

Integrated Impact Assessment Report for Service Specifications

Service Specification Reference Number	1782		
Service Specification Title	Open Fetal Surgery to treat fetuses with 'congenital open spina bifida', (the main types of which are myelomeningocele and myeloschisis) (Children)		
Lead Commissioner	Bernie Stocks	Clinical Lead	Tim Watts
Finance Lead	Jazz Nandra	Analytical Lead	Jazz Nandra

Integrated Impact Assessment – Index

Section A – Activity	Section B - Service	Section C – Finance
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this service specification to NHS England
A4 Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this service specification to the NHS as a whole
A5 Service Setting		C5 Funding
A6 Coding		C6 Financial Risks Associated with Implementing this service specification
A7 Monitoring		C7 Value for Money
		C8 Cost Profile

--	--	--

About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- 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 service specification documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact

A1 Current Patient Population & Demography / Growth

A1.1 Prevalence of the disease/condition.	Based on epidemiological estimates, approximately 100 babies are born in England each year with myelomeningocele and myeloschisis, of which 90 will not be suitable for prenatal surgery and up to 10 will. <i>Source: Service Specification Proposition section 3.2</i>				
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	Approximately 10 patients will be eligible (i.e. 10% of the patient cohort as described in A1.1) <i>Source: Specification Working Group</i> Please specify				
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	<u>Other</u> Please specify Feto-maternal				
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	See A1.3 above <i>Source: Specification Working Group</i> Please specify Click here to enter text.				
A1.5 How is the population currently distributed geographically?	<u>Evenly</u> If unevenly, estimate regional distribution by %: <table border="1" style="margin-left: 20px;"> <tr> <td>North</td><td>enter %</td></tr> <tr> <td>Midlands & East</td><td>enter %</td></tr> </table>	North	enter %	Midlands & East	enter %
North	enter %				
Midlands & East	enter %				

	<table border="1"> <tr> <td>London</td><td>enter %</td></tr> <tr> <td>South</td><td>enter %</td></tr> </table> <p>Source: Service specification proposition section 6</p> <p>Please specify</p> <p>No known geographic element to this service.</p>	London	enter %	South	enter %							
London	enter %											
South	enter %											
A2 Future Patient Population & Demography												
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service specification) in 2, 5, and 10 years?	<p><u>Constant</u></p> <p>If other, Click here to enter text.</p> <p>Source: Service specification proposition section 3.1</p>											
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	<p><u>No</u></p> <p>Please specify</p> <p>Click here to enter text.</p> <p>Source: Service specification proposition section 6/other</p>											
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?	<table border="1"> <tr> <td>YR2 +/-</td><td>7</td></tr> <tr> <td>YR3 +/-</td><td>0</td></tr> <tr> <td>YR4 +/-</td><td>0</td></tr> <tr> <td>YR5 +/-</td><td>0</td></tr> <tr> <td>YR10 +/-</td><td>0</td></tr> </table> <p>Due to part year effect.</p>	YR2 +/-	7	YR3 +/-	0	YR4 +/-	0	YR5 +/-	0	YR10 +/-	0	
YR2 +/-	7											
YR3 +/-	0											
YR4 +/-	0											
YR5 +/-	0											
YR10 +/-	0											
Are these numbers in line with ONS growth assumptions for the age												

specific population? If not please justify the growth assumptions made.	<p><i>Source: Service specification proposition section 3.2</i></p> <p><u>Yes</u></p> <p>Click here to enter text.</p>
A3 Activity	
A3.1 What is the purpose of new service specification?	<p><u>Provide service specification for a new service approved to be commissioned by NHS England for the first time in accordance with PSSAG / other recommendation</u></p> <p>*PSSAG (Prescribed Specialised Services Advisory Group)</p> <p>Please specify</p> <p>Click here to enter text.</p>
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	<p>Circa 100 babies receive post-natal repair for spina bifida in England per annum, but only up to 10 women and their fetuses would meet the inclusion criteria set out in the specification, which is evidence based, including the MOMs trial criteria NEJM 2011.</p> <p><i>Source: Specification Working Group, Data from current European Open Fetal Surgery Centres.</i></p> <p>Please specify</p> <p>Click here to enter text.</p>
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	<p>10 in England</p> <p><i>Source: Specification Working Group.</i></p> <p>Please specify</p> <p>Click here to enter text.</p>

