 - signs of increased work of breathing (use of accessory respiratory muscles, and thoracoabdominal paradox)

There is a safety concern with SBT. Prolongation of a failing SBT could cause muscle fatigue, discomfort, hemodynamic instability, or worsened gas exchange. There is no data showing that SBTs contribute to any adverse outcomes if promptly terminated when SBT failure is identified. If ventilatory muscle overload is going to occur, it will often occur early in the SBT. Therefore, the initial few minutes of an SBT need to be closely monitored. The outcome of the SBT is not dependant on whether the SBT is performed with a low level of continuous positive airway pressure, low levels of pressure support, or simply as T-piece breathing.

The task force recommends that the removal of the artificial airway from a patient who has successfully been discontinued from ventilatory support should be based on assessments of airway patence and the ability of the patient to protect the airway. Airway assessments generally include assessing the quality of the cough with airway suctioning, the absence of excessive secretions, or the frequency of airway suctioning (e.g., every two hours or more).

The task force recommends that the cause for the SBT failure needs to be determined. Once reversible causes for the SBT failure are corrected, and the patient meets the criteria for weaning/discontinuance, additional SBTs should be performed within 24 hours. A failed SBT is often due to persistent respiratory system abnormalities. Issues that may contribute to SBT failure are: adequacy of pain control, appropriate sedation, fluid status, control of myocardial ischemia, bronchodilator needs, and the presence of other disease processes.

The task force recommends that patients receiving mechanical ventilation for respiratory failure who fail an SBT should receive a stable, nonfatiguing, comfortable form of ventilatory support. There are a number of modes of partial ventilatory support to support patients who have failed an SBT, including the following:

- SIMV (synchronized intermittent mandatory ventilation) patient work adjusted by number of supplied machine breaths
- PSV
- SIMV and PSV patient work adjusted by combining adjustments of SIMV and PSV
- VS (volume support) patient work adjusted by PSV with a guaranteed minimum V_T (tidal volume) (PSV level adjusts automatically according to clinician V_T setting)
- VAPS(PA) [volume-assisted pressure support (pressure augmentation) patient work adjusted by PSV with guaranteed minimum V_T (additional flow is supplied at end inspiration if necessary to provide clinician V_T setting)]
- MMV (mandatory minute ventilation) patient work adjusted by SIMV with a guaranteed V_E (minute ventilation) (machine breath rate automatically adjusts according to clinician V_E setting)
- APRV (airway pressure-release ventilation) patient work adjusted by pressure difference between inflation and release (i.e., the less the pressure difference, the more spontaneous breaths are required)

None of the studies evaluated by the task force offers evidence that gradual ventilatory support is superior to stable ventilatory support between SBTs. The clinical focus for patients who failed an SBT should be on maintaining muscle uploading, optimizing sedation and comfort needs, and avoiding complications rather than aggressive ventilatory support reduction. Assisted modes of ventilatory support are generally preferable to machine controlled settings, since assisted modes may help to avoid muscle disuse atrophy and reduce sedation needs.

The main issues for ventilator dependence in postsurgical patients are depressed respiratory drive and pain. Pain management, optimal sedation, and ventilator strategies offer opportunities to shorten the duration of mechanical ventilation. Randomized controlled trials have identified that in postcardiac surgery patients, a lower anesthetic/sedation regimen permitted earlier extubation. The mean effect was seven hours. Similar effects were seen in other postsurgical populations. Ventilator modes that guarantee a breath rate and minute ventilation (assist control modes, IMV, and MMV) are necessary in patients with unreliable respiratory drives.

Randomized controlled trials have indicated that outcomes for mechanically ventilated patients who were managed by nonphysician health care professionals (HCPs) (e.g., respiratory therapists and nurses) using HCP-driven protocols were improved over control patients with standard care. Patients were removed from the ventilator earlier with fewer complications related to the ventilator. The use of a standardized approach to management rather than a specific modality of ventilator support improve outcomes. The choice of a specific protocol is best left to each institution. Patient populations will dictate different protocols.

There are general concepts that may make a protocol successful. Protocols should complement and not replace clinical judgment. HCP-driven protocols should not be static tools, but dynamic tools that accommodate new clinical data and practices. Institutions must be willing to commit the necessary resources to develop and implement HCP protocols.

