NHS England

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1803
Policy Title	Extracorporeal membrane oxygenation (ECMO) for bridge to lung transplant (all ages) [1803]
Proposal	**for routine commission**(ref A3.1)

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About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes with each theme setting out a number of questions.
- All figures should be provided up to 5 years only.
- The cost per patient methodology is impact against Year 0 rather than incrementally against the previous year.
- All questions are answered by selecting a drop-down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.
- A bespoke financial model should be developed unless agreed otherwise. This will be worked up against a checklist of inputs/considerations. This will include the approach to regional allocations which will also be outlined in the Commissioning Plan.

Section A - Activity Impact	
A1 Activity *To be completed by the Clinical Policy Team*	
A1.1 Provide the number of patients eligible for the treatment. If different, also provide the number of patients accessing treatment. Include OPCS codes where applicable.	22 *Source: PWG, data from NHS BT extrapolated to national cohort* Please specify X58.1 for ECMO 21 adults with an estimation of one paediatric case per annum. On 31st March 2019 283 patients from England were on the national lung transplant list. In 1819 138 lung transplants took place.
A2 Existing Patient Pathway (complete where additional information outside the policy proposition is likely to be beneficial) *To be completed by the Clinical Policy Team*	
A2.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Lung transplantation is routinely performed for selected patients with respiratory failure. However, approximately 25% of patients on the waiting list die before a suitable donor becomes available or are removed from the waiting list due to deteriorating health rendering lung transplantation futile and inappropriate. Traditionally, mechanical ventilation (MV) has formed the mainstay of this bridging support but it is not sufficient for all patients and has been associated with complications and poor post-transplant outcomes (Todd et al 2017) which means that lung transplants are rarely performed in invasively ventilated patients any more. Patients who endure an acute deterioration are highly unlikely to survive without extracorporeal support. *Source: NHS BT and Policy Evidence Review*

A2.2 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Choose to initiate treatment c) Comply with treatment	If not known, please specify Click here to enter text or 'Not applicable'.. a) 100 b) 100 c) 100 d) enter % *Source:* PWG
A3 Comparator (next best alternative treatment) Patient Pathway **(NB: comparator/next best alternative does not refer to current pathway but to an alternative option)** *To be completed by the Clinical Policy Team*	
A3.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** If yes, Click here to enter text. *Source: required*
A3.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criterion following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	'Not applicable'. a) enter % b) enter % c) enter % d) enter % e) enter % *Source: required*
A4 New Patient Pathway	

To be completed by the Clinical Policy Team	
A4.1 Specify the nature and duration of the proposed new treatment or intervention. For example, patients receive a course of treatment over 6 cycles with the drug being administered via IV infusion on days 1 and 3 of each cycle. Include OPCS codes where applicable.	**Time limited** For time limited treatments, specify frequency and/or duration, as well as start and stop rates and mortality rates, as well as details of what happens if a patient does not start or stop. ECMO is a technique for providing respiratory support for patients whose lungs are no longer able to sustain life despite all other therapeutic and supportive interventions. Treatment is provided for critically ill people in a level 3 critical care area. Data from one hospital can be used to understand length of time on ECMO as this Trust has been using ECMO BTT and listing patients super urgently. The average wait time on the SULAS was eight days between May 2017 and January 2019. The activity related to ECMO prior to lung transplantation may be identified in SUS using the OPCS code X58.1 Extracorporeal membrane oxygenation – and the relevant ICD10 code for lung transplantation Z94.2. *Source: NHS BT*
A5 Treatment Setting *To be completed by the Clinical Policy Team*	
A5.1 How is this treatment delivered to the patient?	Lung transplantation is delivered in 5 adult centres and 2 paediatric centres in England. Patients would be on ITU in these hospitals. This small patient cohort would be on ITU in these hospitals already prior to ECMO being agreed as a treatment option.

A5.2 What is the current number of contracted providers for the eligible population by region?	These services are commissioned to provide lung transplantation in England and would be where patients would be put on ECMO. **Adult services by Region** London: Royal Brompton and Harefield NHS Foundation Trust; East of England: Royal Papworth Hospital NHS Foundation Trust; Midlands - University Hospitals Birmingham NHS Foundation Trust North West Region: University Hospital of South Manchester NHS Foundation Trust; North East: The Newcastle Upon Tyne Hospitals NHS Foundation Trust; **Paediatric services by Region** London: Great Ormond Street Hospital for Children NHS Foundation Trust North East: The Newcastle Upon Tyne Hospitals NHS Foundation Trust; These services currently use ECMO to bridge lung transplant patients in the immediate post post-operative period only.
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	No change in delivery setting and no change in capacity requirements. Eligible patients would be in ITUs in hospital already, the use of ECMO would be an additional treatment option available for a small number of patients who meet the clinical criteria.
A6 Coding	

