GIG CYMRU NHS WALES

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Welsh Health Specialised Services Committee (WHSSC)

# Specialised Services
# Policy Position Statement PP251

## Extracorporeal Membrane Oxygenation (ECMO) as a bridge to lung transplant (all ages)

*February 2023*

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| **Description** | NHS Wales will routinely commission this specialised service in accordance with the criteria described in this policy |
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# Contents



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## Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission Extracorporeal Membrane Oxygenation (ECMO) as a bridge to lung transplant for people of all ages in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed the relevant guidance issued by NHS England[1] and has concluded that ECMO should be made available as a bridge to lung transplant.

### Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgment, knowledge and expertise when deciding whether it is appropriate to apply this policy position statement.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian, or Local Authority.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy position statement.

[1] Extracorporeal membrane oxygenation (ECMO) as a bridge to lung transplant (all ages)

# 1. Introduction

This Policy Position Statement has been developed for the planning and delivery of Extracorporeal Membrane Oxygenation (ECMO) as a bridge to lung transplant for people of all ages resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

## 1.1 Plain language summary

Lung transplantation is routinely performed for selected patients with respiratory failure in whom there are no other options for treatment. Several types of lung disease can result in respiratory failure where a person's lungs can no longer get enough oxygen into their blood and clear enough carbon dioxide out.

Symptoms of respiratory failure include worsening shortness of breath, rapid breathing, fatigue, anxiety, confusion and then death. These tend to be in patients with cystic fibrosis (CF), pulmonary hypertension (PH), chronic obstructive pulmonary disease (COPD), and idiopathic pulmonary fibrosis (IPF).

Due to the scarcity of organ donors, patients are put on a waiting list until suitable lungs for transplantation become available. Approximately 25% of patients on the waiting list die from respiratory failure before a suitable donor becomes available or are removed from the waiting list because they become too ill. Some of these patients can be given respiratory support to keep them alive until a transplant organ becomes available. This is known as bridge to lung transplant.

In the past mechanical ventilation has been used for bridge to lung transplant but it has been associated with severe complications and poor post-transplant outcomes. Lung transplants are now rarely performed in mechanically ventilated patients. Therefore, there are currently no treatments available for deteriorating patients with terminal respiratory failure. Such patients are removed from the lung transplant waiting list and given end-of life care.

Extracorporeal Membrane Oxygenation (ECMO) is a technique for providing respiratory support for those people whose lungs are no longer able to function effectively despite all other therapeutic and supportive interventions. Blood is removed from the patient's circulation and passes through a gas exchange device which puts oxygen into the blood and removes carbon dioxide before being returned to the circulation. ECMO can only be used to treat patients for a relatively short period of time. Traditionally patients have been sedated and bedbound while on ECMO but now all patients are encouraged to exercise and take part in physiotherapy.

## 1.2 Aims and Objectives

This Policy Position Statement defines the commissioning position of WHSSC on the use of Extracorporeal Membrane Oxygenation (ECMO) as a bridge to lung transplant for people of all ages.

The objectives of this policy are to:

- ensure commissioning for the use of ECMO is evidence based
- ensure equitable access to ECMO
- define criteria for people with respiratory failure to access treatment
- improve outcomes for people with respiratory failure.

## 1.3 Epidemiology

In the 'Annual Report on Cardiothoracic Organ Transplantation' for 2020/2021[2] there were 257 patients on the waiting list for lung transplant on 31st March 2021, including 5 urgent lung patients. Underlying conditions of patients waiting for a lung transplant include cystic fibrosis and bronchiectasis, fibrosing lung disease, COPD and emphysema, and primary pulmonary hypertension.

A review of the utilisation of the Super Urgent Lung Allocation Scheme (SULAS) from May 2017 [when it was introduced] to February 2019 (20 months) showed there have been 19 adult registrations and no paediatric registrations onto this list (NHSBT Cardiothoracic Advisory Group, 2019).

