Anthem

Medical Policy

Subject: Extracorporeal Carbon Dioxide Removal
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Description/Scope

This document addresses the use of extracorporeal carbon dioxide removal ($ECCO_2R$), a minimally invasive, low-flow veno-venous or venous-arterial procedure used to treat acute hypercapnic respiratory failure or as an alternative to standard extracorporeal membrane oxygenation (ECMO).

Position Statement

Investigational and Not Medically Necessary:

Extracorporeal carbon dioxide removal is considered **investigational and not medically necessary** for all conditions, including but not limited to acute hypercapnic respiratory failure.

Rationale

The Hemolung® Respiratory Assist System (RAS) (ALung Technologies, Inc, Pittsburgh, PA, USA) has been proposed as an $ECCO_2R$ device. The ultimate goal of $ECCO_2R$ or ECMO is to prevent or minimize the use of invasive ventilation. The Hemolung received De Novo clearance from the U.S. Food and Drug Administration (FDA) in November of 2021 and previously received investigational device exemption (IDE) status in September of 2017. The VENT-AVOID trial, a prospective, randomized, controlled, pivotal trial began enrolling participants in approximately 30 facilities in February 2018.

Clinical Trials

In a prospective, randomized trial, Bein and colleagues (2013) evaluated the use of arteriovenous extracorporeal CO_2 elimination ($avECCO_2$-R) with low tidal volume ventilation in individuals with acute respiratory distress syndrome (ARDS). A total of 79 individuals with established ARDS with moderate hypercapnia were enrolled. Forty individuals were randomized to receive $avECCO_2$-R with mechanical ventilation at a low tidal volume rate of 3 ml/kg/PBW. Thirty-nine control-group individuals received only mechanical ventilation at a rate of 6 ml/kg/PBW. The primary outcome was the proportion of ventilator-free days (VFD) at 28 and 60 days. There were no statistical differences between the groups in VFD-28 (10.0 ± 8 days, 9.3 ± 9 days in the control group; p=0.779) or VFD-60 (33.2 ± 20 days, 29.2 ± 21 days in the control group; p=0.469). Mortality rates were low (17.5% in the treatment group, 15.4% in the control group) and did not differ between the groups. In the treatment group, $ECCO_2$-R-related complications graded as temporary and moderate occurred in 3 individuals. The authors concluded that the use of low tidal volume ventilation combined with $ECCO_2$-R was safe and feasible but was not associated with a significant reduction in the duration of mechanical ventilation needed.

The safety and feasibility of low-flow veno-venous $ECCO_2R$ treatment using Hemolung RAS was evaluated in a small, prospective study involving 15 individuals with moderate ARDS who were mechanically ventilated (Fanelli, 2016). The authors aimed to study lower tidal volumes in combination with $ECCO_2R$ in an attempt to reduce the likelihood of ventilator-induced lung injury. Individual tidal volumes (VT) were reduced from 6 mg/kg/predicted body weight (PBW) to 4 mg/kg/PBW; positive end-expiratory pressure (PEEP) was increased from 23 to 25 cm H_2O. $ECCO_2R$ began when individuals developed respiratory acidosis at pH < 7.25 and $PaCO_2$ > 60 mmHg. The potential for weaning from ultra-protective ventilation and $ECCO_2R$ was assessed daily. Participants who remained stable for at least 12 hours with plateau pressure (Pplat) < 25 cm H_2O and $PaCO_2$ < 50 mmHg (allowing for respiratory rate [RR] up to 30-35/min) were discontinued from $ECCO_2R$ and the venous catheter removed. At baseline, all participants had a $PaO_2/FiO_2 \leq 200$ and they were ventilated with a conventional protective ventilation strategy. After initiation of $ECCO_2R$, a VT of 4.29 ± 0.5 mL/kg was achieved and respiratory acidosis was significantly corrected, with pH and $PaCO_2$ returning to within 10% of baseline values obtained at VT=6 mL/kg. The median number of days on $ECCO_2R$ was 3 (range, 2-4). The reduction in VT was associated with a significant reduction in Pplat from 27.7 ± 1.6 to 23.9 ± 1 cm H_2O ($p<0.05$) at day 1 and this difference remained significant throughout the study period. Two study-related adverse events were reported including intravascular hemolysis and kinking of the $ECCO_2R$ catheter. The overall mortality at day 28 was 47%. Among the 8 survivors, 6 were successfully weaned from both $ECCO_2R$ and mechanical ventilation while 2 were still dependent on ventilator support at 28 days. Larger, more comprehensive randomized clinical trials are needed in order to further evaluate the feasibility, safety and efficacy of $ECCO_2R$ therapies.

