



# **Clinical Commissioning Policy Proposition:**

## **Penile prosthesis surgery for end stage erectile dysfunction**

**Version Number: NHS England B14X10/01**

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# **Clinical Commissioning Policy Proposition: Penile prosthesis surgery for end stage erectile dysfunction**

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## Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

## Plain Language Summary

Erectile dysfunction is when a male is unable get an erection or sustain an erection well enough to allow for sexual intercourse. There are a number of reasons for this including other medical conditions such as diabetes, side effects of medications and problems affecting the nerves or blood supply to the penis. A male who is having problems with erections will see his GP who will try a range of treatment options. Often, changes to lifestyle, medications or a penis pump are enough to improve symptoms. If these do not work, there is also an injection which may allow for the erection to occur. In the event that none of these treatment options work, penile prosthesis may be considered.

Penile prosthesis is a surgical procedure that aims to replace the normal mechanism of getting an erection. The surgeon can either insert a semi-rigid rod into the penis or insert a device that can be pumped to cause an erection. These operations are performed at a specialist implant centre after multidisciplinary team discussion.

NHS England has concluded that there is sufficient evidence to support a policy to routinely commission penile prosthesis surgery in males with end stage erectile dysfunction.

## 1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission penile prosthesis for males with end stage erectile dysfunction.

This document also describes the proposed criteria for commissioning, proposed governance arrangements and proposed funding mechanisms.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

A final decision as to whether penile prosthesis surgery for men with end stage erectile dysfunction will be routinely commissioned is planned to be made by NHS England by June 2016 following a recommendation from the Clinical Priorities Advisory Group.

## 2. Proposed Intervention and Clinical Indication

Male erectile dysfunction is the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual intercourse. The pathophysiology of erectile dysfunction may be vasculogenic, neurogenic, hormonal, anatomical, drug-induced, psychogenic in nature, due to pelvic or spinal cord trauma, pelvic surgery or any treatment for pelvic cancers including radiotherapy.

Penile prosthesis implantation involves the surgical insertion of a rod or cylinder inside the penis. This can be a malleable rod or an inflatable hydraulic system which can allow the penis to become rigid.

This policy specifies the use of penile prosthesis as a surgical option for men with end stage erectile dysfunction who have failed treatment with pharmacotherapies including oral medications, intracavernous injections, intraurethral vasoactive agents as well as external vacuum devices. The main outcome of implanting a penile prosthesis is to allow males to have penetrative sexual intercourse benefiting the patient and their partner. As such, the best measure of clinical effectiveness is patient-partner satisfaction surveys. The ability to have penetrative intercourse correlates directly with the WHO criteria for psychological well being and penile prosthesis represents the only opportunity for a small cohort of males with end stage erectile dysfunction to achieve restorative function of the penis for sexual intercourse. Similar to patients who undergo incontinence surgery (a last-line treatment for urinary incontinence), the outcomes for males with end stage erectile dysfunction are difficult to measure using traditional evaluation techniques such as randomised controlled trials (RCTs) as there are no comparable treatment options for these groups. As such, both clinical evidence and expert opinion are vital in the evaluation of this commissioning policy.

### 3. Definitions

Male erectile dysfunction is the persistent inability to attain and maintain an erection sufficient to permit satisfactory sexual intercourse. The pathophysiology of erectile dysfunction may be vasculogenic, neurogenic, hormonal, anatomical, drug-induced, psychogenic in nature, or due to trauma. This includes patients who have erectile dysfunction due to treatments for pelvic cancers (including urological and colorectal cancers), diabetes, Peyronie's disease, and patients undergoing penile reconstruction.

End stage erectile dysfunction is when patients have tried all other treatment options including drug therapy (with a PDE5 inhibitor e.g. sildenafil), intracavernous or intraurethral vasoactive agents (e.g. Alprostadil) and external devices such as vacuum devices.

Penile prosthesis implantation involves the surgical insertion of a rod or cylinder inside the penis. There are two types of penile prosthesis, malleable and inflatable. In general, inflatable devices are preferable as they provide better results for patients. Inflatable prosthesis can also be antibiotic coated or non-antibiotic coated. Antibiotic coated implants can be pre-coated in antibiotic by the manufacturer or soaked in antibiotic intraoperatively, prior to implantation. Malleable devices give less natural rigidity and are harder to conceal.

- Malleable implant. These implants never change in size and are similar in some ways to a goose neck lamp as the neck of the lamp maintains a certain position when not manipulated, but can be bent or straightened. The malleable penile implant is generally maintained in a downward position, and then bent into an upward position prior to intercourse. Malleable implants are often used for indications such as; acute priapism, or patients who do not have the dexterity to manipulate the pump used for inflatables. It is estimated that malleable devices are used in less than 10% of patients.
- Inflatable, two part implant. This device does not contain a reservoir, only the cylinders and a pump. As the pump is used, fluid is transferred between the pump and the cylinders. The advantage is that there is no need to place a reservoir.
- Inflatable, three piece implant. This device consists of cylinders that are placed within the penis, a pump that is placed within the scrotum, and a reservoir that is placed adjacent to the bladder. The prosthesis is activated by squeezing a pump which transfers fluid from the reservoir to the cylinders, causing the penis to become rigid.

### 4. Aim and Objectives

The policy aims to define NHS England's commissioning position on penile prosthesis.