A4 Patient Pathway	
A4.1 Patient pathway Describe the current patient pathway and service.	Pre-natal repair in Europe. Pathway is similar to proposed pathway, with initial and follow on outpatient review and any additional inpatient treatment in England. <i>Source: Specification Working Group.</i>
A4.2. What are the current service access and stopping criteria?	Babies born with a diagnosis of myelomeningocele require transfer to a paediatric neurosurgical centre. Surgery to repair the myelomeningocele should be carried out within 48 hours of birth. Surgery is offered to all infants with this diagnosis unless there are severe life threatening co-morbidities that mean the child is unlikely to survive the neonatal period. Source: Specification Working Group
A4.3 What percentage of the total eligible population are: a) Referred b) Meet any existing criteria for care c) Considered to meet any existing exclusion criteria	If not known, please specify Click here to enter text. a) 100% b) Up to 10 patients = up to 10% c) 100% of b) Source: Specification Working Group
A4.4 What percentage of the total eligible population is expected to: a) Be referred to the proposed service b) Be eligible for care according to the proposed criteria for the service c) Take up care according to the proposed criteria for the service d) Continue care according to the proposed criteria for the service?	If not known, please specify n/a a) 100% b) Up to 10% c) 100% of b) d) 100% of c) e) <i>Source: Specification working Group.</i>

A4.5 Specify the nature and duration of the proposed new service or intervention.

Time limited

For time limited services, specify frequency and/or duration.

Presentation and identification of the condition occurs circa 19+0 weeks gestation at the anomaly scan. If the woman meets the criteria and is willing to proceed with surgery on her fetus, and her fetus also meets the inclusion criteria, surgery must take place before 25.6 weeks gestation.

Source: Specification Working Group; MOMS Trial 2011, Leuven Clinical team.

A5 Service Setting

A5.1 How is this service delivered to the patient?

Select all that apply:

Emergency/Urgent care attendance	<input type="checkbox"/>
Acute Trust: inpatient	<input checked="" type="checkbox"/>
Acute Trust: day patient	<input checked="" type="checkbox"/>
Acute Trust: outpatient	<input checked="" type="checkbox"/>
Mental Health provider: inpatient	<input type="checkbox"/>
Mental Health provider: outpatient	<input type="checkbox"/>
Community setting	<input type="checkbox"/>
Homecare	<input type="checkbox"/>
Other	<input type="checkbox"/>

Please specify:

[Click here to enter text.](#)

A5.2 What is the current number of contracted providers for the eligible population by region?	<table border="1"> <tr> <td>NORTH</td> <td>0</td> </tr> <tr> <td>MIDLANDS & EAST</td> <td>0</td> </tr> <tr> <td>LONDON</td> <td>0</td> </tr> <tr> <td>SOUTH</td> <td>0</td> </tr> </table>	NORTH	0	MIDLANDS & EAST	0	LONDON	0	SOUTH	0								
NORTH	0																
MIDLANDS & EAST	0																
LONDON	0																
SOUTH	0																
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	<p>yes Please specify:</p> <p>This service specification will lead to a provider selection process to identify a small number of (one to two) Fetal Surgery Centres with the requisite expertise and experience to undertake open pre-natal surgery.</p> <p><i>Source:</i> Specification Working Group</p>																
<p>A6 Coding</p>																	
<p>A6.1 Specify the datasets used to record the new patient pathway activity.</p> <p>*expected to be populated for all commissioned activity</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>Aggregate Contract Monitoring *</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level contract monitoring</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Patient level drugs dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Patient level devices dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Devices supply chain reconciliation dataset</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary Usage Service (SUS+)</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Mental Health Services DataSet (MHSDS)</td> <td><input type="checkbox"/></td> </tr> <tr> <td>National Return**</td> <td><input checked="" type="checkbox"/></td> </tr> </table>	Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>	Patient level contract monitoring	<input checked="" type="checkbox"/>	Patient level drugs dataset	<input type="checkbox"/>	Patient level devices dataset	<input type="checkbox"/>	Devices supply chain reconciliation dataset	<input type="checkbox"/>	Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>	Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>	National Return**	<input checked="" type="checkbox"/>
Aggregate Contract Monitoring *	<input checked="" type="checkbox"/>																
Patient level contract monitoring	<input checked="" type="checkbox"/>																
Patient level drugs dataset	<input type="checkbox"/>																
Patient level devices dataset	<input type="checkbox"/>																
Devices supply chain reconciliation dataset	<input type="checkbox"/>																
Secondary Usage Service (SUS+)	<input checked="" type="checkbox"/>																
Mental Health Services DataSet (MHSDS)	<input type="checkbox"/>																
National Return**	<input checked="" type="checkbox"/>																

