Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First	**Submission Date**: 4/1/2024
Policy Number: ccp.1445	**Effective Date:** 4/2020 **Revision Date:** March 1, 2024
Policy Name: Home invasive positive pressure ventilation	

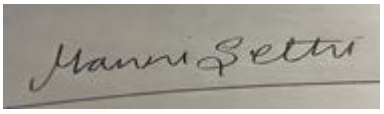
Type of Submission – Check all that apply:

- [ ] **New Policy**
- [x] **Revised Policy***
- [ ] **Annual Review – No Revisions**
- [ ] **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Family of Health Plans

Home invasive positive pressure ventilation

Clinical Policy ID: CCP.1445

Recent review date: 3/2024

Next review date: 7/2025

Policy contains: BiPAP; continuous positive airway pressure; CPAP; invasive ventilation; home care; life support; noninvasive ventilation; pediatrics.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Home positive pressure ventilation with an invasive interface (e.g., tracheostomy) is clinically proven and, therefore, medically necessary life support when the following criteria are met (American Association for Respiratory Care, 2007, Make, 1998):

- The ventilator is approved by the U.S. Food and Drug Administration for use in the home and with an invasive interface.
- The member meets discharge criteria for medical, respiratory, and psychological stability (American Thoracic Society, 2005; Sterni, 2016).
- A comprehensive discharge plan is in place to ensure a safe physical environment and adequate resources for care in the home (American Thoracic Society, 2005; Sterni, 2016).
- Any of the following indications:
    - Member meets criteria for noninvasive ventilation but has uncontrollable airway secretions or impaired swallowing leading to chronic aspiration and repeated pneumonias (See clinical policy CCP.1452).
    - Member has persistent symptomatic respiratory insufficiency and failure of or inability to tolerate noninvasive ventilation (See clinical policy CCP.1452).
    - Member has severely weakened or paralyzed respiratory muscles requiring at least 20 hours of ventilator support, and member or provider prefers invasive ventilation.

Home positive pressure ventilation with a noninvasive interface is medically necessary for pediatric members prescribed continuous or bilevel positive airway pressure when both criteria are met (American Association for Respiratory Care, 2004):

- The prescription cannot be delivered using a traditional respiratory-assist device.

- The positive pressure ventilator has noninvasive capabilities and has been approved for home use in this population.

The multifunction ventilator (i.e., the Ventilation, Oxygen, Cough, Suction, Nebulization device, Ventec Life Systems, Bothell, Washington) is clinically proven and, therefore, medically necessary for members who meet criteria for both home positive pressure ventilation and at least one of the following durable medical equipment: portable oxygen concentrator; cough stimulator; suction pump; or nebulizer.

A second ventilator in the home setting is medically necessary for any of the following indications (American Association for Respiratory Care, 2007; Make, 1998):

- For members who require at least 20 hours of mechanical ventilation of life support per day.
- For members who live in an area where a replacement ventilator cannot be provided within an acceptable timeframe without compromising the member's medical condition.

Battery backup is medically necessary for members on home mechanical ventilation for any of the following indications (Make, 1998):

- When power failures are common.
- When a member may suffer adverse consequences during even brief outages.

Prior approval is required for initiating home mechanical ventilation. Re-authorization is required at least every six months subject to member's compliance of at least 80% of prescribed use.

Limitations

Home invasive positive pressure ventilation is considered not medically necessary life support for non-life-threatening conditions or when used as a respiratory assistance device (e.g., continuous positive airway pressure, auto-titrating positive airway pressure, bilevel positive airway pressure, or adaptive servo-ventilation) as treatment for any of the following documented diagnoses:

- Obstructive sleep apnea.
- Central sleep apnea.
- Hypoventilation syndrome (primary cause not obstructive sleep apnea or central sleep apnea.
- Restrictive thoracic disorder with no or mild chronic obstructive pulmonary disease by history or testing.
- Severe chronic obstructive pulmonary disease.