Between April 1st 2017 and March 31st 2018 there were 214 lung transplants carried out in England. Based on activity at Harefield Hospital over the last seven years it has been estimated that up to 10% of lung transplant patients might utilise ECMO bridge to lung transplant. This would result in approximately 21 patients receiving ECMO bridge to lung transplant annually in England. Extrapolating this to the population of Wales would mean approximately 1 patient per year receiving ECMO bridge to lung transplant.

Currently up to 15 children of all ages are listed for lung transplant each year in England and the number of transplants in the paediatric population remains low. Ambulatory ECMO could be considered in a select group of paediatric patients (adolescents with height >140cm) so it may be anticipated that there would be up to 1 ECMO episode per year in paediatric patients. For Wales, this would mean 1 paediatric patient approximately every decade.

## 1.4 Current Treatment

Lung transplantation is routinely performed for selected patients with respiratory failure in whom there are no other options for treatment. Due

[2] Annual Report On Cardiothoracic Organ Transplantation Report 2020/2021

to the scarcity of organ donors, patients are put on a waiting list until suitable lungs for transplantation become available. However, approximately 25% of patients on the waiting list are critically ill and die from respiratory failure before a suitable donor becomes available or are removed from the waiting list due to deteriorating health rendering lung transplantation futile and inappropriate[3].

In the past, mechanical ventilation (MV) has been used as a support to 'bridge' these patients to transplant but it is not sufficient for all patients and has been associated with serious complications and poor post-transplant outcomes. This means that lung transplants are now rarely performed in mechanically ventilated patients. ECMO is an alternative means of providing support as bridge until an organ becomes available.

## 1.5 Proposed Treatment

NHS Blood and Transplant (NHS BT) are responsible for organ allocation. In May 2017 NHS BT introduced a Super Urgent Lung Allocation Scheme (SULAS) which gives priority to critically ill patients awaiting transplants. The waiting time to lung transplant for this group of critically ill patients is on average 8 days. The introduction of this change to the national waiting list gives this group of patients a realistic chance of a transplant within a short timeframe. SULAS listing is only available to patients on ECMO or equivalent treatment.

ECMO is provided for critically ill people in a level 3 critical care area. Blood is removed from the patient's circulation and passes through a gas exchange device before being returned to the circulation. ECMO removes blood from the venous circulation which is then pumped through a gas exchange device and is returned to either the arterial circulation (venoarterial (VA) ECMO) or the venous circulation (veno-venous (VV) ECMO). VV ECMO provides respiratory support only whereas VA ECMO can provide full cardiorespiratory support.

The rationale for the use of ECMO in these critically ill patients who are refractory to maximal respiratory support is that it is the only treatment available that will allow them a chance to survive to transplant. Without ECMO these patients will inevitably die within hours.

Developments in ECMO technology combined with improvements in patient selection have made it possible to successfully bridge to transplant a group of carefully selected extremely sick patients[4] and have resulted in 1-year

[3] NHS Blood and Transplant (NHSBT) (2017). Annual report on cardiothoracic organ transplantation: Report for 2016/2017. NHSBT

[4] Hoetzenecker K, Donahoe L, Yeung JC, Azad S, Fan E, Ferguson ND, Del Sorbo L, de Perrot M, Pierre A, Yasufuku K, Singer L, Waddell TK, Keshavjee S, Cypel M. Extracorporeal life support as a bridge to lung transplantation-experience of a high-

survival post-transplant nearly equivalent to that seen in patients not receiving any bridging support, and a near doubling of the 5-year post-transplant survival over this time[5]. Traditionally, patients on ECMO have been sedated and bedbound to prevent inadvertent cannula dislodgement and to deal with agitation but it can also be performed on patients who are awake and ambulating[6].