<table>
<tr><td>A6.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity</td><td>Select all that apply:
<table><tr><td>Aggregate Contract Monitoring *</td><td>☐</td></tr><tr><td>Patient level contract monitoring</td><td>☐</td></tr><tr><td>Patient level drugs dataset</td><td>☐</td></tr><tr><td>Patient level devices dataset</td><td>☐</td></tr><tr><td>Devices supply chain reconciliation dataset</td><td>☐</td></tr><tr><td>Secondary Usage Service (SUS+)</td><td>☒</td></tr><tr><td>Mental Health Services Dataset (MHSDS)</td><td>☐</td></tr><tr><td>National Return**</td><td>☒</td></tr><tr><td>Clinical Database**</td><td>☐</td></tr><tr><td>Other**</td><td>☒</td></tr></table>**If National Return, Clinical database or other selected, please specify: Data on each patient would be returned to NHS BT as part of monthly monitoring reports.</td></tr>
<tr><td>A6.2 Specify how the activity related to the new patient pathway will be identified.</td><td>Patient level data will be submitted by centres to NHS BT.</td></tr>
<tr><td>A6.3 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u>
If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).
Click here to enter text.</td></tr>
</table>

	If the device is not excluded from Tariff **nor** covered within existing National or Local prices, please specify details of action required and confirm that this has been discussed with the HCTED team. Click here to enter text.
A6.4 **Identification Rules for Activity:** How are activity costs captured? (e.g., are there first and follow up outpatient appointments?)	**Already captured by an existing specialised service line (NCBPS code) within the PSS Tool but needs amendment** If activity costs are already captured, please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). NCBPS29F Extra corporeal membrane oxygenation If activity costs are already captured, please specify whether this service needs a separate code. **No** If the activity is captured but the service line needs amendment, please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. Not as yet If the activity is not captured, please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item.
Section B - Service Impact *To be completed by the Lead Commissioner*	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Lung transplantation including management of patients on the waiting list is delivered in 5 adult centres and 2 paediatric centres. Referral into these services would internal or from other specialised services *Source: required*

B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: Click here to enter text. *Source: required*
B2 Geography & Access	
B2.1 How is the service currently accessed (e.g., self-referral, referral from GP, secondary care, other)	Please specify: Referral are from specialised respiratory centres.
B2.2 What impact will the new policy have on the sources of referral?	**No impact** Please specify: Click here to enter text.
B2.3 Is the new policy likely to improve equity[1] of access?	**Increase** Please specify: National access to both listing and transplantation is monitored by NHS BT on behalf of NHS England and reported on annually. Though this data we know is geographic access is currently equitable. Access to ECMO BTT is at present inequitable across England as one Trust only is currently use ECMO BTT for a small number of patients. *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*

[1] https://www.england.nhs.uk/wp-content/uploads/2016/02/nhse-specific-duties-equality-act.pdf

B2.4 Is the new policy likely to improve equality[1] of access and/or outcomes?	**No impact** Please specify: Use of ECMO BTT would not lead to changes being made with regard to access to treatment for patients with protected characteristics. *Source: Equalities Impact Assessment (NB. this should be completed during Clinical Build/Impact Assessment phases)*
B3 Commissioning Responsibility	
B3.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. new service (NHS England responsibility), future CCG lead, devolved commissioning arrangements, STPs)	**No change - NHSE** Please specify: Click here to enter text.
Section C - Finance Impact *To be completed by the Finance Lead with the exception of C1.2*	
C1 Tariff/Pricing	
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	*Select all that apply:*

Drugs	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff – pass through	☐
	Excluded from tariff – other	☐
Devices	Not separately charged – part of local or national tariffs	☐

		Excluded from tariff (excluding HCTED programme) – pass through	☐
		Excluded from tariff (excluding HCTED) – other	☐
		Via HCTED model	☐
	Activity	Paid entirely by National Tariffs	☐
		Paid entirely by Local Tariffs	☒
		Partially paid by National Tariffs	☐
		Partially paid by Local Tariffs	☐
		Part/fully paid under a Block arrangement	☐
		Part/fully paid under Pass-Through arrangements	☐
		Part/fully paid under Other arrangements	☐
C1.2 **Drug Costs** *(to be completed by the Clinical Policy Team)* Where not included in national or local tariffs, list each drug or combination, dosage, quantity, **list** price including VAT if applicable and any other key information e.g. Chemotherapy Regime, homecare costs. Provide a basis for this assumption. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable		
C1.3 **Device Costs** *(to be completed by LC)* Where not included in national or local tariff, list each element of the excluded device, quantity, **list or expected** price including VAT if applicable and any other key information.	Not applicable		

NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	
C1.4 **Activity Costs covered by National Tariffs** *(to be completed by Finance)* List key HRG codes and descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %). Include details of first and follow up outpatient's appointment etc.	Not applicable
C1.5 **Activity Costs covered by Local Tariff** *(to be completed by Finance)* List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	Providers charge for ECMO on a locally agreed bed day rate. The only Trust who currently provides ECMO as BTT are the Royal Brompton and Harefield. The Trust has supplied its costs for the service to support modelling. This is based on its ECMO bed day cost plus additional consumables. As there has only been a couple of Paeds cases so the model uses an average Paeds ECMO cost including consumables
C1.6 **Other Activity Costs not covered by National or Local Tariff** *(to be completed by Finance)* Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval/notification mechanisms required either during implementation or permanently?	**No** Please specify: Click here to enter text.
C2 Average Cost per Patient	
C2.1 What is the average cost per patient per year for 5 years, including follow-up where required?	The weighted average cost per patient is £42,218. The treatment is a one-off treatment not on going.

