Integrated Impact Assessment Report for Service Specifications			
Service Specification Reference Number	1758		
Service Specification Title	Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse		
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Finance Lead	Jazz Nandra	**Analytical Lead**	

Integrated Impact Assessment – Index		
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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.	15% of all women having any type of surgery for stress urinary incontinence will develop frequency and urgency which will require treatment. 20-30% will not have satisfactory treatment of their stress urinary incontinence following surgery. 1-4% will have long term difficulty emptying their bladder and will need to self-catheterise or have surgery to correct this. 1% of women will have chronic pain at surgical and pelvic sites following any surgery for stress urinary incontinence (this is more common in women with underlying chronic pain conditions such as ME and fibromyalgia.) These complications are common to all stress incontinence operations and result in none complex revision surgery. Mesh specific complications are vaginal exposure (small and large) and extrusion of mesh into adjacent organs. Asymptomatic vaginal erosions of any size would require none complex surgery whilst larger symptomatic vaginal exposure and all extrusions would require complex surgery. It is estimated that the following number of patients will have none complex and complex vaginal mesh complications:- 1. None-Complex = 300-400 2. Complex = 50-100. For the purposes of the impact assessment a mid-point of 75 has been used as baseline. *Source: Service Specification Proposition section 3*
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	Complex = 50-100. For the purposes of the impact assessment a mid-point of 75 has been used as baseline.

<table>
<tr><td></td><td>Source: Service Specification Proposition section 3
Please specify
Click here to enter text.</td></tr>
<tr><td>A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.</td><td>Adults
Source: Service Specification Proposition section 3</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria</td><td>As outlined above, the patients will be adults including patients aged less than 40 years and patients aged 60 years and above.
Source: Service Specification Proposition section 3</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Evenly</u>
If unevenly, estimate regional distribution by %:<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>Source: Service specification proposition</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service</td><td><u>Other - detail below</u>
If other, Possible reductions over time if the number of mesh insertions</td></tr>
</table>

<table>
<tr><td>specification) in 2, 5, and 10 years?</td><td>decline or if mesh insertion as a treatment option is suspended/stopped
Source: Service specification proposition section 3</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Only anticipated changes linked to national population growth rather than changes specific to this cohort.
Source: Service specification proposition section 3/ other</td></tr>
<tr><td>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?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table><tr><td>YR2 +/-</td><td>1</td></tr><tr><td>YR3 +/-</td><td>2</td></tr><tr><td>YR4 +/-</td><td>3</td></tr><tr><td>YR5 +/-</td><td>4</td></tr><tr><td>YR10 +/-</td><td>6</td></tr></table>Source: Financial Model/ published ONS tables

<u>Yes</u>
Click here to enter text.</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new service specification?</td><td><u>Provide service specification document for a service already commissioned by NHS England in accordance with 'The Manual' but without a published specification</u> and to support a procurement programme
Please specify
*PSSAG (Prescribed Specialised Services Advisory Group)</td></tr>
</table>

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	Complex = 50-100. For the purposes of the impact assessment a mid-point of 75 has been used as baseline. *Source: Service specification proposition section 3*
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	Complex = 50-100. For the purposes of the impact assessment a mid-point of 75 has been used as baseline. *Source: Service specification proposition section 3*
A4 Patient Pathway	
A4.1 **Patient pathway** Describe the current patient pathway and service. .	For complex vaginal mesh complications women are seen in specialised gynaecology or female urology centres: • Be referred either from primary, secondary or tertiary care through local networks to units offering MDT review and complex mesh removal surgery. • Be assessed in the outpatient setting by a named specialist gynaecologist or specialist urologist. • Have appropriate investigations of lower urinary tract and gastrointestinal tract function. These investigations will often already have been done by the referring centre and must be made available. • Discuss their treatment options with a multi-disciplinary team including a specialist Gynaecologist, a specialist Urologist, Consultant Radiologist with a special Interest in Female Urology/Urogynaecology, a Specialist Nurse / Physiotherapist and a Colorectal Surgeon when appropriate. • Be counselled about all the relevant management options including non-surgical. • Undergo complex surgery as recommended by the MDT. • Be returned to the referring clinician with a plan of management if