	<table border="1"> <tr> <td>Clinical Database**</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Other**</td> <td><input type="checkbox"/></td> </tr> </table>	Clinical Database**	<input checked="" type="checkbox"/>	Other**	<input type="checkbox"/>	<p>**If National Return, Clinical database or other selected, please specify: A clinical database will be established.</p>										
Clinical Database**	<input checked="" type="checkbox"/>															
Other**	<input type="checkbox"/>															
<p>A6.2 Specify how the activity related to the new patient pathway will be identified.</p>	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td>OPCS v4.8</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>ICD10</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Service function code</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>Main Speciality code</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>HRG</td> <td><input checked="" type="checkbox"/></td> </tr> <tr> <td>SNOMED</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Clinical coding / terming methodology used by clinical profession</td> <td><input checked="" type="checkbox"/></td> </tr> </table>		OPCS v4.8	<input checked="" type="checkbox"/>	ICD10	<input checked="" type="checkbox"/>	Service function code	<input checked="" type="checkbox"/>	Main Speciality code	<input checked="" type="checkbox"/>	HRG	<input checked="" type="checkbox"/>	SNOMED	<input type="checkbox"/>	Clinical coding / terming methodology used by clinical profession	<input checked="" type="checkbox"/>
OPCS v4.8	<input checked="" type="checkbox"/>															
ICD10	<input checked="" type="checkbox"/>															
Service function code	<input checked="" type="checkbox"/>															
Main Speciality code	<input checked="" type="checkbox"/>															
HRG	<input checked="" type="checkbox"/>															
SNOMED	<input type="checkbox"/>															
Clinical coding / terming methodology used by clinical profession	<input checked="" type="checkbox"/>															
<p>A6.3 Identification Rules for Drugs: How are any drug costs captured?</p>	<p><u>Not applicable</u></p> <p>If already specified in the current NHS England Drug / Devices List, please specify drug name and indication for all that apply: Click here to enter text.</p> <p>If drug(s) NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead: Click here to enter text.</p>															
<p>A6.4 Identification Rules for Devices: How are device costs captured?</p>	<p><u>Not applicable</u></p> <p>If device(s) covered by an existing category of HCTED please specify the</p>															

	<p>Device Category (as per the National Tariff Payment System Guidance) for all that apply:</p> <p>Click here to enter text.</p> <p>If device(s) 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.</p> <p>Click here to enter text.</p>
<p>A6.5 Identification Rules for Activity:</p> <p>How are activity costs captured?</p>	<p><u>Already captured by an existing specialised service line (NCBPS code) within the PSS Tool but needs amendment</u></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</p> <p>NCBPS23M -Paediatric Neurosciences.</p> <p>If activity costs are already captured please specify whether this service needs a separate code. Choose an item.</p> <p>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.</p> <p>The fetal surgery indicated in this specification currently meets the broad criteria of the Paediatric Neurosurgery specialised service line and therefore, would need to be included. The information team have been requested to make the amendment by the PSS Lead.</p> <p>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.</p>
A7 Monitoring	
A7.1 Contracts	<u>Yes - population of clinical databases</u>

