Commissioning Policy (WM/22)

Extracorporeal Cardiac Life Support (Paediatrics) (ECLS)

Version 2 – June 2010

1. Definitions

*Designated provider* means a provider trust which has been assessed and approved by the West Midlands Strategic Commissioning Group to provide a particular specialised service. The assessment is conducted against known capacity requirements and quality standards.

*Nominated provider* means a provider trust which has been approved by the Specialised Commissioning Team (West Midlands) to provide a particular specialised service without a formal assessment. This label implies that the service area and/or the provider is still waiting formal comprehensive assessment.

*Prior Approval* means the prior approval by the responsible Primary Care Trust for an individual patient or a group of patients to access care or treatment, including diagnostics, under a Prior Approval Scheme as set out in paragraphs 3.3 to 3.8 of Schedule 3 Part 1 of the Standard NHS Acute Services Contract 2009/10.

*An individual funding request* is a request received from a provider, or a patient with explicit support from a clinician, which seeks funding for a single identified patient for a specific treatment.

*Exceptional clinical circumstances* refers to a patient who has clinical circumstances which, taken as a whole, are outside the range of clinical circumstances presented by a patient within the normal population of patients with the same medical condition and at the same stage of progression as the patient.
Responsible Primary Care Trust means the Primary Care Trust which discharges the Secretary of State’s functions under the National Health Service Act 2006 for an individual patient.

2. The policy

2.1 This policy applies to any patient for whom a West Midland’s PCT is the Responsible Commissioner.

2.2 Activity will only be sanctioned at a nominated provider or designated provider of ECLS.

The local nominated provider is: Birmingham Children’s Hospital

2.3 ECLS will be commissioned in line with the following patient selection criteria:

ECLS will only be considered in cardiac patients with cardiac (circulatory) failure which is refractory to conventional therapy provided the underlying disease process is potentially reversible. The following patient groups will be considered for support:

Preoperative
- Patients with a surgically correctable cardiac lesion but who cannot be stabilised prior to surgery
- As a bridge to intrathoracic organ transplantation in patients with end stage cardio-circulatory failure prior to transfer to an appropriate centre. This would be carried out only following acceptance by the transplant centre.

Postoperative
- Failure to separate from cardiopulmonary bypass (CPB) following surgical correction / palliation
- Refractory low cardiac output post correction / palliation of surgical lesion
- Low cardiac output following resuscitation from cardiopulmonary arrest following cardiac surgery

Non surgical
- Refractory low cardiac output secondary to a reversible cause

The decision to place a patient on ECLS will be on an individual case basis using internationally accepted criteria and will involve discussion between the patient’s consultant and the ECLS team. Parents must be fully informed of the risks and benefits of ECLS support, including the fact that such support is only temporary and withdrawal of ECLS may result in the death of the child at that time.

The following are contraindications to the use of ECLS:

- Ongoing cardiopulmonary resuscitation (except in cases of drowning or hypothermia where CPR is not considered to be a contraindication)
- Irreversible multi-organ dysfunction
- Brain death
- Contraindication to prolonged anticoagulation
- Prolonged mechanical ventilation (>10 days for neonates; >7 days for children)
- Severely reduced long-term functional ability
- Gestation less than 34 weeks post conceptual age

**Stopping ECLS**

Each child is predicted to receive an average of four days mechanical circulatory (ECLS) support.

The reported world experience suggests that failure of recovery by 72 hours support is associated with a very poor prognosis.

The ECLS team will formally review and manage the patient daily.

The ECLS team will co-ordinate a multi-disciplinary meeting on day 3, 5 and 7 to decide on future management. No sign of clinical recovery after ECLS support for 5 days is a poor prognostic indicator suggestive that withdrawal from treatment should be considered.

2.4 Provision of ECLS to any patient falling outside the criteria set out above will not routinely be funded and such a patient would need to become the subject of an individual funding request.

2.5 Group prior approval applies to this treatment.

2.6 The responsible PCT is prepared to consider providing funding for individual patients who are able to demonstrate exceptional clinical circumstances. Any such applications will be considered by the PCT under its Individual Funding Request policy and other relevant policies and operating procedures.

Individual funding requests should be initially sent to the West Midlands Specialised Commissioning Team.

2.7 The nominated provider should ensure that all activity is audited annually and patient outcomes assessed. The provider should ensure that this information is available on request (which will normally be requested at the time of review of this policy). Information which is gathered should include:

- Minimum data set: age, GP, PCT of residence, ethnicity
- Indications for ECLS
- Number of days on ECLS
- Length of stay in PICU
- Number of pumps/oxygenators actually consumed per patient
- Outcomes: death/ discharge
  - clinical state at discharge
    (ideally process for clinical state at one year and 5 years to be monitored)
- Unexpected adverse incidents
3. Commissioning structure

This service is commissioned by the Specialised Commissioning Team (West Midlands) on behalf of the 17 Primary Care Trusts in the West Midlands.

4. Documents which have informed this policy

- West Midlands Specialised Commissioning Team Operational Procedures: Priority Setting (in development)
- West Midlands Specialised Commissioning Team Operational Procedures: Individual Funding Requests
- West Midlands Strategic Group Commissioning Policy 1: Ethical Framework to support priority setting and resource allocation within collaborative commissioning arrangements
- West Midlands Strategic Group Commissioning Policy 4: Use of cost-effectiveness, value for money and cost effectiveness thresholds
- West Midlands Strategic Group Commissioning Policy 16: Prior approval
- West Midlands Strategic Group Commissioning Policy 9: Individual funding requests
- Background paper for West Midlands PCTs, Business case for the development of a cardiac extra corporeal life support (ECLS) capability at Birmingham Children's Hospital, October 2008
• NHS Confederation Priority Setting Series, 2008,
  http://www.nhsconfed.org/publications/prioritysetting/Pages/Prioritysetting.aspx

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<td>Version</td>
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<tr>
<td>Date of next review</td>
<td>Any revisions to the policy will be based on local and national evidence of effectiveness and cost effectiveness together with recommendations and guidelines from local, national and international clinical professional bodies. Minimum 3 yearly</td>
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<td>Acknowledgements</td>
<td>Dr Kristina Routh, Dr Fiona Reynolds</td>
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