In 2021, McNamee and colleagues published the results of a multicenter, randomized, allocation-concealed, open-label clinical trial investigating whether lower tidal volume ventilation facilitated by $ECCO_2R$ compared with standard care improves outcomes in individuals with acute hypoxemic respiratory failure requiring intensive care. A total of 412 participants were randomized to receive lower tidal volume ventilation facilitated by $ECCO_2R$ for at least 48 hours (n=202) with a maximum of 7 days, or standard care with conventional low tidal volume ventilation (n=210). The primary outcome was all-cause mortality 90 days after randomization. The 90 day mortality rate was 41.5% in the $ECCO_2R$ group compared to 39.5% in the standard care group, a difference of 2.0% (95% confidence interval [CI], -7.6% to 11.5%; p=0.68). There were significantly fewer mean ventilator-free days at day 28 in the $ECCO_2R$ group (7.1 days) compared to the standard care group (9.2 days; mean difference, -2.1 [95% CI, -3.8 to -0.3]; p=0.02). There were no significant between-group differences in other secondary outcomes which included: duration of ventilation, need for ECMO at day 7, mortality at 28 days, and duration of ICU or hospital stay. Serious adverse events were reported for 62 participants (31%) in the $ECCO_2R$ group and 18 participants (9%) in the standard care group. Serious adverse events included intracranial hemorrhage in 9 participants (4.5%) compared to 0 (0%) and bleeding at other sites in 6 participants (3.0%) compared to 1 (0.5%) in the $ECCO_2R$ and standard care groups, respectively. Overall, 21 participants experienced 22 serious adverse events related to the study device. The trial was stopped early due to futility and feasibility following recommendations from the study's data monitoring and ethics committee. Lower tidal volume ventilation facilitated by $ECCO_2R$ did not result in a reduction in mortality at 90 days compared to standard care in

individuals requiring mechanical ventilation for acute hypoxemic respiratory failure. The authors note that it is possible the trial was underpowered to detect a clinically important difference, particularly because the trial was stopped before recruitment of the planned sample size (n=1120) was achieved.

Azzi (2021) reported the results of a retrospective controlled trial involving 51 subjects with acute exacerbation of chronic obstructive pulmonary disease (COPD) and failure of noninvasive mechanical ventilation. Subjects were treated with $ECCO_2R$ or invasive mechanical ventilation (n=26 vs. 25, respectively). At baseline, the two groups were similar, with the exception that the $ECCO_2R$ group had significantly higher BMI (30 kg/m² vs 25 kg/m², p=0.035). The primary endpoint was to record $ECCO_2R$ failure, defined as transition to invasive mechanical ventilation or death by day 90. Failure of $ECCO_2R$ treatment was reported in 5 (19%) subjects, with 4 (15%) intubated and 1 dying before intubation due to multiple organ failure. Among the intubated subjects, 3 were no longer alive at day 90. A total of 7 (28%) subjects in the control group died before 90 days (between group difference p=0.26). No significant differences between groups were reported with regard to improvements in pH and $PaCO_2$ values. Similarly, no significant differences between groups were reported in either ICU or overall hospital length of stay. Major bleeding events occurred in 6 (23%) subjects in the $ECCO_2R$ group, with $ECCO_2R$ treatment discontinued due to bleeding for 3 (11%) subjects. Other adverse events reported included hemolysis due to $ECCO_2R$ (n=3), thrombocytopenia <100 G/L (n=6), circuit thrombosis leading to premature discontinuation of $ECCO_2R$ (n=3). In the control group, 8 (32%) subjects experienced ventilator-associated pneumonia, 25 hemodynamic instability events with catecholamine administration requirement occurred in 19 subjects (76%), and self-extubation was observed in 6 subjects. A total of 3 (12%) subjects died due to invasive mechanical ventilation-related complications. The authors concluded that $ECCO_2R$ provided significant improvement of pH and $PaCO_2$ in this population and led to avoidance of invasive ventilation in 85% of cases with low complication rates. The results of this study are promising, but hampered by several methodological flaws, including retrospective before-after observational study design.