Contraindications to mechanical ventilation provided in the home setting include (American Academy of Pediatrics (Carlo, 1999); American Association for Respiratory Care, 2007; American Thoracic Society, 2005; Make, 1998):

- Lack of an appropriate discharge plan.
- Unsafe physical environment as determined by the patient's discharge planning team.
- Presence of fire, health or safety hazards including unsanitary conditions.
- Inadequate basic utilities (such as heat, air conditioning, electricity including adequate amperage and grounded outlets).
- Inadequate resources for care in the home (e.g., financial, personnel).
- Inadequate medical follow-up.
- Inability of member to care for self if no caregiver is available.
- Inadequate respite care for caregivers.
- Inadequate numbers of competent caregivers (A minimum of two competent caregivers is required).
- Member's choice not to receive home mechanical ventilation.

- Presence of physiologic instability of a medical condition requiring a higher level of care or resources than can be provided in the home. Examples include (American Association for Respiratory Care, 2007):
    - Fraction of inspired oxygen requirement > .40.
    - Large fluctuations in fraction of inspired oxygen.
    - Positive end expiratory pressure > 10 cm H_2O.
    - Need for continuous invasive monitoring in adult patients.
    - Lack of mature tracheostomy.
    - Hemodynamic instability.
    - Inadequate treatment of underlying reversible disorders that may contribute to the member's symptoms.

Alternative covered services

- Home care services (e.g., respiratory care, nursing care).
- Specialty consultation.
- Guideline-directed care.
- Skilled nursing or long-term care facility.
- Inpatient care.

Background

Invasive mechanical ventilation refers to the administration of positive pressure into the pulmonary system through an inserted endotracheal or tracheostomy tube. This modality operates by forcibly conveying a pre-set blend of gases, predominantly oxygen along with other gases, into the central airways, culminating in the distribution to the alveoli (Hyzy, 2023) . The term "prolonged mechanical ventilation" and variations of the term describe mechanically ventilated individuals who are no longer in the acute phase of mechanical ventilation. The Centers for Medicare & Medicaid Services and the National Association for Medical Direction of Respiratory Care (Huntzinger, 2006) have adopted a more quantifiable definition based on duration of mechanical ventilation: "*at least 21 consecutive days of mechanical ventilation for six or more hours per day*." However, this definition fails to phenotypically characterize the cohorts of individuals receiving prolonged mechanical ventilation or consider the range of devices available to the individual at home (Rose, 2017).

The U.S. Food and Drug Administration classifies mechanical ventilators based on intended use and location of use. A ventilator for continuous home use is a Class II device intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the inhaled gas; adult, pediatric, and neonatal ventilators are included in this generic type of device (U.S. Food and Drug Administration, 2022). Two device product codes classify ventilators for home use. Product code NOU corresponds to a life support ventilator as durable medical equipment that must be tracked in the event of a recall. Product code ONZ corresponds to a new type of volume-assist ventilator that can be used invasively or noninvasively to deliver a mix of 50 psi of oxygen and room air, maintaining a minimum fraction of inspired oxygen of approximately 36%; the device is intended to aid adult patients who are spontaneously breathing but who need some volume augmentation — especially during ambulation or exercise.

Ventilator technology has evolved in recent years, with some single devices able to support multiple operating modes. In 2017, the US Food and Drug Administration (FDA) approved a multifunction ventilator under its 510(k) process (U.S. Food and Drug Administration, 2017). The device, known as VOCSN and produced by Ventec Life Systems, integrates five critical functions, which are reflected in its name: Ventilator, Oxygen concentrator, Cough assist, Suction, and Nebulizer.

Findings

We included three overviews of systematic reviews (Brurberg, 2016a, 2016b, 2016c), two independent systematic reviews (MacIntyre, 2016; Radunovic, 2017) and six professional guidelines from the American College of Chest Physicians (Make, 1998), the American Thoracic Society (2005; Sterni, 2016), the American Association for Respiratory Care (2004, 2007), and the National Association for Medical Direction of Respiratory Care (Huntzinger, 2006) in this policy.