C3 Overall Cost Impact of this Policy to NHS England	
C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. Use list prices where drugs and devices are included. Commercial in confidence discounts are not included therefore the actual cost pressure may be lower than stated.	**Based on a start date of October 2020** Year 1: £464k Year 2: £929k Year 3: £929k Year 4: £929k Year 5: £929k
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	N/A
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been identified, and calculated?	N/A
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost neutral** Budget impact for providers:

	Cost neutral
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost pressure** Year 1: £464k Year 2: £929k Year 3: £929k Year 4: £929k Year 5: £929k
C4.3 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No** Please specify: Click here to enter text.
C5 Funding	
C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	CPAG prioritisation reserve
C6 Financial Risks Associated with Implementing this Policy	

Year	Cost
Year 1	£464k
Year 2	£929k
Year 3	£929k
Year 4	£929k
Year 5	£929k

C6.1 Describe the parameters used to generate the low, mid and high case scenarios for patient numbers and activity. Specify the range.	Not Applicable
C6.2 What scenario has been recommended and why? What would be the impact of a discounted scenario?	Not Applicable due to low volume of patients within the policy
C7 Cost Profile	
C7.1 Factors which impact on costs	**No** If yes, specify type and range: Click here to enter text.

The full integrated impact assessment should be used for all clinical commissioning policies and for policy statements which are proposing a for routine commissioning position. The rapid impact assessment template should be used for urgent policy statements and for policy statements which are proposing not for routine commissioning

Appendix A – Current Patient Population & Demography / Growth (for Public Health Lead to complete)

		Source	*Please specify any further detail*
Number of patients who meet the proposed commissioning criteria and who would be treated if the proposal is approved per year.	*22*		

<table>
<tr>
<td>Age group for which the treatment is proposed according to the proposed criteria</td>
<td>All ages, though the majority of use will be in adults, use in children will be rare and has been assessed at only one patient per year.(</td>
<td>Actual data from NHS BT, summarised in the additional report which accompanied the consultation (65,33,33.29,66, 38,24,23,61,57,19,43,57,44,34, 33,55,35,30)</td>
<td></td>
</tr>
<tr>
<td>Age distribution of the patient population eligible according to the proposed criteria</td>
<td>All ages. According to the criteria for transplantation all patients must be biologically fit, regardless of age. In practice, most recipients are less than 65 years of age as there is an increase in co-morbidity with the ageing process.</td>
<td>NHS England service specification 170006/S lung transplantation in adults</td>
<td></td>
</tr>
<tr>
<td>How is the population currently geographically distributed</td>
<td>Evenly
<table>
<tr><td>North</td><td>enter %</td></tr>
<tr><td>Midlands & East</td><td>enter %</td></tr>
<tr><td>London</td><td>enter %</td></tr>
<tr><td>South</td><td>enter %</td></tr>
</table>
</td>
<td>Policy proposition (section 6)

Annual assessment is made of geographic equity of access to transplant. 1819 data shows equity across England. The funding would best be distributed according to the provider transplant activity, with the paediatric funding split across the 2 paediatric lung transplant centres.</td>
<td>Activity can be broadly expected to split over the transplant centres according to activity.

<u>Lung Transplant data by centre</u>
<table>
<tr><th>Provider</th><th>Lung tx activity 18/19</th><th>% total</th><th>Waiting list 31/3/19</th><th>% total</th></tr>
<tr><td>Harefield</td><td>48</td><td>0.35</td><td>112</td><td>0.33</td></tr>
<tr><td>Manchester</td><td>19</td><td>0.14</td><td>58</td><td>0.17</td></tr>
<tr><td>Papworth</td><td>42</td><td>0.31</td><td>35</td><td>0.10</td></tr>
<tr><td>UHB</td><td>14</td><td>0.10</td><td>46</td><td>0.13</td></tr>
<tr><td>Newcastle</td><td>13</td><td>0.10</td><td>92</td><td>0.27</td></tr>
<tr><td>Total</td><td>136</td><td>1</td><td>343</td><td>1</td></tr>
</table>
</td>
</tr>
</table>

What are the growth assumptions for the disease / condition?	*Small – ONS growth only used*	*Policy proposition (section 6)*	
Is there evidence of current inequalities in access to service or outcomes?	*ECMO is currently not funded as part of the lung transplant programme as a bridge to transplant, only post-transplant*		
Is there evidence that implementing the policy/service specification will improve current inequities of access or outcomes?	*Royal Brompton and Harefield currently use ECMO as a BTT so there is currently inequity in access to treatment. Funding will ensure equity of access and will be monitored*		