Tracheotomy is usually performed in patients who fail to wean. The problems associated with tracheotomy include perioperative complications related to surgery and long-term airway injury. Based on studies, the timing of the tracheotomy can be from 2–21 days and is done sooner if prolonged ventilation is anticipated as with neuromuscular diseases. Insufficient evidence exists to support that the timing of tracheotomy alters the duration of mechanical ventilation in critically ill patients. The task force recommends that patients who benefit from early tracheotomy include: those who require high levels of sedation to tolerate translaryngeal tubes, those with marginal respiratory mechanics in whom a tracheotomy might lower the risk of muscle overload, those that might gain psychological benefits (e.g., ability to eat orally and ability to speak), and those in whom mobility may assist physical therapy.

Studies have concluded that up to 20% of medical ICU patients met the 21-day United States Health Care Financing (HCFA) definition of prolonged mechanical ventilation. This can be attributed to the advancement in technologies and treatments. There is evidence that many patients who were previously deemed unweanable may achieve ventilator independence in long-term facilities. Studies have shown that patients who are on prolonged ventilator dependence were discontinued from the ventilator up to three months, and occasionally six months, after intubation. The weight of evidence is that several months of attempts at ventilator discontinuance are required before most patients ventilated for acute respiratory failure can be declared permanently ventilator dependent. The task force recommends a patient requiring prolonged mechanical ventilation for respiratory failure should not be considered permanently ventilator dependent until three months of weaning attempts have failed unless the patient has clearly irreversible disease (e.g., high spinal cord injury or advanced amyotrophic lateral sclerosis).

The task force recommends that when the patient has failed ventilator discontinuance, and is medically stable for transfer from the ICU, they should be transitioned to a facility that has demonstrated success and safety in accomplishing ventilator discontinuance. Numerous observational studies that report outcomes in > 100 patients in which prolonged mechanical ventilation is defined as > 21 days of ventilator dependency have reported the efficacy and safety of ventilator discontinuance for those patients transferred to units dedicated to that activity. Fifty-two percent of the patients were successfully discontinued from mechanical ventilation.

The type of facilities that were involved in the studies included:

- Licensed long-term acute care hospitals which are required by HCFA to maintain a length of stay > 25 days. They are often freestanding hospitals which may have their own ICUs. They can be called regional weaning centers.
- Step-down units or noninvasive respiratory care units which have no specific length of stay requirements. These units can reside within a host hospital and primarily serve that hospital.

The available studies on discontinuing prolonged mechanical ventilation show similarities despite differences in patient populations and physical facilities. Ventilator support is gradually reduced using common modes of partial support: SIMV and PSV. At the point of approximately half support, the patient is switched to the SBT, with SBTs of increasing duration. Psychological support, patience, and avoidance of muscle overload are important with these patients.

Summary

Observational studies have demonstrated success in weaning patients from prolonged mechanical ventilation following ICU treatment for acute illnesses that are usually superimposed on chronic diseases. Depending on the availability within the community, noninvasive respiratory care units or step-down units usually within a hospital or long-term care facilities or regional weaning centers can successfully accomplish ventilator weaning/discontinuance. Health care organizations have generated standards of practice or clinical practice guidelines to care for the ventilator-dependent patient.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

Revenue Codes [†]	Description
0121	Med/Surg/Gyn Room & Board-2 BD
0131	Med/Surg/Gyn Room & Board-3-4 BD
0151	Med/Surg/Gyn Room & Board-Ward
0193	Sub-acute care, level 3
0194	Sub-acute care, level 4
0206	Intermediate intensive care unit
0209	Other intensive care unit

DRG	Description
208	Respiratory system diagnosis with ventilator support<96 hours
951	Other factors influencing health status

ICD-9-CM Diagnosis Codes	Description
96.70	Continuous invasive mechanical ventilation of unspecified duration
96.71	Continuous invasive mechanical ventilation for less than 96 consecutive hours

ICD-9-CM Diagnosis Codes	Description
V46.13	Encounter for weaning from respirator [ventilator]

Not medically necessary/Not covered when used to report ventilator weaning:

Revenue Codes [†]	Description
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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	3/15/2008	0432	Ventilator Weaning

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