Nagler (2022) reported the results of a retrospective comparative study involving 47 consecutive subjects experiencing respiratory failure requiring intervention and treated with either venovenous ECMO (n=24) or $ECCO_2R$ (n=23). Hemostatic changes between groups were assessed by application of linear mixed effect models. The authors reported no significant differences between groups with regard to change in platelet count (p=0.529) or D-dimer measures (p=0.332). Measures for changes in fibrinogen levels indicated significant differences between groups during treatment (p=0.003). Day 1 fibrinogen level changes from baseline were -0.9% in the $ECCO_2R$ group and -6.1% in the ECMO group. On Day 4, those changes were -0.4% in the $ECCO_2R$ group and -5.6% in the ECMO group. No significant differences between groups were reported with regard to rate of system exchanges, transfusion requirements, number of positive blood cultures, ICU mortality, in-hospital mortality, or 28 day mortality. The authors concluded that their findings suggest that $ECCO_2R$ is not significantly different from VV ECMO in terms of hemocompatibility. The authors concluded that their results indicate a benefit to $ECCO_2R$ with regard to time to improvement in respiratory acidosis, respiratory physiology, patient comfort, and dyspnea. The lack of randomization blinding and other methodological factors impair the generalizability of these results.

Barrett (2022) reported on an RCT involving 18 subjects with acute exacerbation of COPD at high risk of noninvasive ventilation failure (GOLD stage 3) assigned to treatment with either $ECCO_2R$ (n=9) or continued noninvasive ventilation (n=9). Respiratory rates were reported to be significantly different between groups at baseline and 12 hour post-treatment initiation, with $ECCO_2R$ being significantly higher vs. the noninvasive ventilation group (22 breaths/min vs. 17 breaths/min, p=0.038). Arterial pH was not significantly different between the two groups, but partial pressure of arterial CO2 (PaCO2) was significantly lower with $ECCO_2R$ group vs. the noninvasive ventilation group at 4 hours (6.8 kPa vs. 8.3 kPa; p=0.024). Serum bilirubin levels at day 2 were significantly higher with $ECCO_2R$ group vs. the noninvasive ventilation group (14 umol/L vs. 5 umol/L; p=0.013). Likewise, platelets count were lower in the $ECCO_2R$ group at day 2 (96 vs. 225×109/L; p=0.044). Fibrinogen remained significantly higher with $ECCO_2R$ group at baseline, day 1 and day 2 (p< 0.001), days 1 and 2. No severe or life-threatening complications were reported in either group, including major bleeding or transfusion. The number of non-severe complications related to noninvasive ventilation was higher than $ECCO_2R$, primarily due to discomfort. One subject in the $ECCO_2R$ groups required infusion of platelets and another required invasive ventilation due to hospital acquired pneumonia. Overall, the ICU and hospital length of stays were significantly longer with $ECCO_2R$ group vs. noninvasive ventilation group (161:45 hours vs. 45:49 hours, p=0.001; 240:00 hours vs. 124:00 hours, p=0.014; respectively). Survival to 90 days was not significantly different between groups. As with previous studies, significant benefits to $ECCO_2R$ were reported. However, similar to earlier studies, serious methodological flaws limit the generalization to a wider population.