Diagnoses for which home ventilation may be indicated include: neuromuscular disorders; chest wall deformity; central nervous system disorders that affect neurologic control of ventilation (e.g., central hypoventilation syndrome or obesity hypoventilation); obstructive sleep apnea with failure to improve with nasal continuous positive airway pressure; and chronic obstructive pulmonary disease with severe hypercapnia or nocturnal desaturation (American Association for Respiratory Care, 2007; American Thoracic Society, 2005; Make, 1998).

Patients who fail to maintain an adequate respiratory status by themselves may require prolonged mechanical ventilation as life support. The evidence from systematic reviews supporting home noninvasive ventilation is of higher quality than that of invasive ventilation but is limited in its ability to conclude with certainty that prolonged mechanical ventilation confers an additional benefit to survival, quality of life, sleep, or hospital admission rates. Participants enrolled in studies were heterogeneous with respect to age, diagnosis and the progression of their disease, and ethical limitations prevented establishing higher quality controlled studies in many circumstances (Brurberg, 2016a, 2016b, 2016c, MacIntyre, 2016; Radunovic, 2017).

A Cochrane review found no studies directly comparing efficacy of invasive and non-invasive ventilation in improving short-term survival in patients with acute respiratory failure from neuromuscular disease and chest wall disorders (Luo, 2017). This upheld the findings of a large literature review (Simonds, 2016).

Current guidelines included in this policy recommend a preference for noninvasive methods over invasive methods and positive pressure ventilation over negative pressure ventilation, where feasible. In general, noninvasive ventilation is indicated for nocturnal support only, while invasive ventilation through a tracheostomy is indicated for individuals with more severe disease requiring continuous 24 hour per day support. For patients needing support somewhere in between, the decision must be individualized.

The evidence examining home invasive ventilation is limited to lower quality, observational research largely carried out several decades ago in adult populations, and corresponding guidelines are generally consensus-based. Home invasive ventilation is an established treatment for carefully selected individuals with chronic respiratory failure who require life-sustaining ventilator support and can receive it safely and effectively in the residential setting. Low to moderate quality evidence suggests invasive ventilation delivered in the home is preferred to institutional settings for its ability (American Association for Respiratory Care, 2007):

- To sustain and extend life.
- To enhance the quality of life.
- To reduce morbidity.

- To improve or sustain physical and psychological function and, in pediatric individuals, to enhance growth and development.
- To provide cost-effective care.

There is an absence of published evidence demonstrating that a multifunction ventilator results in health outcomes that are superior to those using a traditional home ventilator and existing separate equipment to deliver the same functions. That said, a multifunction ventilator represents a technological advancement in ventilator technology that integrates the functionality of oxygen concentrators, cough stimulation, suction, and drug nebulization into one device.

A smooth and collaborative discharge process from the hospital to home is critical to successful home management of ventilator-dependent individuals. Discharge criteria for mechanically ventilated patients have been developed on the basis of expert consensus; the criteria include medical, respiratory, and psychological stability, and the existence of a comprehensive discharge plan (American Thoracic Society, 2005; Sterni, 2016). Criteria for home referral incorporate discharge readiness and home management of individuals who require prolonged ventilatory support that recognizes the limitations in home care resources that an individual with more severe illness would otherwise be difficult to care for in the home (American Association for Respiratory Care, 2007; Sterni, 2016).

The optimal candidates for prolonged home ventilation are clinically and physiologically stable before discharge, do not require intensive medical and monitoring services, and have adequate caregiver support and coping skills (the American Academy of Pediatrics (Carlo, 1999; American Association for Respiratory Care, 2007; American Thoracic Society, 2005; and the American College of Chest Physicians (Make, 1998). They have received optimal medical therapy for the underlying respiratory disorder and have adequate airway protection and secretion clearance (for noninvasive ventilators), and reversible contributing factors have been treated (e.g., obstructive sleep apnea, hypothyroidism, congestive heart failure, severe electrolyte disturbance). They are without acute infection, life-threatening cardiac dysfunction or arrhythmia, or uncontrolled dyspnea. They have stable metabolic and acid–base status (acceptable arterial blood gases with fraction of inspired oxygen less than 0.40), which can be maintained in the home (Make, 1998).