## 1.6 What NHS Wales has decided

WHSSC has carefully reviewed the relevant guidance issued by NHS England[7]. We have concluded that ECMO should be made available within the criteria set out in section 2.1.

volume transplant center. J Thorac Cardiovasc Surg. 2018 Mar;155(3):1316-1328.e1. doi: 10.1016/j.jtcvs.2017.09.161. Epub 2017 Nov 22. PMID: 29248282.

[5] Hayanga AJ, Aboagye J, Esper S, Shigemura N, Bermudez CA, D'Cunha J, Bhama JK. Extracorporeal membrane oxygenation as a bridge to lung transplantation in the United States: an evolving strategy in the management of rapidly advancing pulmonary disease. J Thorac Cardiovasc Surg. 2015 Jan;149(1):291-6. doi: 10.1016/j.jtcvs.2014.08.072. Epub 2014 Sep 17. PMID: 25524684.

[6] Cypel M, Keshavjee S. Extracorporeal membrane oxygenation as a bridge to lung transplantation. ASAIO J. 2012 Sep-Oct;58(5):441-2. doi: 10.1097/MAT.0b013e3182694a10. PMID: 22929900.

[7] Extracorporeal membrane oxygenation (ECMO) as a bridge to lung transplant (all ages)

# 2. Criteria for Commissioning

The Welsh Health Specialised Services Committee has approved funding of ECMO as a bridge to lung transplant for people of all ages, in line with the criteria identified in the policy.

## 2.1 Inclusion Criteria

Patients eligible for Lung Transplantation, consistent with The International Society of Heart and Lung Transplant Guidelines[8] who subsequently suffer unexpected and sustained acute deterioration (where their own lungs are no longer able to sustain life despite all other therapeutic interventions) can be considered for ECMO support.

This pathway begins once the patient is on the waiting list for a lung transplant (registered on the non-urgent or urgent scheme) under the care of a cardiothoracic transplant centre.

The decision to commence ECMO support will be subject to a multidisciplinary team (MDT) review consisting of the:

- on-call surgeon
- transplant respiratory physician
- duty intensive care consultant.

ECMO support should be considered in patients if there is a reasonable expectation that they:

- will have good rehabilitation potential which usually means a relatively short duration of severe illness to minimise the risks of prolonged ITU stay and post-operative complications
- are likely to remain free from extra-pulmonary organ failure and clinically stable on ECMO without severe infection
- will not clinically deteriorate to the point of becoming dependent on intermittent positive-pressure ventilation (IPPV) in an intensive care unit.

Paediatric patients will need to fulfil the criteria above but may be sedated throughout ECMO.

## 2.2 Exclusion Criteria

Patients will not be eligible for ECMO when the local MDT concludes the patient does not have a reasonable chance of intermediate survival; for example, is felt to be <50% probability of surviving 3-5 years post-transplant.

Patients requiring re-transplantation will not have access to ECMO BTT.

[8] https://ishlt.org/publications-resources/professional-resources/standards-guidelines/professional-guidelines-and-consensus-documents

## 2.3 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

## 2.4 Patient Pathway (Annex i)

This pathway begins once the patient is on the waiting list for a lung transplant (registered on the non -urgent or urgent scheme) under the care of a cardiothoracic transplant centre.

Where a patient on a non-urgent or urgent lung transplant waiting list suffers acute deterioration, their suitability for ECMO and SULAS will be discussed by the MDT at the lung transplant centre. If the patient is suitable, they are placed on ECMO; if the patient is not suitable, they remain on the non-urgent or urgent waiting list.

## 2.5 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

## 2.6 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties and for children, teenagers and young adults.

The following information will be collected for all patients treated with ECMO for bridge to lung transplant and uploaded to the NHS England Quality Surveillance Intelligence System portal:

- Time per patient on ECMO
- Mortality rate on ECMO
- Complications on ECMO
- Period of dialysis if required
- Quality of Life at 3-months and 1-year post-transplant
- Patient survival post-transplant (collected by NHS BT).

