Integrated Impact Assessment Report for Service Specifications	
Service Specification Reference Number	1731
Service Specification Title	Penile Prosthesis Surgery (for end stage erectile dysfunction) Proposal **for routine commission** (source A3.1)

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.	The estimated annual incidence of erectile dysfunction in the male population aged 40 – 70 years in England is 260,837 (European Association of Urology, 2015). It is estimated that only 33% of this population (86,076) are likely to seek advice from a healthcare professional and of those, only 6% are suitable for penile prosthesis surgery (5,165). In addition, end stage erectile dysfunction can occur in patients who have undergone cancer treatment, affecting between 1,900 – 2,000 patients. Therefore, the combined patient cohort that may be suitable for penile prosthesis is therefore estimated to be between 7,065 - 7,165 males. Of this cohort, it is estimated that only between 5-7.5% (356-534) may decide to have a penile prosthesis each year. *Source: Service Specification, Section 3.1*
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	464 The estimated eligible patient numbers are derived from 2018/19 treatment numbers. Of the total number of patients treated in 2018/19, 349 surgeries were primary implants and 115 were revisions. *Source: Secondary Uses Services (SUS), 2019*
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	**Adults**
A1.4 Age distribution of the patient population eligible according to	40 – 70 years. Erectile dysfunction appears to be more prevalent in older

the proposed service specification commissioning criteria	patients and patients aged above 75 years are less likely to receive treatment. *Source: Service Specification, Section 3.1/ Clinical Commissioning Policy for Penile Prosthesis Surgery for End Stage Erectile Dysfunction (Ref: NHS England 16059/P)*
A1.5 How is the population currently distributed geographically?	The target population typically includes men aged over 40 so the geographic distribution of patients is expected to be in line with this. *Source: Service Specification, Section 3.1/ Clinical Commissioning Policy for Penile Prosthesis Surgery for End Stage Erectile Dysfunction (Ref: NHS England 16059/P)*
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?	**Increasing** It is assumed that the number of new cases grows in line with the aged 40-70 male population in England. *Source: Service Specification, Section 3.1/ Clinical Commissioning Policy for Penile Prosthesis Surgery for End Stage Erectile Dysfunction (Ref: NHS England 16059/P)*
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	**No** *Source: Service Specification, Proposition Section 3.1/ Clinical Commissioning Policy for Penile Prosthesis Surgery for End Stage Erectile*

<table>
<tr><td></td><td>Dysfunction (Ref: NHS England 16059/P)</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>180</td></tr><tr><td>YR5 +/-</td><td>350</td></tr><tr><td>YR10 +/-</td><td>0</td></tr></table>
Within the first 3 years of implementation, the number of primary implant surgeries is expected to increase and revision surgeries are expected to fall. By year 10, the numbers of patients undergoing penile prosthesis surgery are expected to reach steady state.

Source: Clinical Commissioning Policy for Penile Prosthesis Surgery for End Stage Erectile Dysfunction (Ref: NHS England 16059/P)

<u>No</u>

The number of procedures performed per annum are expected to increase once the service becomes more routinely available through formally designated centres. Steady state is expected after year 5.</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>

*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?	464 The estimated eligible patient numbers are derived from 2018/19 treatment numbers. *Source: Secondary Uses Services (SUS), 2019*
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	464 The estimated eligible patient numbers are derived from 2018/19 treatment numbers. *Source: Secondary Uses Services (SUS), 2019*
A4 Patient Pathway	
A4.1 **Patient pathway** Describe the current patient pathway and service.	Penile prosthesis surgery transferred from clinical commissioning groups (CCGs) to NHS England in April 2017, and as a result there are no designated centres for this surgery. Patients are currently referred to urological centres for their surgery. Surgery is carried out by a penile surgeon either in a day case setting or involving an over-night stay. Following surgery, patients are usually assessed pre-operatively at various intervals. It is common over time for the implant to stop working; revision rates after 10 years post implementation can be up to 25%. *Source: Service Specification*
A4.2. What are the current service access and stopping criteria?	Penile prosthesis surgery is only commissioned for patients with end stage erectile dysfunction. Patients are assessed for surgery by a specialist