	surgery is not indicated or declined by the patient. *Source: Service specification proposition section 2*
A4.2. What are the current service access and stopping criteria?	Referral into uro-gynaecology/ female urology service for treatment. *Source: current referral pathway*
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 not known – currently treatment is provided in a range of centres with variable outcomes. a) 100% b) 100% c) 0 *Source: current pathway*
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 Click here to enter text. a) 100% b) 100% c) 100%. d) 100% *Source: Specification Working Group modelling discussion*
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. • All patients following surgery will have: • A post-operative follow up visit with the Complex Mesh Removal Service • A post discharge telephone follow up by a nurse specialised (2-4 weeks post-surgery) • A face to face outpatient review (at 4 months and 12 months post-surgery)

<table>
<tr><td></td><td>

- The majority of patients will be referred back to the referring MDT for annual telephone follow up reviews for up to 5 years post-surgery
- The referring Uro-MDT will update the Mesh MDT regarding patient outcomes after their annual telephone reviews
- On discharge from the Specialised Complex Urogynaecology/ Female Urology Conditions Centre (at 5 years) there will be clear instructions for the GP to refer back if there are any new issues.

Source: Service specification proposition section 2

</td></tr>
<tr><td colspan="2">A5 Service Setting</td></tr>
<tr><td>A5.1 How is this service delivered to the patient?</td><td>

Select all that apply:

Emergency/Urgent care attendance	☐
Acute Trust: inpatient	☒
Acute Trust: day patient	☐
Acute Trust: outpatient	☒
Mental Health provider: inpatient	☐
Mental Health provider: outpatient	☐
Community setting	☐
Homecare	☐
Other	☐

</td></tr>
</table>

A5.2 What is the current number of contracted providers for the eligible population by region?

NORTH	7
MIDLANDS & EAST	5
LONDON	3
SOUTH	4

A5.3 Does the proposition require a change of delivery setting or capacity requirements?

yes

Please specify:

NHS England will need to formally procure providers for this service, and consolidate activity to providers that can meet the requirements within the specification. This will reduce the number of centres currently providing this complex work. Non-complex mesh removal will remain in a larger number of centres who can demonstrate compliance with the Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse Service Specification.

Source: Service specification proposition

A6 Coding

A6.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

Aggregate Contract Monitoring *	☒
Patient level contract monitoring	☒
Patient level drugs dataset	☐
Patient level devices dataset	☒
Devices supply chain reconciliation dataset	☐

	<table><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: Professional database returns for BAUS/ BSUG and any national registries that are established.
A6.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:*<table><tr><td>OPCS v4.8</td><td>☒</td></tr><tr><td>ICD10</td><td>☒</td></tr><tr><td>Service function code</td><td>☐</td></tr><tr><td>Main Speciality code</td><td>☒</td></tr><tr><td>HRG</td><td>☒</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table>
A6.3 **Identification Rules for Drugs:** How are any drug costs captured?	**Not applicable** 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. 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.
A6.4 **Identification Rules for Devices:** How are device costs captured?	**Not applicable** If device(s) covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance) for all that apply: Click here to enter text. 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. Click here to enter text.
A6.5 **Identification Rules for Activity:** How are activity costs captured?	**Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool** If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). 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. Click here to enter text. If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. **No**

A7 Monitoring	
A7.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule. Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England specialised services commissioning.	**Yes - other** Please specify Will need to link with professional organisations to get reports into Quality Dashboards.
A7.2 **Business intelligence** Is there potential for duplicate reporting?	**No** If yes, please specify mitigation: Click here to enter text.
A7.3 **Contract monitoring** Is this part of routine contract monitoring?	**No** If no, please specify contract monitoring requirement: Once the service is procured it will be subject to contract monitoring
A7.4 **Dashboard reporting** Specify whether a dashboard exists for the proposed service?	**No** If yes, specify how routine performance monitoring data will be used for dashboard reporting. Click here to enter text. If no, will one be developed? Yes
A7.5 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new	**No** If yes, specify how performance monitoring data will be used for this purpose.