Candidates for home noninvasive ventilation have chronic, stable, or slowly progressive respiratory failure, defined as either (Make, 1998):

- Significant daytime carbon dioxide retention (≥ 50 mm Hg) with appropriately compensated pH.
- Mild daytime or nocturnal carbon dioxide retention (45 to 50 mm Hg) with symptoms attributable to hypoventilation (e.g., morning headaches, restless sleep, nightmares, enuresis, daytime hypersomnolence, etc.).
- Significant nocturnal hypoventilation or oxygen desaturation.

Criteria for home invasive ventilation take into account the need for prolonged invasive ventilatory support and the ability to provide such support in the home. The American College of Chest Physicians (Make, 1998) stresses the etiology of respiratory failure and the probability of ventilator liberation as important factors in determining the need for prolonged or lifelong invasive ventilatory support. Indications for invasive ventilation encompass individuals who cannot be weaned or those with progressive disease that requires increasing ventilatory support, such as (American Association for Respiratory Care, 2007, Make, 1998):

- Criteria for noninvasive ventilation met but with uncontrollable airway secretions or impaired swallowing leading to chronic aspiration and repeated pneumonias.
- Persistent symptomatic respiratory insufficiency and failure or inability to tolerate noninvasive ventilation.
- Severely weakened or paralyzed respiratory muscles requiring at least 20 hours of ventilator support, and patient or provider prefers invasive ventilation.

Stable ventilator parameters that are readily achievable in the home are (American Association for Respiratory Care, 2007, Make, 1998):

- No large fluctuations in fraction of inspired oxygen.
- Fraction of inspired oxygen < .40.
- Limited use of positive end expiratory pressure (e.g., ≤ 5 cm H_20).
- Avoidance of intermittent mandatory ventilation.
- Assist/control or pressure-limited mode (pediatrics) (American Thoracic Society, 2007).
- Minimal fluctuations in airway resistance and compliance.
- Peak pressure varies ≤ ±5 cm H_20.

Neonates and infants discharged home receiving continuous positive airway pressure will require positive pressure ventilators with noninvasive capabilities that are approved for home use for those populations. The American Association for Resipratory Care (2004) recommends a commercially available circuit used in conjunction with a continuous flow source, an infant ventilator, or a suitably equipped multipurpose ventilator to deliver continuous positive airway pressure using the most common nasal interfaces. It issued no preference for type of system other than to match the system with the needs of the patient.

In 2021, we added no new relevant information to the policy.

In 2022, we added two systematic reviews. One of these consisted of 60 studies of adult patients in settings with at least 50% on invasive mechanical ventilation. In the 19 studies of patients treated at home, most of whom were followed for up to seven years, mortality was 46% (436 of 940); about half required one hospitalization; rates of ventilator failure were low; and 94% of the time was spent outside a hospital (Sison, 2021).

A systematic review/meta-analysis of 50 studies of children with neuromuscular disease showed no difference in mortality and hospitalization rates between non-invasive ventilation and invasive mechanical ventilation (AlBalawi, 2022).

In 2023, we added a study of 116 chronic respiratory failure patients on home mechanical ventilation who were re-admitted to the hospital, of which 36% were “early” (within 30 days of discharge). Among early readmissions, the rate of aspiration was higher (*P* = .003) than readmissions after 30 days; and nasogastric tube feeding, sequelae of pneumonia/acute respiratory distress syndrome, and central nervous system disorders were significantly associated with early readmission. The article asserts the rate of hospital readmissions to patients on home mechanical ventilation is increasing (Kim, 2023).