	MDT. All patients must undergo pre-operative counselling. Patients are usually discharged from the service one year after surgery but can contact the treating hospital at any time if complications occur. *Source: Service Specification*
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 a) 100% b) 100% c) 0% The estimated eligible patient numbers are derived from 2018/19 treatment numbers. *Source: Service Specification*
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 a) 100% b) 100% c) 100% d) 100% The estimated eligible patient numbers are derived from 2018/19 treatment numbers. *Source: Service Specification*
A4.5 Specify the nature and duration of the proposed new service	**Time limited**

<table>
<tr><td>or intervention.</td><td>Surgery takes place either as a day case procedure or involves one overnight stay. Follow-up care is provided at the following intervals post-operatively: (i) 2 weeks; (ii) 6 weeks; (iii) 3 months; (iv) 1 year.

Source: Service Specification, Section 2.2</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:<table><tr><td>Emergency/Urgent care attendance</td><td>☐</td></tr><tr><td>Acute Trust: inpatient</td><td>☒</td></tr><tr><td>Acute Trust: day patient</td><td>☒</td></tr><tr><td>Acute Trust: outpatient</td><td>☐</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>A5.2 What is the current number of contracted providers for the eligible population by region?</td><td>In 2018/19, 26 providers performed penile prosthesis surgery with 17 providers implanting less than 10 penile prostheses in the year.</td></tr>
</table>

A5.3 Does the proposition require a change of delivery setting or capacity requirements?	**Yes** It is anticipated that a local provider selection process, run by regional commissioning teams, will be required to designate centres. Some regions may wish to use the Any Qualified Provider (AQP) framework. Providers will need to ensure they are able to meet the requirements as outlined in the service specification including MDT infrastructure and minimum surgical volumes.
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 ☐ Secondary Usage Service (SUS+) ☒ Mental Health Services DataSet (MHSDS) ☐ National Return** ☐ Clinical Database** ☒ Other** ☐ **Data must be submitted to the British Association of Urological Surgeons

<table>
<tr><td></td><td>National Penile Prosthesis Audit.</td></tr>
<tr><td>A6.2 Specify how the activity related to the new patient pathway will be identified.</td><td>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></td></tr>
<tr><td>A6.3 Identification Rules for Drugs:
How are any drug costs captured?</td><td><u>Not applicable</u></td></tr>
<tr><td>A6.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not excluded from Tariff and covered within existing National or Local prices</u></td></tr>
<tr><td>A6.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u></td></tr>
<tr><td colspan="2">A7 Monitoring</td></tr>
</table>

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 - population of clinical databases** Completion of the BAUS penile prosthesis audit.
A7.2 **Business intelligence** Is there potential for duplicate reporting?	**No**
A7.3 **Contract monitoring** Is this part of routine contract monitoring?	**Yes**
A7.4 **Dashboard reporting** Specify whether a dashboard exists for the proposed service?	**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 service specification?	**No**
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Currently, penile prosthesis surgery can be provided by any specialist urology centre, of which there are 54 providers in England. In 2018/19, penile prosthesis surgery was provided across 26 providers, with one

<table>
<tr><td></td><td>provider accounting for almost 50% of all penile prosthesis surgeries and 17 of the 26 providers implanted less than 10 penile prostheses in the year.

Source: Secondary Uses Services (SUS), 2019</td></tr>
<tr><td>B1.2 Will the specification change the way the commissioned service is organised?</td><td><u>Yes</u>

See section A5.3.</td></tr>
<tr><td>B1.3 Will the specification require a new approach to the organisation of care?</td><td><u>Other</u>

See section A5.3</td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:<table><tr><td>GP</td><td>☒</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new service specification have on the sources of referral?</td><td><u>Increase</u>

Establishment of designated centres is expected to result in an increase in referrals.</td></tr>
</table>