service specification?	Click here to enter text.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	This service is currently organised across specialised services but the overall service model is not yet commissioned. *Source: Current model*
B1.2 Will the specification change the way the commissioned service is organised?	**Yes** Please specify: Smaller number of providers *Source: Service specification proposition*
B1.3 Will the specification require a new approach to the organisation of care?	**Implement a surgical service and network model of care to support appropriate selection of treatment and MDT to MDT disussions** Please specify: New network and MDT to MDT working with specialised gynaecology/ female urology.
B2 Geography & Access	
B2.1 Where do current referrals come from?	*Select all that apply:* GP ☒ Secondary care ☒

	Tertiary care ☒ Other ☐
B2.2 What impact will the new service specification have on the sources of referral?	**No impact** Please specify: This service specification will not impact on the sources of referral. It will allow for referrals to be made to a designated commissioned service.
B2.3 Is the new service specification likely to improve equity of access?	**Increase** Please specify: The service specification will ensure that women are referred to units who meet the standards as set out. *Source: Equalities Impact Assessment*
B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	**Increase** Please specify: The service specification will ensure that women are referred to units who meet the standards as set out *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Procurement action** Please specify:
B3.2 **Time to implementation:**	**Yes - go to B3.3**

Is a lead-in time required prior to implementation?	If yes, specify the likely time to implementation: 6-9 months to allow for regional assessment and any required procurement/ contract notice to be served.
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**Yes** If yes, outline the plan: • Service specification agreed Aug 2018 • Procurement commences in September 2018 • Go live with new service from 1 4 2019
B3.4 Is a change in provider physical infrastructure required?	**Yes** To meet service specification requirements. This will be a newly configured service.
B3.5 Is a change in provider staffing required?	**Yes** To meet service specification requirements there may be a change in provider staffing, but anticipated that some centres will already be working to this model and therefore have the staffing available to support this..
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**Yes** New network arrangements will need to be put in place to support the referral process and follow up arrangements. Specification provides clarity over required clinical interdependencies to maintain good patient outcomes.
B3.7 Are there changes in the support services that need to be in place?	**No** Please specify: Will already be in place for most providers as similar to other specialised gynaecology/ female urology services.
B3.8 Is there a change in provider and/or inter-provider governance	**Yes**

<table>
<tr><td>required? (e.g. ODN arrangements / prime contractor)</td><td>To cover MDT to MDT discussion</td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td><u>Decrease</u>

The number of centres commissioned will be limited given the need to maintain competency. There will be a redirection of activity these providers once commissioned.

Please complete the table:
<table>
<tr><th>Region</th><th>Current no. of providers</th><th>Future State expected range</th><th>Provisional or confirmed</th></tr>
<tr><td>North</td><td>7</td><td>1</td><td>P</td></tr>
<tr><td>Midlands & East</td><td>5</td><td>1</td><td>P</td></tr>
<tr><td>London</td><td>3</td><td>1</td><td>P</td></tr>
<tr><td>South</td><td>4</td><td>1</td><td>P</td></tr>
<tr><td>Total</td><td>19</td><td>4</td><td>P</td></tr>
</table>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table>
<tr><td>Publication and notification of new service specification</td><td>☒</td></tr>
<tr><td>Market intervention required</td><td>☒</td></tr>
<tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☒</td></tr>
</table></td></tr>
</table>

	Price-based selection process to maximise cost effectiveness ☐ Any qualified provider ☐ National Commercial Agreements e.g. drugs, devices ☐ Procurement ☒ Other ☒ Please specify: Designation
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: Low activity numbers will require this to be commissioned at a regional level.
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	*Select all that apply:* **Drugs** – Not separately charged – part of local or national tariffs ☐ **Drugs** – Excluded from tariff – pass through ☐ **Drugs** – Excluded from tariff - other ☐ **Devices** – Not separately charged – part of local or national tariffs ☒