<p>Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p> <p>Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England specialised services commissioning.</p>	<p>Please specify</p>
<p>A7.2 Business intelligence</p> <p>Is there potential for duplicate reporting?</p>	<p><u>No</u></p> <p>If yes, please specify mitigation: Click here to enter text.</p>
<p>A7.3 Contract monitoring</p> <p>Is this part of routine contract monitoring?</p>	<p><u>Yes</u></p> <p>If no, please specify contract monitoring requirement:</p>
<p>A7.4 Dashboard reporting</p> <p>Specify whether a dashboard exists for the proposed service?</p>	<p><u>No</u></p> <p>If yes, specify how routine performance monitoring data will be used for dashboard reporting. Click here to enter text.</p> <p>If no, will one be developed? Yes</p>
<p>A7.5 NICE reporting</p> <p>Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new service specification?</p>	<p><u>No</u></p> <p>If yes, specify how performance monitoring data will be used for this purpose.</p>
<p>Section B - Service Impact</p>	

B1 Service Organisation					
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	<p><i>Pre-natal surgery is funded by the DHSC in mainland Europe under the S2 arrangement.</i></p> <p>Source: NHS England – The Manual</p>				
B1.2 Will the specification change the way the commissioned service is organised?	<p><u>Yes</u></p> <p>Please specify:</p> <p>NHS England will undertake a provider selection process to determine one to two providers with appropriate expertise and infrastructure.</p> <p>Source: <i>required</i></p>				
B1.3 Will the specification require a new approach to the organisation of care?	<p><u>Implement a new model of care</u></p> <p>Please specify:</p> <p>District General Hospital Local Maternity Units refer to Regional Fetal Medicine Units as now, which will undertake preliminary diagnostics and then refer to the 1-2 nationally-commissioned Fetal Surgery Centre (FSC) specialist units for a clinical opinion as to whether the woman and her fetus meet the inclusion criteria on the basis of initial and subsequent test results, further tests and physical assessment. Surgery then follows if all inclusion criteria are met and the woman consents.</p>				
B2 Geography & Access					
B2.1 Where do current referrals come from?	<p>Select all that apply:</p> <table border="1"> <tr> <td>GP</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Secondary care</td> <td><input checked="" type="checkbox"/></td> </tr> </table>	GP	<input type="checkbox"/>	Secondary care	<input checked="" type="checkbox"/>
GP	<input type="checkbox"/>				
Secondary care	<input checked="" type="checkbox"/>				

	<table border="1"> <tr> <td>Tertiary care</td><td><input checked="" type="checkbox"/></td></tr> <tr> <td>Other</td><td><input type="checkbox"/></td></tr> </table> <p>Please specify:</p>	Tertiary care	<input checked="" type="checkbox"/>	Other	<input type="checkbox"/>
Tertiary care	<input checked="" type="checkbox"/>				
Other	<input type="checkbox"/>				
B2.2 What impact will the new service specification have on the sources of referral?	<p><u>No impact</u></p> <p>Please specify:</p> <p>Click here to enter text.</p>				
B2.3 Is the new service specification likely to improve equity of access?	<p><u>No impact</u></p> <p>Please specify:</p> <p>Click here to enter text.</p> <p><i>Source: Equalities Impact Assessment</i></p>				
B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	<p><u>No impact</u></p> <p>Please specify:</p> <p><i>Source: Equalities Impact Assessment</i></p>				
B3 Implementation					
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	<p><u>Procurement action</u></p> <p>Please specify:</p> <p>A provider selection process will be carried out to invite applications from providers who meet a set of essential criteria including expertise, experience and relevant infrastructure.</p>				

