SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	*TBC*
Service	Penile Prosthesis Surgery (for end stage erectile dysfunction)
Commissioner Lead	*For local completion*
Provider Lead	*For local completion*

1. Scope

1.1 Prescribed Specialised Service

This Service Specification (the "Specification") covers the provision of penile prosthesis surgery for men with end stage erectile dysfunction.

1.2 Description

The scope of specialised services is set out within the Prescribed Specialised Services Manual (the "Manual"). The Manual states that penile prosthesis surgery, when provided by Highly Specialist Urological Surgery Centres (the "Centre(s)"), is commissioned by NHS England, within its responsibilities for commissioning highly specialist adult urological surgery services for men (Manual, Chapter 58A).

1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

NHS England commissions penile prosthesis surgery, when this is provided by commissioned Centres and in strict accordance with its published clinical commissioning policy for penile prosthesis surgery. Clinical Commissioning Groups (CCGs) commission initial diagnostics for erectile dysfunction, together with first and second line treatments.

2. Care Pathway and Clinical Dependencies

2.1 Service Overview

Erectile dysfunction is when a male is unable to gain or maintain an erection sufficient enough to allow sexual intercourse or sexual activity. There are a number of reasons for this, including:

- Medical conditions such as diabetes;
- Side effects of medication; and
- Any condition affecting the nerves or blood supply to the penis (for example pelvic or spinal trauma or pelvic surgery for cancer).

First-line, or primary, treatment for erectile dysfunction is managed in primary care where a number

of treatments can be offered, including lifestyle changes and oral medication. Where primary treatment fails, a referral to a urology service will be made for secondary care treatment options, which includes the use of a vacuum erection device. Where these treatment options fail, a patient can be trained to use medication which is self-injected into the penis or inserted into the urethra. Only after all of these treatment options have failed can the patient be considered to have end-stage erectile dysfunction and, in such cases, penile prosthesis surgery can be offered as a final treatment option.

Penile prosthesis is a highly specialist surgical procedure that is only available by tertiary referral. Based on an assessment of epidemiology and historic treatment figures, it is anticipated that initially four Centres in England will be required to deliver penile prosthesis surgery. This number may change over time in order to ensure future demand can be suitably met.

2.2 The Specialist Centre

Penile prosthesis surgery must be performed in a specialist penile prosthesis centre (the "Centre") undertaking complex penile surgery services on site. The Centre must provide a urology service with a specialist penile prosthesis MDT team on site. In addition, the Centre must have experience in performing complex penile surgery (excluding gender re-assignment surgery) as outlined in Appendix 1.

The Centre must serve a minimum population of at least 5 million and be working as part of a network of providers, each providing a urology service. The Centre must define its population catchment area and referring providers in conjunction with Commissioners; this must be documented in the Centre's operational policy. The Centre must have documented referral and access arrangements that are consistent for all patients and referring clinicians operating within the network.

Patients will be managed by a specialist penile prosthesis MDT at the Centre performing penile prosthesis surgery, and must include a specialist service run by urological surgeons and access to psychological support and andrology/clinical nurse specialists. The penile prosthesis MDT is responsible for assessing a patient's suitability for surgery and overseeing their treatment.

On referral to the Centre, the patient will be assessed for their suitability for penile prosthesis surgery.

Patients suitable for a penile prosthesis will receive preoperative counselling (from either the andrology clinical nurse specialist or the consultant urological surgeon) regarding the different types of penile prostheses and must undergo training on how to use the devices. This also allows patients to understand the short and long term risks as well as being fully informed about the complications, ensuring full management of the patient's expectations.

Penile prosthesis surgery can be performed as a day case procedure but more commonly involves overnight stay, depending on the type of implant used. Patients must undergo a post-operative clinical follow-up and again be taught how to manipulate a semi-rigid prosthesis or taught how to use the scrotal pump in the case of an inflatable prosthesis.

Further follow-up continues up to one year after surgery. Typically patients will be reviewed by the surgical team at the following intervals after surgery: (i) at 2 weeks post-surgery in order to check the wounds and start cycling the device if it is an inflatable prosthesis; (ii) at 6 weeks post-surgery to ensure wound has healed and that the prosthesis is not infected and can be used for sexual activity; (iii) at 3 months post-surgery to check for position and malfunction and ensure sexual activity is possible; and (iv) finally at one year post surgery to check for device malfunction, migration of components or erosion of the prosthesis. Should the patient experience any problems after this point, patients are encouraged to contact the Centre for review.