In 2023, Boyle published the results of a pre-specified secondary analysis for the REST trial previously, reported by McNamee in 2021, to assess 2-year outcomes. Of the 412 subjects originally enrolled into the REST trial, 1-year mortality data was available for 401 (97.3%) with no significant difference between groups. Two-year mortality data was available for 391 subjects (94.9%) again with no significant difference between groups. The time-to-death up to 2 years was similar between groups (HR, 1.08; log-rank test p=0.61). The St. George's Respiratory Questionnaire was completed by 116 (53%) subjects alive at 1 year. Partial responses were also received, but no data were provided for the total number of responses. No significant differences between groups were reported with regard to SGRQ total score (p=1.00) or subscale components for symptoms (p=0.52), activity (p=0.91), or impacts (p=0.83). Montreal Cognitive Assessment (MoCA)-Blind Questionnaire was completed by 115 (56%) patients alive at 1 year, and no significant difference was reported between groups with regard to the proportion who had mild, moderate, or severe cognitive impairment (p=0.41). The authors concluded, that lower-tidal volume ventilation vv-ECCO2 R does not affect 1-year mortality when used to treat ARDS with moderate-to-severe acute hypoxaemic respiratory failure. Additionally, they concluded that among reporting subjects, there was "no treatment effect on long-term respiratory function, post-traumatic stress disorder, cognitive dysfunction or health-related quality of life."

There have been a limited number of additional articles, primarily pilot studies, case studies and retrospective reviews, published in the peer-reviewed literature addressing the use of $ECCO_2R$ in treating acute hypercapnic respiratory failure (Abrams, 2013; Allescher, 2021; Bermudez, 2015; Bonin, 2013; Burke, 2013; Moss, 2016, Redwan, 2016). In a review of the technology, Camporota and colleague (2016) note that "At present $ECCO_2R$ should be considered a research tool, rather than an accepted clinical procedure. There is a clear need for further robust research, particularly prospective, randomized, controlled studies."

Meta-analyses and Other Evidence

In 2015, Sklar and associates performed a systematic review on $ECCO_2R$ use to treat hypercapnic respiratory failure in COPD exacerbations. A total of 10 studies, primarily case series, with 87 individuals were included. In an analysis of the potential of $ECCO_2R$ plus noninvasive ventilation (NIV) to prevent intubation, there was a success rate of 92.8% (65/70 individuals). In those 17 individuals already receiving invasive mechanical ventilation (IMV), the rate of successful extubation was 52.9% (9/17 individuals). Results reported in 3 studies regarding hospital mortality were mixed, with 2 studies reporting positive results while 1 retrospective review showed no significant difference in mortality at 28 days. There were a total of 11 major complications (major bleeding, venous

perforation, pneumothorax or death) and 30 minor complications reported amongst 8 studies. While the studies reported high success rates overall, the quality of the evidence is considered low given the potential selection bias associated with case series data. The authors concluded that randomized controlled trials are needed to further evaluate the use of $ECCO_2R$ in COPD exacerbations.

In 2021 two meta-analyses were published evaluating $ECCO_2R$. In the first, Yu et al. included 25 studies involving 826 subjects undergoing $ECCO_2R$ for hypercapnic respiratory failure of any etiology. The study was designed to compare venous $ECCO_2R$ to arterial $ECCO_2R$. The primary finding was that ICU length of stay was significantly shorted in the venous $ECCO_2R$ group (p=0.05). No differences in in-hospital mortality was reported. In the second, Zhu et al. included 15 studies involving 532 subjects with ARDS or COPD. They reported that when compared to control treatments, $ECCO_2R$ did not significantly alter 28-day mortality (p=0.51) or ICU or hospital length of stay (p=0.44 and p=0.928, respectively). The overall adverse event rate was 35% (p<0.001), with bleeding being the most frequent (22%). Both of these studies involved trials with weak methodologies, and the data is not strengthened by their combination.

In 2022, Worku published a meta-analysis involving 10 studies addressing the use of $ECCO_2R$ for moderate to severe ARDS involving 421 subjects. They reported no significant changes in oxygenation, respiratory rate or PEEP due to $ECCO_2R$. Additionally, no significant interactions between driving pressure reduction and baseline driving pressure, partial pressure of arterial carbon dioxide or PaO2:FiO2 ratio were identified in metaregression analysis. Similar to other reports, they identified bleeding and hemolysis as the most common complications. Additionally, they commented,

> Heterogeneity amongst studies and devices, a paucity of randomised controlled trials, and variable safety reporting calls for standardisation of outcome reporting. Prospective evaluation of optimal device operation and anticoagulation in high quality studies is required before further recommendations can be made.

Conclusion

To date, the evidence addressing the use of $ECCO_2R$ is limited to a small number of studies of poor quality. As noted above by Worku (2022) data from prospective, high powered trials using standardized approached to therapy and metrics is needed to fully assess the clinical utility of this technology.