In 2024, we found that the American College of Chest Physicians (Khan, 2023) released a clinical practice guideline and expert panel report recommending the use of invasive home mechanical ventilation via tracheostomy for patients with neuromuscular diseases when noninvasive ventilation fails, or is not tolerated. This recommendation applies particularly to those experiencing worsening bulbar function, frequent aspiration, insufficient cough, episodes of chest infection despite adequate secretion management, or declining lung function. However, given the very low certainty of evidence, it is a conditional recommendation (Khan, 2023)

The panel reviewed 390 abstracts and a selection of 10 studies (n = 1329) that examined the effect tracheostomy invasive ventilation had on extending survival for patients with amyotrophic lateral sclerosis and other neuromuscular diseases. The evidence — largely drawn from observational studies — indicates a very low certainty due to risks of bias, imprecision, and inconsistency. Patients on tracheostomy invasive ventilation generally see an increased mean survival rate compared to those without any ventilation or on non-invasive ventilation (Khan, 2023). However, this potential benefit is tempered by associated challenges, including higher hospitalization rates, sleep dysfunction, and diminished life satisfaction.

References

On January 2, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Mechanical Ventilation” (MeSH), “Home Care Services” (MeSH), “home ventilator,” “invasive mechanical ventilation” and “tracheostomy ventilation. We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

AlBalawi MM, Castro-Codesal M, Featherstone R, et al. Outcomes of long-term non-invasive ventilation use in children with neuromuscular disease: Systematic review and meta-analysis. *Ann Am Thorac Soc*. 2022;19(1):109-119. Doi: 10.1513/AnnalsATS.202009-1089OC.

American Association for Respiratory Care. AARC clinical practice guideline. Long-term invasive mechanical ventilation in the home — 2007 revision & update. *Respir Care.* 2007;52(8):1056-1062. Doi: http://rc.rcjournal.com/content/52/8/1056/tab-pdf.

American Association for Respiratory Care. AARC clinical practice guideline. Application of continuous positive airway pressure to neonates via nasal prongs, nasopharyngeal tube, or nasal mask — 2004 revision & update. American Association for Respiratory Care website. https://www.aarc.org/wp-content/uploads/2014/08/09.04.1100.pdf. Published September 2004.

American Thoracic Society. Statement on home care for patients with respiratory disorders. *Am J Respir Crit Care Med.* 2005;171(12):1443-1464. Doi: 10.1164/rccm.2504001.

Brurberg KG, Dahm KT. NIPH systematic reviews: Executive summaries. Effect of long-term mechanical ventilation (LTMV) part 3 — COPD and cystic fibrosis. Oslo, Norway: Knowledge Centre for the Health Services at The Norwegian Institute of Public Health. https://www.fhi.no/en/publ/2014/effect-of-long-term-mechanical-ventilation-ltmv-part-3--copd-and-cystic-fib/. Published December 9, 2014. Updated May 12, 2016. (a)

Brurberg KG, Landmark B, Haavelsrud K, Kirkehei I, Reinar LM. NIPH systematic reviews: Executive summaries. Effect of long-term mechanical ventilation (LTMV) part 2 — thoracic restrictive disorders or adipositas hypoventilation syndrome. Oslo, Norway: Knowledge Centre for the Health Services at The Norwegian Institute of Public Health. https://www.fhi.no/en/publ/2012/effect-of-long-term-mechanical-ventilation-ltmv-part-2--thoracic-restrictiv/. Published December 9, 2014. Updated May 12, 2016. (b)

Brurberg KG, Landmark B, Kirkehei I, Reinar LM. NIPH systematic reviews: Executive summaries. Effect of long-term mechanical ventilation (LTMV) part 1 — neuromuscular disease or central respiratory failure. Oslo, Norway: Knowledge Centre for the Health Services at The Norwegian Institute of Public Health. https://www.fhi.no/en/publ/2012/effect-of-long-term-mechanical-ventilation-ltmv-part-1--neuromuscular-disea/. Published December 9, 2014. Updated May 12, 2016. (c)

Carlo WA, Ambalavanan N. Conventional mechanical ventilation: Traditional and new strategies. *Pediatr Rev*. 1999;20(12):e117-e126. https://pubmed.ncbi.nlm.nih.gov/10587537/.

Huntzinger A. NAMDRC recommendations for prolonged mechanical ventilation. *Am Fam Physician.* 2006;73(7):1277-1284. https://www.aafp.org/afp/2006/0401/p1277.html.