Information on age of patient and clinical history will be recorded and presented to the Cardiothoracic Transplant annual clinical meeting. The application of the eligibility criteria by centre and overall impact of this policy on the waiting list will be kept under review in collaboration with NHS BT. Future need for review of starting and stopping criteria and the patient pathway will be decided in collaboration with NHS BT.

## 2.7 Responsibilities

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

Clinicians considering treatment should:

- discuss all the alternative treatments with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances an IPFR must be submitted.

Eligible patients placed on ECMO should be registered for the Super Urgent Lung Allocation Scheme (as per NHSBT Policy 231/3[9]).

Patients receiving ECMO support while conscious and self -ventilating (which can include having a tracheostomy with intermittent support) have the highest expectation of a good outcome following lung transplantation

[9] NHS Blood and Transplant (NHSBT) (2018). Lung Candidate Selection Criteria. NHSBT POL231/3.

and can be supported to lung transplantation with ECMO bridge to lung transplant.

Patients will need to be appropriately consented and consideration given to the potential for end of life scenarios to be available to patients awake on ECMO without an offer of suitable organs.

## 3. Documents which have informed this policy

The following documents have been used to inform this policy:

- **NHS England policies**
  - Clinical Commissioning Policy: Extracorporeal membrane oxygenation (ECMO) as a bridge to lung transplant (all ages) (210501P) [URN 1803]

This document should be read in conjunction with the following documents:

- **NHS Wales**
  - All Wales Policy: Making Decisions in Individual Patient Funding requests (IPFR).

## 4. Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision.

# 5. Putting Things Right

## 5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for NHS Putting Things Right. For services provided outside NHS Wales the patient or their representative should be guided to the NHS Trust Concerns Procedure, with a copy of the concern being sent to WHSSC.

## 5.2 Individual Patient Funding Request (IPFR)

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, an IPFR should be submitted.

Further information on making IPFR requests can be found at: Welsh Health Specialised Services Committee (WHSSC) | Individual Patient Funding Requests

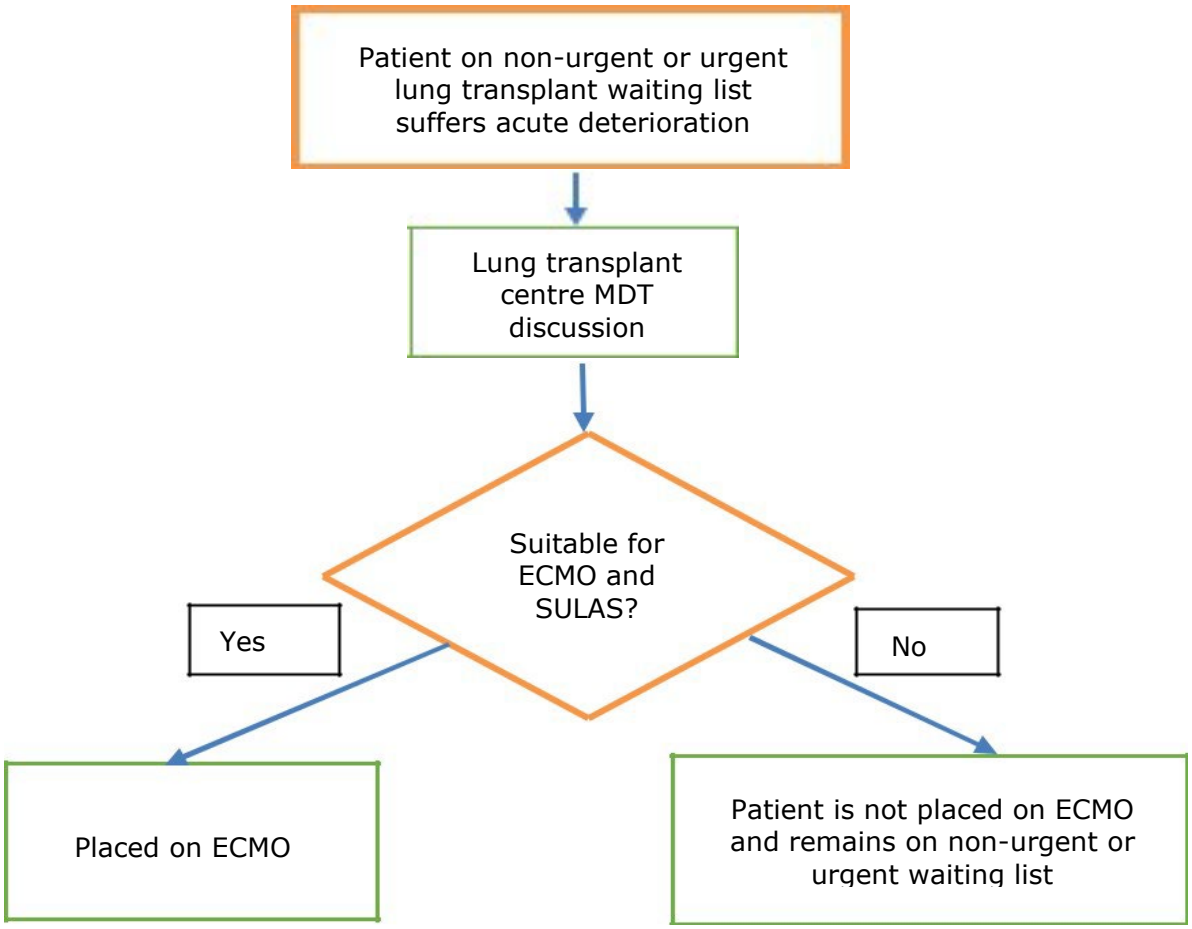
# 6. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