<table>
<tr><td></td><td><table>
<tr><td></td><td>Excluded from tariff (excluding ZCM) – pass through</td><td>☐</td></tr>
<tr><td></td><td>Excluded from tariff (excluding ZCM) – other</td><td>☐</td></tr>
<tr><td></td><td>Via Zero Cost Model</td><td>☐</td></tr>
<tr><td rowspan="7">Activity</td><td>Paid entirely by National Tariffs</td><td>☒</td></tr>
<tr><td>Paid entirely by Local Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by National Tariffs</td><td>☐</td></tr>
<tr><td>Partially paid by Local Tariffs</td><td>☐</td></tr>
<tr><td>Part/fully paid under a Block arrangement</td><td>☐</td></tr>
<tr><td>Part/fully paid under Pass-Through arrangements</td><td>☐</td></tr>
<tr><td>Part/fully paid under Other arrangements</td><td>☐</td></tr>
</table></td></tr>
<tr><td>C1.2 Drug Costs
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.
NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>N/A</td></tr>
<tr><td>C1.3 Device Costs
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.
NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</td><td>N/A</td></tr>
<tr><td>C1.4 Activity Costs covered by National Tariff</td><td>All activity costs are covered by National Tariff such as:</td></tr>
</table>

<table>
<tr><td>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</td><td>• Outpatient multi-professional gynaecology attendances (first/ follow up).
• Mesh Surgery tariffs between £1,314 (HRGs: LB51A/ B) and £4,657 (HRGs: MA02A).
• Critical Care has been estimated as a percentage of the patient cohort.</td></tr>
<tr><td>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 is has been derived, validated and tested.</td><td>N/A</td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>N/A</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u>
Please specify: Click here to enter text.</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>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</td><td><table><tr><td>YR1</td><td>£2,664.00</td></tr><tr><td>YR2</td><td>£2,664.00</td></tr><tr><td>YR3</td><td>£2,664.00</td></tr><tr><td>YR4</td><td>£2,664.00</td></tr><tr><td>YR5</td><td>£2,664.00</td></tr></table></td></tr>
</table>

the model?	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.	**Cost neutral** Please specify: Activity already happening with specialised commissioning centres, which will be consolidated into a smaller number of centres to maintain competency.
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 service specification 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: **No impact on CCGs** Budget impact for providers: **No impact on providers**
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral** **Year 1: £0.0m**

	Year 2: £0.0m **Year 5: £0.0m**
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	N/A
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No**
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.	As the service specification is cost neutral, there is no call on the 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?	Demand may increase if more women experience complex complications over the level anticipated.
C6.2 How can these risks be mitigated?	Modelling has been undertaken on mid-point of activity levels to mitigate risk.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Higher levels of activity tested. All HRGs linked to vaginal mesh were considered to ensure accurately reflect costs – as activity is already paid for by NHSE, not anticipated to have a material impact if there is variance to this. Anticipate reduction in women needed revision surgery with

<table>
<tr><td></td><td>reduced number of centres delivering improved outcomes.</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>Middle activity range and agreed HRG costs to provide most realistic scenario, without any savings from improved clinical outcomes and secondary interventions not easily identified.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the service is cost effective as evidenced in the evidence review?</td><td><u>There is no published evidence of cost-effectiveness</u></td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:<table>
<tr><td>Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the service is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new service specification has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☒</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
</table></td></tr>
</table>

	The data does not support a high level of certainty about the impact on value ☐
C8 Non-Recurrent Costs	
C8.1 Are there non-recurrent revenue costs associated with this service specification?	**No** If yes, please specify and indicate whether these would be incurred or passed through to NHS England: Click here to enter text. If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact. Choose an item.
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	**No** If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs). Click here to enter text.