<p>B3.2 Time to implementation:</p> <p>Is a lead-in time required prior to implementation?</p>	<p><u>Yes - go to B3.3</u></p> <p>If yes, specify the likely time to implementation: Up to four weeks.</p>
<p>B3.3 Time to implementation:</p> <p>If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p>	<p><u>No - go to B3.4</u></p> <p>If yes, outline the plan:</p>
<p>B3.4 Is a change in provider physical infrastructure required?</p>	<p><u>No</u></p> <p>Please specify:</p> <p>The providers who would be in scope for this service would already have the expertise, the clinical record of undertaking this procedure, be able to demonstrate appropriate outcomes and have the physical infrastructure in place such as appropriate outpatient facilities, inpatient wards, theatres and high level diagnostics.</p>
<p>B3.5 Is a change in provider staffing required?</p>	<p><u>Yes</u></p> <p>Please specify:</p> <p>The required staff should already be employed in the units which would be interested in providing this service, in order to meet the requirement to have pre-existing experience and expertise although the whole time equivalents may need to increase.</p>

<p>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</p>	<p><u>Yes</u> Please specify:</p> <p>a) appropriate caseload to maintain expertise in the treatment of the condition;</p> <p>b) Infrastructure - Co-located (all facilities on one site): fetal surgery clinic capacity, fetal MRI neuroradiology, neonatal intensive care unit (NICU), obstetric high dependency unit, adult intensive care unit, inpatient ward for the care of pregnant women which is staffed by midwives to monitor fetus and nurses, fetal medicine theatre lists, theatres. Fetal surgery will be undertaken in units which have a NICU on site.</p> <p>c) Equipment: technology for MDTs</p> <p>d) Staffing: Obstetrics; Fetal Medicine specialist with expertise in Fetal Surgery (an obstetrician who is a fetal medicine specialist with training in uterine surgery and in undertaking open fetal surgery for spina bifida repair); Fetal medicine; Fetal Surgery, Neonatal medicine (NICU); Paediatric neurosurgery; Paediatric neurodisability; obstetric anaesthetist with expertise in fetal anaesthesia, fetal neuroradiologist or paediatric radiologist comfortable with knowledge and skills of the developing brain and the early diagnosis of brain anomalies to review MRI, adult critical care unit.</p>
<p>B3.7 Are there changes in the support services that need to be in place?</p>	<p><u>No</u> Please specify: All of the above components in B3.6 should already be in place</p>
<p>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p>	<p><u>No</u> Please specify: Providers will be commissioned for the first time in England for this procedure.</p>
<p>B3.9 Is there likely to be either an increase or decrease in the</p>	<p>Choose an item.</p>

number of commissioned providers? If yes, specify the current and estimated number of providers required in each region

Please complete the table:

Region	Current no. of providers	Future State expected range	Provisional or confirmed
North	0	0 to 1	select
Midlands & East	0	0 to 1	select
London	0	0 to 1	select
South	0	0 to 1	select
Total		Maximum of 1-2 units	select

Please specify:

To meet the Provider Selection criteria, providers will need to meet essential criteria and will serve the whole of England. No more than two units will be required because of the very small number of patients involved.

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

Select all that apply:

Publication and notification of new service specification	<input checked="" type="checkbox"/>
Market intervention required	<input type="checkbox"/>
Competitive selection process to secure increase or decrease provider configuration	<input checked="" type="checkbox"/>
Price-based selection process to maximise cost effectiveness	<input type="checkbox"/>
Any qualified provider	<input checked="" type="checkbox"/>
National Commercial Agreements e.g. drugs, devices	<input type="checkbox"/>