B2.3 Is the new service specification likely to improve equity of access?	**Increase** *Source: Equalities Impact Assessment*
B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	**Increase** *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Provider selection action**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**Yes - go to B3.3**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4**
B3.4 Is a change in provider physical infrastructure required?	**Unknown** A local provider selection process will need to take place. Providers will need to demonstrate they are able to deliver the core requirements as outlined in the service specification.
B3.5 Is a change in provider staffing required?	**Unknown**

	A local provider selection process is anticipated. Providers will need to demonstrate they are able to deliver the core requirements as outlined in the service specification.
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	**No**
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	**Not yet known** In 2018/19, penile prosthesis surgery was provided across 26 providers. Of the 26 providers performing this surgery in 2018/19, only five providers managed to implant over 20 penile prostheses in the given financial year and as mandated in the service specification. Similar activity numbers are anticipated for 2019/20. However, it is important to note that currently 50% of surgeries being performed in this indication are carried out by one provider. It is anticipated that as centres are formally designated to provide this surgery across all NHSE&I Regions to provide penile prosthesis surgery (through a local provider selection process) patients are likely to opt to have their surgery closer to home. With this in mind, the number of required providers commissioned per region may alter over time and based on current activity levels, it is

<table>
<tr><td></td><td>anticipated that there may need to be somewhere between 10 – 15 centres across England.</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>
<tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr>
<tr><td>Any qualified provider</td><td>☒</td></tr>
<tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr>
<tr><td>Procurement</td><td>☐</td></tr>
<tr><td>Other</td><td>☒</td></tr>
</table></td></tr>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
<tr><td>B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)</td><td><u>No</u>

Although first line and second line treatments for erectile dysfunction are commissioning by CCGs, surgery for end stage erectile dysfunction is commissioned by NHS England (transferred from CCGs in April 2017).</td></tr>
<tr><td colspan="2">Section C - Finance Impact</td></tr>
<tr><td colspan="2"></td></tr>
</table>

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 ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost 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**

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.

Not applicable.

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.	Not applicable – device cost is included in tariff.
C1.4 **Activity Costs covered by National Tariff** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	HRG LB74Z - Implantation of Penile Prosthesis LB47Z – Penis Major Open Procedures LB48Z – Penis Intermediate Open Procedures
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.	Not applicable.
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	Not applicable.
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**No**
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?	A financial model has not been developed. This is because the service specification has been developed to support implementation of a clinical commissioning policy which was approved by CPAG in May 2016. The

Are there any changes expected in year 6-10 which would impact the model?	funding for this service was agreed and approved by CPAG when reviewing the associated clinical commissioning policy. However, based on the clinical commissioning policy, the estimated costs per patient were expected to be: • £2,969 per patient for revision surgery; and • £8,647 for primary surgery.
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** Funding for this service was agreed and approved in May 2016 in line with approval of the relevant clinical commissioning policy.
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 – this service transferred from CCGs to NHS England in April 2017.
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: **Cost neutral** Budget impact for providers:

	Unknown The cost impact on providers is expected to be minimal however should be assessed through any local provider selection processes.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost neutral** See section C2.1/C3.1.
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?	**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.	Not applicable – see section C2.1/C3.1.
C6 Financial Risks Associated with Implementing this Service specification	
C6.1 What are the material financial risks to implementing this service specification?	Cost to providers to implement the service specification could be greater than anticipated. Activity volumes could exceed predicted numbers.
C6.2 How can these risks be mitigated?	Service specification alignment to original clinical commissioning policy.

<table>
<tr><td></td><td>Predicted activity volumes calculated using extensive modelling tool to support development of the clinical commissioning policy. Activity volumes for 17/18 and 18/19 already below original anticipated activity levels.</td></tr>
<tr><td>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</td><td>None – development of the service specification has been aligned to the relevant clinical commissioning policy.</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>Not applicable – see section C6.2/C6.3 above.</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>

Source: Commissioning Policy for Penile Prosthesis Surgery for End Stage Erectile Dysfunction (Ref: NHS England 16059/P)</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>
</table></td></tr>
</table>

	The data supports a high level of certainty about the impact on value ☐ 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**
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	**No** See section C4.1.