Healthy Blue

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) is currently being evaluated as an $ECCO_2R$ device. The ultimate goal of $ECCO_2R$ or ECMO is to prevent or minimize the use of invasive ventilation. Hemolung is not currently U.S. Food and Drug Administration (FDA) approved, but did receive 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.

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 acute respiratory distress syndrome (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 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 ARDS. A total of 79 individuals with established ARDS with moderate hypercapnia 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.

In 2015, Sklar and associates performed a systematic review on $ECCO_2R$ use to treat hypercapnic respiratory failure in chronic obstructive pulmonary disease (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 three studies regarding hospital mortality were mixed, with two studies reporting positive results while one retrospective review showed no significant difference in mortality at 28 days. There were a total of 11 major complications (major bleeding, venous performation, pneumothorax or death) and 30 minor complications reported amongst eight 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.

There have been a limited number of 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; 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."

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., 11 million individuals have been diagnosed with COPD (ALA, 2019). Approximately 200,000 ARDS cases are reported each year, with a mortality rate of 30-50% (ALA, 2019). 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. Current standard treatments to oxygenate the blood as well as removing 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. This system is not yet FDA approved.

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:

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	
	All diagnoses

References

Peer Reviewed Publications:

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12. Lund LW, Federspiel WJ. Removing extra CO(2) in COPD patients. Curr Respir Care Rep. 2013; 2:131-138.
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17. Rodenstein D. The human CO2 market. Respirology. 2016; 21(7):1150-1151.
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Government Agency, Medical Society, and Other Authoritative Publications:

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Websites for Additional Information

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    - Asthma
    - COPD

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ALung
ECCO2R
Extracorporeal carbon dioxide removal
Hemolung Respiratory Assist System
Respiratory dialysis system

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	11/05/2020	Medical Policy & Technology Assessment Committee (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.