# Annex i Patient Pathway



# Annex ii Codes

| Code Category | Code | Description |
|---|---|---|
| ICD-10 | J96 | Respiratory failure |
| OPCS-4 | X58.1 | Extracorporeal membrane oxygenation |

# Annex iii Abbreviations and Glossary

## Abbreviations

**BTT** Bridge to Lung Transplant

**ECMO** Extracorporeal Membrane Oxygenation

**IPFR** Individual Patient Funding Request

**IPPV** Intermittent Positive-Pressure Ventilation

**MDT** Multi-disciplinary team

**MV** Mechanical Ventilation

**SULAS** Super Urgent Lung Allocation Scheme

**WHSSC** Welsh Health Specialised Services Committee

## Glossary

### Bridge to Lung Transplant (BTT)

Patients with end stage lung disease waiting for a lung transplant who have acutely worsening respiratory failure may need respiratory support to keep them alive until a transplant is available, i.e. to bridge them to transplant.

### Extracorporeal Membrane Oxygenation (ECMO)

A technique for providing respiratory support for those people whose lungs are no longer able to sustain life despite all other therapeutic and supportive interventions. Blood is removed from the patient's circulation and passes through a gas exchanged device before being returned to the circulation.

### Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

### Intermittent positive-pressure ventilation (IPPV)

Intermittent positive-pressure ventilation, the provision of mechanical ventilation by a machine designed to deliver breathing gas until equilibrium is established between the patient's lungs and the ventilator.

### Level 3 Critical Care

Patients requiring advanced respiratory support alone or monitoring and support for two or more organ systems. This level includes all complex patients requiring support for multi-organ failure.

**Mechanical Ventilation (MV)**

A type of artificial ventilation where a ventilator assists or replaces breathing, often with a tube placed down the trachea under sedation. It is used when a patient's own breathing cannot support them.

**Super Urgent Lung Allocation Scheme (SULAS)**

This was introduced in 2017 with the aim of improving access to transplants for the sickest patients on the transplant list. Previously, patients were prioritised by individual transplant centres when a suitable donor became available. Patients who are rapidly deteriorating on waiting lists can now be registered for a super urgent transplant.

**Welsh Health Specialised Services Committee (WHSSC)**

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.