	<table border="1"> <tr> <td>Procurement</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Other</td> <td><input checked="" type="checkbox"/></td> </tr> </table>	Procurement	<input type="checkbox"/>	Other	<input checked="" type="checkbox"/>	Please specify: To be confirmed but there will be essential criteria.												
Procurement	<input type="checkbox"/>																	
Other	<input checked="" type="checkbox"/>																	
B4 Place-based Commissioning																		
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	No Please specify: Click here to enter text.																	
Section C - Finance Impact																		
C1 Tariff/Pricing																		
C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway	<p><i>Select all that apply:</i></p> <table border="1"> <tr> <td rowspan="3">Drugs</td> <td>Not separately charged – part of local or national tariffs</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Excluded from tariff – pass through</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Excluded from tariff - other</td> <td><input type="checkbox"/></td> </tr> <tr> <td rowspan="4">Devices</td> <td>Not separately charged – part of local or national tariffs</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Excluded from tariff (excluding ZCM) – pass through</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Excluded from tariff (excluding ZCM) – other</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Via Zero Cost Model</td> <td><input type="checkbox"/></td> </tr> </table>		Drugs	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff – pass through	<input type="checkbox"/>	Excluded from tariff - other	<input type="checkbox"/>	Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>	Excluded from tariff (excluding ZCM) – pass through	<input type="checkbox"/>	Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>	Via Zero Cost Model	<input type="checkbox"/>
Drugs	Not separately charged – part of local or national tariffs	<input type="checkbox"/>																
	Excluded from tariff – pass through	<input type="checkbox"/>																
	Excluded from tariff - other	<input type="checkbox"/>																
Devices	Not separately charged – part of local or national tariffs	<input type="checkbox"/>																
	Excluded from tariff (excluding ZCM) – pass through	<input type="checkbox"/>																
	Excluded from tariff (excluding ZCM) – other	<input type="checkbox"/>																
	Via Zero Cost Model	<input type="checkbox"/>																

	<table border="1"> <tr> <td data-bbox="1084 97 1245 512" rowspan="7">Activity</td> <td data-bbox="1245 97 2056 156">Paid entirely by National Tariffs</td> <td data-bbox="2056 97 2145 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1245 156 2056 215">Paid entirely by Local Tariffs</td> <td data-bbox="2056 156 2145 215"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1245 215 2056 274">Partially paid by National Tariffs</td> <td data-bbox="2056 215 2145 274"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1245 274 2056 333">Partially paid by Local Tariffs</td> <td data-bbox="2056 274 2145 333"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1245 333 2056 392">Part/fully paid under a Block arrangement</td> <td data-bbox="2056 333 2145 392"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1245 392 2056 451">Part/fully paid under Pass-Through arrangements</td> <td data-bbox="2056 392 2145 451"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1245 451 2056 512">Part/fully paid under Other arrangements</td> <td data-bbox="2056 451 2145 512"><input type="checkbox"/></td> </tr> </table> <p data-bbox="1084 564 2145 639">Only post-natal surgery part of the pathway is currently commissioned through fetal surgery providers.</p>	Activity	Paid entirely by National Tariffs	<input type="checkbox"/>	Paid entirely by Local Tariffs	<input checked="" type="checkbox"/>	Partially paid by National Tariffs	<input type="checkbox"/>	Partially paid by Local Tariffs	<input type="checkbox"/>	Part/fully paid under a Block arrangement	<input type="checkbox"/>	Part/fully paid under Pass-Through arrangements	<input type="checkbox"/>	Part/fully paid under Other arrangements	<input type="checkbox"/>
Activity	Paid entirely by National Tariffs		<input type="checkbox"/>													
	Paid entirely by Local Tariffs		<input checked="" type="checkbox"/>													
	Partially paid by National Tariffs		<input type="checkbox"/>													
	Partially paid by Local Tariffs		<input type="checkbox"/>													
	Part/fully paid under a Block arrangement		<input type="checkbox"/>													
	Part/fully paid under Pass-Through arrangements		<input type="checkbox"/>													
	Part/fully paid under Other arrangements	<input type="checkbox"/>														
<p>C1.2 Drug Costs</p> <p>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.</p> <p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	Not applicable															
<p>C1.3 Device Costs</p> <p>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.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p>	Not applicable															
<p>C1.4 Activity Costs covered by National Tariff</p> <p>List all the HRG codes, HRG descriptions, national tariffs (excluding</p>	N/A															