Background/Overview

Approximately 24 million adults in the United States (U.S.) show evidence of impaired lung function (ACCP, 2015). The American Lung Association (ALA) reported that in the U.S., 16.4 million individuals have been diagnosed with COPD (ALA, 2021). Approximately 200,000 ARDS cases are reported each year, with a mortality rate of 30-50% (ACCP, 2020). Both COPD and ARDS can cause hypercapnic respiratory failure.

Hypercapnic respiratory failure occurs when there is a failure to remove carbon dioxide from the body. The partial pressure of carbon dioxide in arterial blood levels ($PaCO_2$) is elevated and typically is present along with hypoxemia. Standard treatments to oxygenate the blood as well as remove carbon dioxide include EMCO or mechanical ventilation.

$ECCO_2R$ therapy has been proposed as an alternative treatment, and is designed to provide CO_2 removal at lower blood flow rates (350-550 mL/min) than ECMO. This low flow rate allows for significant CO_2 removal but only minimal blood oxygenation. However, these lower blood flow rates permit the use of smaller catheters. The goal of $ECCO_2R$ is to reduce ventilation requirements in individuals who are either failing NIV or to minimize ventilator associated morbidity.

$ECCO_2R$ circuits always consist of two cannulas, drainage and return cannulas, and a membrane lung in which the gas exchange takes place. These circuits can be venovenous (VV) or arteriovenous (AV) systems. In the AV system, the individual's blood pressure provides the pump to move the blood across the membrane. In the VV system, a pump must be included in the circuit (Camporota, 2016).

The HEMOLUNG RAS is noted to be the first fully-integrated system for respiratory dialysis, to provide partial extracorporeal support. The device received FDA De Novo clearance in 2021.

Definitions

Acute respiratory distress syndrome (ARDS): A rapidly progressive disease in which the alveoli fill with fluid, making breathing and gas exchange very difficult. ARDS occurs when there is direct or indirect trauma to the lungs.

Extracorporeal life support (ECLS): Life supporting procedures which are carried out outside the body and include cardiopulmonary support extracorporeal CO_2 removal, and ECMO.

Extracorporeal membrane oxygenation (ECMO): An invasive technique used to provide total respiratory support by bypassing the heart and lung and providing oxygenation and CO_2 removal. ECMO is generally considered a surgical procedure and performed in the intensive care setting.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure codes, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

37799	Unlisted procedure, vascular surgery [when specified as extracorporeal carbon dioxide removal]

ICD-10 Procedure

5A0920Z	Assistance with respiratory filtration, continuous

ICD-10 Diagnosis

References

Peer Reviewed Publications:

