

CLINICAL PRIORITIES ADVISORY GROUP
06 and 07 November 2018

Agenda Item No	02.2
National Programme	Women and Children
Clinical Reference Group	Paediatric Neurosciences
URN	170106S

Title (Insert Service Specification title in full)

Open fetal surgery to treat fetuses with open spina bifida

Actions Requested	<ol style="list-style-type: none"> 1. Support the adoption of the service specification proposition 2. Recommend the relative priority
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Proposition

This is a new service specification for a service currently commissioned by NHS England.

Spina bifida occurs in early pregnancy (before the sixth week) in around 4 in 10,000 pregnancies. It is where the spinal column and spinal cord are not properly formed, leaving nerves exposed. The exact cause is unknown. Several factors may be associated with the condition, such as insufficient folate (a B vitamin) in the diet and there are also hereditary factors.

Every person with spina bifida is unique, meaning there is a large variety of possible effects, from mild to severe. Typical problems include weakness in the feet or legs, leading to an inability to walk in some children and problems with bladder and bowel control. It can also lead to excess fluid building up in the brain, (a condition called hydrocephalus). In the UK, surgery is currently offered after the baby is born although open fetal (in utero) surgery is available in mainland Europe and some women from the UK are accessing this. This access was confirmed via the agreement of an Urgent Clinical Commissioning Policy Statement in November 2017.

This specification sets out the proposal for the provision of open fetal (in-utero) surgery and supporting medical services.

Clinical Panel recommendation

The Clinical Panel previously agreed an Urgent Clinical Commissioning Policy Statement.

The committee is asked to receive the following assurance:

1.	The Head of Clinical Effectiveness confirms the proposal has completed the appropriate sequence of governance steps and includes where necessary an: Evidence Review; Clinical Panel Report.
2.	The Head of Acute Programmes confirms the proposal is supported by an: Impact Assessment; Stakeholder Engagement Report; Consultation Report; Equality Impact and Assessment Report; Service Specification Proposition. The relevant National Programme of Care Board has approved these reports.
3.	The Director of Finance (Specialised Commissioning) confirms that the impact assessment has reasonably estimated a) the incremental cost and b) the budget impact of the proposal.
4.	The Operational Delivery Director (Specialised Commissioning) confirms that the service and operational impacts have been completed.
5.	The Director of Nursing (Specialised Commissioning) confirms that the proposed quality indicators have been adequately defined.

The following documents are included (others available on request):

1.	Service Specification Proposition
2.	Consultation Report
3.	Evidence Summary - not applicable
4.	Clinical Panel Report - not applicable
5.	Equality Impact and Assessment Report

The Benefits of the Proposition

No	Metric	Summary of benefit (where applicable)
1.	Survival	
2.	Progression free survival	
3.	Mobility	
4.	Self-care	

5.	Usual activities	
6.	Pain	
7.	Anxiety / Depression	
8.	Replacement of more toxic treatment	
9.	Dependency on care giver / supporting independence	
10.	Safety	
11.	Delivery of intervention	

Considerations from review by the Rare Disease Advisory Group

RDAG supported the service specification for open fetal surgery to treat fetuses with 'open spina bifida'. Members noted that, if an EU-wide provider selection process was undertaken, providers from mainland Europe might bid for the contract.

Pharmaceutical considerations

Not applicable.

Considerations from review by National Programme of Care Board

POC Board support: The proposal received the support of the Women and Children's PoC Board following the September 2018 meeting.

Benefit of Service Specification: Although some women decide to terminate their pregnancy, others do choose to continue with the pregnancy. When a pregnancy is continued, the baby will have postnatal surgery in the woman's regional paediatric neurosurgery unit shortly after it is born.

The Management of Myelomeningocele (MOMS) trial, which is the only evidence-based randomised control trial for this surgery and was published in the New England Journal of Medicine in 2011, demonstrated that certain babies in the womb could benefit from fetal surgery. In the MOMS trial, 77 babies with spina bifida which were operated on whilst still in the womb had:

i) less severe hindbrain herniation; ii) less need for a shunt operation (a tube to drain excess fluid around the brain (hydrocephalus) by one year of age and iii) better leg function at 30 months of age compared to babies who had surgery after

birth. On further follow-up, the babies operated before birth also seemed to have better bladder function, but that evidence is not yet conclusive.

Children who have received pre-natal surgery should have:

- i) less severe hindbrain herniation;
- ii) less need for a shunt operation (a tube to drain hydrocephalus) by one year of age and
- iii) better leg function at 30 months of age.

Also some should have better bladder function.

Implementation timescale: Provider selection required, leading to a likely service implementation date of 01 04 2019.