MFF), volume and other key costs (e.g. specialist top up %)		
C1.5 Activity Costs covered by Local Tariff 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 it has been derived, validated and tested.	Surgery is covered by local tariff estimated cost c£12.62k plus market forces factor.	
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	English women who meet the inclusion criteria have been able to travel to mainland Europe for pre-natal surgery for a number of years under the DHSC's S2 arrangement.	
C1.7 Are there any prior approval 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 estimated cost per patient to NHS England, in years 1-5, including follow-up where required? Are there any changes expected in year 6-10 which would impact the model?	YR1	£14.5K
	YR2	£14.5K
	YR3	£14.5K
	YR4	£14.5K
	YR5	£14.5K
	If yes, please specify:	
C3 Overall Cost Impact of this Service specification to NHS England		

C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.	<p><u>Cost pressure</u> The cost pressure is related to the procedure being proposed.</p> <p>Year 1: £43.577K (Part year effect) Year 2: £14526K Year 5: £145.26K</p> <p>Please specify: Click here to enter text.</p>
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable
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?	Not applicable
C4 Overall cost impact of this service specification to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	<p>Budget impact for CCGs: <u>Cost neutral</u> The specification is considered to be cost neutral. If the service specification is not approved, there would be additional longer term cost pressure which is likely to be higher than the cost of the service.</p> <p>Budget impact for providers: <u>Cost neutral</u> Please specify:</p>

	The neurological and other outcomes for babies who receive this procedure are better than those who receive post-natal surgery instead due to stopping the deterioration of the nerve tissue by the amniotic fluid which would otherwise continue.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	<p><u>Cost neutral</u></p> <p>Please specify:</p> <p>The life-long burden of care will be reduced following pre-natal surgery as compared to post-natal surgery due to: i) reduced need for shunting (40% v 82% for post-natal repair; reduced need for surgery for Chiari II malformation (1% v 5%; Walking independently on examination 42% v 21%); and mental development index. (Source: NEJM - MOMS trial 2011).</p>
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	<p><u>Yes</u></p> <p>Please specify:</p> <p>Whilst the child will still have spina bifida, the life-long health, social support, education and other support costs to the child and their family are less as the child is able to function more normally.</p>
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 Service specification			
C6.1 What are the material financial risks to implementing this service specification?	Not applicable.		
C6.2 How can these risks be mitigated?	Not applicable		
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable		
C6.4 What scenario has been approved and why?	Not applicable		
C7 Value for Money			
C7.1 What published evidence is available that the service is cost effective as evidenced in the evidence review?	<p><u>Published evidence indicates service specification has the potential to be cost-effective</u></p> <p>Please specify:</p> <ol style="list-style-type: none"> 1. MOMs trial NEJM March 17 2011 Vol 364, no 11. A randomised trial of prenatal versus postnatal repair of myelomeningocele 2. <i>Evaluating the cost-effectiveness of prenatal surgery for myelomeningocele: a decision analysis Werner et al, Ultrasound Obstet Gynecol 2012; 40:158-164</i> 		
C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?	<p>Select all that apply:</p> <table border="1"> <tr> <td>Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification</td> <td><input checked="checked" type="checkbox"/></td> </tr> </table>	Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification	<input checked="checked" type="checkbox"/>
Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification	<input checked="checked" type="checkbox"/>		

	Available pricing data suggests the service is lower cost compared to current/comparator treatment	<input type="checkbox"/>
	Available clinical practice data suggests the new service specification has the potential to improve value for money	<input type="checkbox"/>
	Other data has been identified	<input type="checkbox"/>
	No data has been identified	<input type="checkbox"/>
	The data supports a high level of certainty about the impact on value	<input type="checkbox"/>
	The data does not support a high level of certainty about the impact on value	<input type="checkbox"/>
	Please specify: Click here to enter text.	
C8 Non-Recurrent Costs		
C8.1 Are there non-recurrent revenue costs associated with this service specification?	<p><u>No</u></p> <p>If yes, please specify and indicate whether these would be incurred or passed through to NHS England:</p> <p>Click here to enter text.</p> <p>If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact.</p> <p>Choose an item.</p>	
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	<p><u>No</u></p> <p>If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs).</p> <p>Click here to enter text.</p>	