1. Abrams DC, Brenner K, Burkart KM, et al. Pilot study of extracorporeal carbon dioxide removal to facilitate extubation and ambulation in exacerbations of chronic obstructive pulmonary disease. Ann Am Thorac Soc. 2013; 10(4):307-314.
2. Allescher J, Rasch S, Wiessner JR, et al. Extracorporeal carbon dioxide removal with the Advanced Organ Support system in critically ill COVID-19 patients. Artif Organs. 2021; 45(12):1522-1532.
3. Azzi M, Aboab J, Alviset S, et al. Extracorporeal CO2 removal in acute exacerbation of COPD unresponsive to non-invasive ventilation. BMJ Open Respir Res. 2021; 8(1):e001089.
4. Barrett NA, Hart N, Daly KJR, et al. A randomised controlled trial of non-invasive ventilation compared with extracorporeal carbon dioxide removal for acute hypercapnic exacerbations of chronic obstructive pulmonary disease. Ann Intensive Care. 2022; 12(1):36.
5. Bein T, Weber-Carstens S, Goldmann A, et al. Lower tidal volume strategy (≈3 ml/kg) combined with extracorporeal CO2 removal versus 'conventional' protective ventilation (6 ml/kg) in severe ARDS: the prospective randomized Xtravent-study. Intensive Care Med. 2013; 39(5):847-856.
6. Bermudez CA, Zaldonis D, Fan MH, et al. Prolonged use of the Hemolung Respiratory Assist System as a bridge to redo lung transplantation. Ann Thorac Surg. 2015; 100(6):2330-2333.
7. Bonin F, Sommerwerck U, Lund LW, Teschler H. Avoidance of intubation during acute exacerbation of chronic obstructive pulmonary disease for a lung transplant candidate using extracorporeal carbon dioxide removal with the Hemolung. J Thorac Cardiovasc Surg. 2013; 145(5):e43-e44.
8. Boyle AJ, McDowell C, Agus A, et al. Acute hypoxaemic respiratory failure after treatment with lower tidal volume ventilation facilitated by extracorporeal carbon dioxide removal: long-term outcomes from the REST randomised trial. Thorax. 2023; 78(8):767-774.
9. Burki NK, Mani RK, Herth FJF, et al. A novel extracorporeal CO2 removal system: results of a pilot study of hypercapnic respiratory failure in patients with COPD. Chest. 2013; 143(3):678-686.
10. Camporota L, Barrett N. Current applications for the use of extracorporeal carbon dioxide removal in critically ill patients. Biomed Res Int. 2016; 2016:9781695.
11. Combes A, Brodie D, Bartlett R, et al.; International ECMO Network (ECMONet). Position paper for the organization of extracorporeal membrane oxygenation programs for acute respiratory failure in adult patients. Am J Respir Crit Care Med. 2014; 190(5):488-496.
12. Del Sorbo L, Fan E, Nava S, Ranieri VM. ECCO(2)R in COPD exacerbation only for the right patients and with the right strategy. Intensive Care Med. 2016; 42(11):1830-1831.
13. Del Sorbo L, Pisani L, Filippini C, et al. Extracorporeal Co2 removal in hypercapnic patients at risk of noninvasive ventilation failure: a matched cohort study with historical control. Crit Care Med. 2015; 43(1):120-127.
14. Fitzgerald M, Millar J, Blackwood B, et al. Extracorporeal carbon dioxide removal for patients with acute respiratory failure secondary to the acute respiratory distress syndrome: a systematic review. Crit Care. 2014; 18(3):222.
15. Kluge S, Braune SA, Engel M, et al. Avoiding invasive mechanical ventilation by extracorporeal carbon dioxide removal in patients failing noninvasive ventilation. Intensive Care Med. 2012; 38(10):1632-1639.
16. Lund LW, Federspiel WJ. Removing extra CO(2) in COPD patients. Curr Respir Care Rep. 2013; 2:131-138.
17. McNamee JJ, Gillies MA, Barrett NA, et al. Effect of lower tidal volume ventilation facilitated by extracorporeal carbon dioxide removal vs standard care ventilation on 90-day mortality in patients with acute hypoxemic respiratory failure: the REST randomized clinical trial. JAMA. 2021; 326(11):1013-1023.
18. Morelli A, Del Sorbo L, Pesenti A, et al. Extracorporeal carbon dioxide removal (ECCO(2)R) in patients with acute respiratory failure. Intensive Care Med. 2017; 43(4):519-530.
19. Moss CE, Galtrey EJ, Camporota L, et al. A retrospective observational case series of low-flow venovenous extracorporeal carbon dioxide removal use in patients with respiratory failure. ASAIO J. 2016; 62(4):458-462.
20. Nagler B, Gleiss A, Füreder L, et al. Comparison of hemostatic changes in pump-driven extracorporeal carbon dioxide removal and venovenous extracorporeal membrane oxygenation. ASAIO J. 2022; 68(11):1407-1413.
21. Pisani L, Corcione N, Nava S. Management of acute hypercapnic respiratory failure. Curr Opin Crit Care. 2016; 22(1):45-52.
22. Redwan B, Ziegeler S, Semik M, et al. Single-site cannulation venovenous extracorporeal CO2 removal as bridge to lung volume reduction surgery in end-stage lung emphysema. ASAIO J. 2016; 62(6):743-746.
23. Rodenstein D. The human CO2 market. Respirology. 2016; 21(7):1150-1151.
24. Schmidt M, Jaber S, Zogheib E, et al. Feasibility and safety of low-flow extracorporeal CO(2) removal managed with a renal replacement platform to enhance lung-protective ventilation of patients with mild-to-moderate ARDS. Crit Care. 2018; 22(1):122.
25. Shekar K, Mullany DV, Thomson B, et al. Extracorporeal life support devices and strategies for management of acute cardiorespiratory failure in adult patients: a comprehensive review. Crit Care. 2014; 18(3):219.
26. Sklar MC, Beloncle F, Katsios CM, et al. Extracorporeal carbon dioxide removal in patients with chronic obstructive pulmonary disease: a systematic review. Intensive Care Med. 2015; 41(10):1752-1762.
27. Ventetuolo CE, Muratore CS. Extracorporeal life support in critically ill adults. Am J Respir Crit Care Med. 2014; 190(5):497-508.
28. Worku E, Brodie D, Ling RR, et al. Venovenous extracorporeal CO2 removal to support ultraprotective ventilation in moderate-severe acute respiratory distress syndrome: A systematic review and meta-analysis of the literature. Perfusion. 2023; 38(5):1062-1079.
29. Yu TZ, Tatum RT, Saxena A, et al. Utilization and outcomes of extracorporeal CO2 removal (ECCO2 R): Systematic review and meta-analysis of arterio-venous and veno-venous ECCO2 R approaches. Artif Organs. 2022;46(5):763-774.
30. Zhu Y, Zhen W, Zhang X, et al. Extracorporeal Carbon Dioxide Removal in Patients with Acute Respiratory Distress Syndrome or Chronic Obstructive Pulmonary Disease: A Systematic Review and Meta-Analysis. Blood Purif. 2022; Aug 29:1-11.