The Centre must report outcomes (including patient-partner satisfaction, infection rates, and mechanical failure rates) into a national penile prosthesis audit which is currently overseen by the British Association of Urological Surgeons (BAUS).

Penile prosthesis surgery will be commissioned in line with the criteria set out in the Clinical

Commissioning Policy for Penile Prosthesis Surgery for end stage erectile dysfunction and this Specification.

Given the geographical reach of penile prosthesis Centres, all Centres must ensure adequate travel arrangements for patients, utilising existing NHS arrangements.

In some networks, surgeons from different providers within the network may form part of the Centre's penile prosthesis surgery service providing an in-reach service. Any in-reach services must adhere to local governance arrangements. These surgeons must be part of the specialist penile prosthesis MDT and must meet the minimum surgical requirements as outlined in this Specification. Any in-reach services and follow-up care pathways must be documented in the Centre's operational policy.

2.2.1 Penile Prosthesis Multi-Disciplinary Team

Decisions to offer a penile prosthesis procedure must be made through a specialist penile prosthesis multi-disciplinary team (MDT) with expertise in performing complex penile surgery (excluding surgery for gender re-assignment).

Urological surgeons must be specifically trained in penile prosthesis surgery and must have expertise in complex penile surgery. This may include a certificate in completion of training (CCT) in urology, sub-speciality training in penile prosthesis surgery or complex penile surgery and/or evidence of mentored training by a high volume penile prosthesis surgeon.

The Centre must hold a specialist penile prosthesis MDT meeting, comprising:

- At least two urological surgeons trained in penile prosthesis surgery and complex penile surgery;
- At least one andrology/clinical nurse specialist (plus cover); and
- At least one Uro-radiologist (plus cover).

The Centre must also have access to at least one clinical psychologist with psychosexual training.

Patients with end stage erectile dysfunction must be discussed in the specialist penile prosthesis MDT. The MDT, together with the patient, will decide whether surgery is indicated and also decide on which prosthesis is most suitable for the patient. It is expected that the MDT will meet at least monthly and will discuss each implant case as well as reviewing outcomes for patients who have undergone penile prosthesis surgery.

2.2.2 Primary prosthesis surgery

The Centre must have a minimum of two urological surgeons undertaking penile prosthesis surgery, with each surgeon implanting a minimum of 25 penile prostheses per annum.

As this is a new service in some areas of the country, a steady increase in activity is expected. Each Centre must perform a minimum of 60 cases per annum during Year 1 of service commencement. Steady state is expected from Year 3 onwards and as a result, each Centre must perform a minimum of 100 penile prostheses per annum from Year 3 of service commencement.

Penile prosthesis surgery must be supported by a theatre team with experience in complex penile surgery.

If mechanical failure or erosion occurs, further revision surgery is usually required to correct the problem. Infection of the prosthesis requires removal of the device and the components. Current estimates indicate that approximately 22% of patients undergo revision surgery within five years of primary implantation (Secondary Usage Service, 2018) due to malfunction or problems related to the initial surgery. It is expected that over time and as expertise grows in the field that the number of patients undergoing revision surgery will fall. The expected revision rate after a primary procedure (within five years of the implant) for Centres at steady state should be less than 1% in line with current best practice.

The Centre must demonstrate effective clinical governance processes are place to review all complications arising post-surgery.

2.2.4 Patient Information

For all patients undergoing surgery, there must be written information, supplementary to that on any general surgery consent form, which as a minimum includes information on the following:

- Pre-operative care;
- Surgical treatment, possible side-effects and aftercare; and
- Access to psychological support.

Services must direct patients to online resources and relevant patient support organisations as appropriate to support patients in understanding their surgery. In addition, services must be able to direct patients to other support services as required.

2.3 Interdependence with Other Services

Penile prosthesis surgery must be aligned with specialist urological centres undertaking complex penile surgery.

There must be access to radiology services to support diagnostic assessment and treatment planning.

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

The Service outlined in this Specification are for patients resident in England*, or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?, Establishing the responsible commissioner and other Department of Health guidance relating to Patients entitled to NHS care or exempt from charges).

*Note: for the purposes of commissioning health services, this EXCLUDES Patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES Patients resident in Wales who are registered with a GP Practice in England.

3.2 Population Needs

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 (UK Health Centre, 2015). Of those seeking medical attention, it is estimated that:

- 80% of patients will respond to oral medications;
- 14% of patients will gain symptomatic relief through other methods (for example intracavernosal injections); and
- 6% of patients will be diagnosed with end stage erectile dysfunction and may be suitable for penile prosthesis.