Hyzy RC, McSparron JI. Overview of initiating invasive mechanical ventilation in adults in the intensive care unit. UpToDate. https://www.uptodate.com/contents/overview-of-initiating-invasive-mechanical-ventilation-in-adults-in-the-intensive-care-unit. Last Updated December 1, 2023.

Khan A, Frazer-Green L, Amin R, Aboussouan LS, McKim D, Gay P, et al. Respiratory management of patients with neuromuscular weakness. *Chest*. 2023;164(2):394-413. doi:10.1016/j.chest.2023.03.011

Kim EY, Suh HJ, Seo GJ, Jang MK, Lim C-M, Huh JW. Predictors of early hospital readmission in patients receiving home mechanical ventilation. *Heart Lung*. 2023;57:222-228. Doi: 10.1016/j.hrtlng.2022.10.004.

King AC. Long-term home mechanical ventilation in the United States. *Respir Care.* 2012;57(6):921-930;discussion 930-922. Doi: 10.4187/respcare.01741.

Lindahl B, Kirk S. When technology enters the home — a systematic and integrative review examining the influence of technology on the meaning of home. *Scand J Caring Sci.* 2019;33(1):43-56. Doi: 10.1111/scs.12615.

Luo F, Annane D, Orlikowski D, et al. Invasive versus non-invasive ventilation for acute respiratory failure in neuromuscular disease and chest wall disorders. *Cochrane Database Syst Rev*. 2017;12(12):CD008380. Doi: 10.1002/14651858.CD008380.pub2.

MacIntyre EJ, Asadi L, McKim DA, Bagshaw SM. Clinical outcomes associated with home mechanical ventilation: A systematic review. *Can Respir J.* 2016;2016:6547180. Doi: 10.1155/2016/6547180.

Make BJ, Gilmartin ME. Mechanical ventilation in the home. *Crit Care Clin.* 1990;6(3):785-796. Doi: 10.1016/S0749-0704(18)30366-X.

Make BJ, Hill NS, Goldberg AI, et al. Mechanical ventilation beyond the intensive care unit. Report of a consensus conference of the American College of Chest Physicians. *Chest.* 1998;113(5 Suppl):289s-344s. Doi: 10.1378/chest.113.5_supplement.289s.

Radunovic A, Annane D, Rafiq MK, Brassington R, Mustfa N. Mechanical ventilation for amyotrophic lateral sclerosis/motor neuron disease. *Cochrane Database Syst Rev.* 2017;10:CD004427. Doi: 10.1002/14651858.CD004427.pub4.

Rose L, McGinlay M, Amin R, et al. Variation in definition of prolonged mechanical ventilation. *Respir Care.* 2017;62(10):1324-1332. Doi: 10.4187/respcare.05485.

Simonds AK. Home mechanical ventilation: An overview. *Ann Am Thorac Soc*. 2016;13(11):2035-2044. Doi: 10.1513/AnnalsATS.201606-454FR.

Sison SM, Sivakumar GK, Caufield-Noll C, et al. Mortality outcomes of patients on chronic mechanical ventilation in different care settings: A systematic review. *Heliyon*. 2021;7(2):e06230. Doi: 10.1016/j.heliyon.2021.e06230.

Sterni LM, Collaco JM, Baker CD, et al. An official American Thoracic Society clinical practice guideline: Pediatric chronic home invasive ventilation. *Am J Respir Crit Care Med.* 2016;193(8):e16-35. Doi: 10.1164/rccm.201602-0276ST.

U.S. Food and Drug Administration. VOCSN Unified Respiratory System. Ventec Life Systems, Inc. 510k letter k162877. Dated April 7, 2017. https://www.accessdata.fda.gov/cdrh_docs/pdf16/K162877.pdf. Published 2017.

U.S. Food and Drug Administration. Continuous ventilator. Code of Federal Regulations 21CFR868.5895. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=868.5895. Last updated November 29, 2022.

Policy updates

2/2020: initial review date and clinical policy effective date: 4/2020

3/2021: Policy references updated.

3/2022: Policy references updated.

3/2023: Policy references updated.

3/2024: Policy references updated.