Government Agency, Medical Society, and Other Authoritative Publications:

1. American College of Chest Physicians (ACCP). Executive Summary: Prevention of Acute Exacerbation of COPD: American College of Chest Physicians and Canadian Thoracic Society Guideline. Chest. 2015; 147(4): 883 - 893.
2. Extracorporeal Life Support Organization (ELSO). General Guidelines for all ECLS Cases. Version 1.4 August 2017. Available at: https://www.elso.org/Portals/0/ELSO%20Guidelines%20General%20All%20ECLS%20Version%201_4.pdf. Accessed on November 14, 2023.
3. U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health. Hemolung Respiratory Assist System (ALung Technologies, Inc. Pittsburgh, PA). De Novo clearance. No. DEN210006. November 13, 2021. Available at:

https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210006.pdf. Accessed on November 14, 2023.

Websites for Additional Information

1. American College of Chest Physicians. Acute Respiratory Distress Syndrome. Updated on October 25, 2022. Available at: https://foundation.chestnet.org/lung-health-a-z/acute-respiratory-distress-syndrome-ards/. Accessed on November 14, 2023.
2. American Lung Association. Lung Health & Diseases. Available at: http://www.lung.org/lung-health-and-diseases/lung-disease-lookup/. Accessed on November 14, 2023.
    - Acute Respiratory Distress Syndrome (ARDS)
    - Asthma
    - COPD
3. American Thoracic Society. Fact Sheets: Topic Specific. Available at:https://www.thoracic.org/patients/patient-resources/topic-specific/. Accessed on November 14, 2023.
4. National Heart, Lung, and Blood Institute. Respiratory Failure. Last updated March 24, 2022. Available at: https://www.nhlbi.nih.gov/health-topics/respiratory-failure. Accessed on November 14, 2023.

Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale, Background/Overview, References and Websites sections.
Reviewed	11/10/2022	MPTAC review. Updated Rationale, Background/Overview, References and Websites sections.
Reviewed	11/11/2021	MPTAC review. Updated Rationale, Background/Overview, References and Websites sections.
Reviewed	11/05/2020	MPTAC review. Updated References, Websites and Index sections
Reviewed	11/07/2019	MPTAC review. Updated References, Websites and Index sections
Reviewed	01/24/2019	MPTAC review. Updated Rationale and References sections. Updated Coding section to remove 5A0935Z, 5A0945Z, 5A0955Z no longer applicable.
Reviewed	01/25/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Rationale, Background and References sections. Updated Coding section to add ICD-10-PCS code 5A0920Z.
New	02/02/2017	MPTAC review. Initial document development.