In addition, erectile dysfunction affects 50% of all patients who have undergone pelvic surgery or radiotherapy (e.g. prostate cancer, anal cancer) and 100% of patients who have undergone pelvic surgery for bladder cancer. Of these additional patients, it is estimated that 20% will progress to end stage erectile dysfunction numbering 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. Between April 2017 and March 2018, 414 patients underwent penile prosthesis implant surgery (including both primary implantation and revision surgery).

3.3 Expected Significant Future Demographic Changes

In line with population trends only.

3.4 Evidence Base

This service specification has been drawn from the following documents:

- NHS England. *Clinical Commissioning Policy: Penile Prosthesis surgery for end stage erectile dysfunction*. August 2016.
- NHS Choices, 2014 http://www.nhs.uk/conditions/Erectiledysfunction/Pages/Introduction.aspx
- ONS, Annual mid-year population estimates, 2014 http://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/bulletins/annualmidyearpopulationestimates/2015-06-25
- British Society for Sexual Medicine. *Guidelines on the management of erectile dysfunction*. September 2013.
- British Association of Urological Surgeons, 2017 https://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Penile%20prostheses.pdf

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

This Specification aims to:

- Ensure all patients have optimum and equitable access to penile prosthesis surgery for end stage erectile dysfunction;
- Ensure penile prosthesis surgery for end stage erectile dysfunction are delivered safely and efficiently across England;
- Support selection of high volume penile prosthesis surgery providers to ensure appropriate service standards are met and reduce the risk of revision surgery for patients; and
- Ensure patients receive adequate and appropriate pre-operative and post-operative care.

NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	
Domain 2	**Enhancing quality of life for people with long-term conditions**	**X**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**X**
Domain 4	**Ensuring people have a positive experience of care**	**X**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**X**

4.2 Indicators Include:

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	Number of penile implants undertaken at centre.	BAUS / Provider	1, 4	Safe and Effective
102	% of patients readmitted within 90 days of surgery due to mechanical failure.	BAUS / Provider	1, 4	Safe and Effective
103	% of patients readmitted within 90 days of surgery due to infection.	BAUS / Provider	1, 4	Safe and Effective
104	% of patients during the last 12 months, who have received revision surgery within 5 years of the original primary implant taking place.	BAUS / Provider	1, 4	Safe and Effective
Patient Experience				
201	There is information for patients and carers	Self declaration	4	Caring , responsive
202	A patient experience exercise is undertaken at least annually.	Self declaration	4	Caring , responsive
203	Patient reported satisfaction	BAUS Audit	4	Caring , effective, responsive
Structure and Process				
301	The Penile Implant service includes team members as detailed within the service specification.	Self declaration	2.3	Well led, safe, caring, responsive, effective
302	The named surgical members detailed above (indicator 101) undertake at least 25 penile prostheses per annum.	Self declaration	2, 3	Safe, caring, effective
303	The Penile Implant service upon commissioning undertakes at least 60 cases per annum.	Self declaration	2, 3, 4	Effective
304	There are arrangements in place whereby patients, when required, are able to access psychological support.	Self declaration	2.3	Well led, safe, caring, responsive, effective
305	There are clinical guidelines in place as detailed within the service specification.	Self declaration	2, 3, 4	Safe, Effective and Well-led
306	There are agreed patient pathways in place	Self declaration	2, 4, 5	Safe, Effective and Well-led
307	The Penile Implant service submits data to the national audits.	Self declaration	2, 4, 5	Safe, effective, well-led

Detailed definitions of indicators, setting out how they will be measured, is included in schedule 6.

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Designated Providers (if applicable)

The designated providers for penile prosthesis surgery are as follows: [PROVIDER NAMES TO BE INSERTED]

6. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

BAUS	The British Association of Urological Surgeons
CCT	Certificate in Completion of Training
CNS	Clinical Nurse Specialist
MDT	Multi-Disciplinary Team
NICE	The National Institute for Health and Care Excellence
ONS	Office for National Statistics

Date published: *<insert publication date>*

Appendix 1

Complex Penile Surgery

N291 Implantation of prosthesis into penis
N283 Plication of corpora of penis
N292 Attention to prosthesis in penis
N287 Graft to penis
N291 Implantation of prosthesis into penis
N262 Partial amputation of penis
N271 Excision of lesion of penis
N282 Reconstruction of penis
N261 Total amputation of penis
N298 Other specified prosthesis of penis
N281 Construction of penis