The objective is to ensure evidence based commissioning with a view to improving outcomes for individuals suffering from end stage erectile dysfunction.

### 5. Epidemiology and Needs Assessment

The prevalence of erectile dysfunction is estimated at 40% of the population of males over the age of 40 (NHS Choices, 2014), numbering between 4.8m and 5.2m people (ONS, Annual mid-year population estimates, 2014), although this estimation includes erectile

dysfunction of all severities as well as transient ED. The incidence of erectile dysfunction is 26 per 1,000 males aged 40-70 (European Association of Urology, 2015). The male population aged 40-70 in England is approximately 10,032,200 (ONS, 2014) giving an annual incidence of 260,837. 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, clinicians estimate that 80% will respond to oral medications (68,861). Of the remaining 20% (17,215), it is estimated that approximately 70% will gain symptomatic relief through other methods (for example Alprostadil injection), leaving 30% (5,165) with no further treatment option and therefore defined as patients with end stage erectile dysfunction who may be suitable for penile prosthesis.

In addition, erectile dysfunction affects 50% of all patients who have undergone pelvic surgery (e.g. for prostate cancer) and 100% of patients who have undergone intervention 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. As survivorship of cancer improves, people are living longer and penile prostheses represent a way of maintaining quality of life for some patients in keeping with the NHS cancer survivorship programme.

The combined patient cohort that may be suitable for penile prosthesis therefore stands at 7,065 - 7,165 males. Clinicians estimate that between 5-7.5% (356-534) of these affected ESED patients could decide to have a penile prosthesis each year. Currently, between 450-500 cases of penile prosthesis are carried out each year with approximately two-thirds of these being new surgeries and the remaining one-third of these being revision surgery (HES data).

## 6. Evidence Base

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of penile prosthesis for end stage erectile dysfunction. As this intervention is for end stage patients with no comparator treatment available, randomisation is difficult and as such, high grade evidence in this field is limited.

Penile Prosthesis implantation (PPI) is predominantly performed in men with severe erectile dysfunction (ED), when unresponsive to oral pharmacotherapy and intracavernous or intraurethral vasoactive agent, or when these therapies are contraindicated. A Medicare based population study (n=53,180) (Lee, Daniel et al, 2015) described an increased prevalence of ED from 2001-2010, although there was a PPI utilisation reduction of 50% from 4.6% to 2.3%. This may reflect the use of other therapies for less severe ED. The PROPER registry (Henry, Gerard et al, 2015) illustrated that the majority of patients undergoing PPI either have had a radical prostatectomy for prostate cancer (28%), have ED caused by diabetes (21.6%), have ED caused by cardiovascular disease (19.6%) or have Peyronie's disease (8.9%). The majority of recent studies have utilised the 3-piece inflatable prosthesis, AMS 700 and Titan Coloplast implant.

We conclude the evidence to support the use of penile prosthesis implantation in men with erectile dysfunction is predominantly of low level evidence, consisting largely of case series (single to multicentre studies). To date there has been no randomised control trials evaluating the use of different implants (antibiotic vs non-antibiotic coated, inflatable vs

malleable). The majority of studies have been conducted in the United States of America with similar population cohorts to those seeking penile prosthesis in the UK.

The majority of studies have been conducted in large volume and experienced implanting centres. Recent case series have demonstrated mechanical durability of the prosthesis. Henry et al (2012) showed the five year survival rate for an IPP was 83% (n=1,069). Vitraelli et al (2013), reported a 10 year survival rate of 77.6% for AMS 700 CX touch pump and 82.5% for AMS 700 CXR in 80 patients. Chung et al (2013) reported a 1.1% intra-operative complication rate whilst Garber et al (2015) reported 0.5% (3/600 prosthesis) patients developed a delayed haematoma following IPP insertion.

Outcomes for penile prosthesis are based on patient and partner satisfaction and the ability to have penetrative intercourse. Studies to date have demonstrated an overall high patient and partner satisfaction rate. 90% of patients in a recent RCT (Pisano et al, 2015) demonstrated an improvement in erectile function and ability to engage in sexual intercourse. Patients that received psychosexual counselling exhibited higher scores in the International Erectile Dysfunction of Inventory of Treatment Satisfaction scale (IIEF) (68.3% vs 53.4%,  $P<0.001$ ) and erotic function scale (52.8% vs 48.2%,  $P=0.007$ ) when compared to those who did not receive specific counselling. A small cohort study (Kilicarslan et al, 2014) found patients reported significantly greater satisfaction (satisfied and very satisfied) on the Erectile Dysfunction Inventory of Treatment Satisfaction (EDITS) when the two piece inflated penile prosthesis was implanted, compared to the malleable prosthesis, 86.9% vs 65.1%. Chung et al (2013) evaluated two types of inflatable prosthesis AMS 700CX and Coloplast Titan, reported that 70% of men were satisfied with cosmetic and functional outcome. Some patients undergoing IPP for erectile dysfunction are following radical prostatectomy, and a study by Menard et al (2011) comparing this cohort with vasculogenic ED patients found that following IPP the patients IIEF scores improved. However those patients in the prostatectomy group did have lower scores than the vasculogenic ED group (63.1 vs 68.5,  $P=0.005$ ). Overall satisfaction rate were not significant with 86.1% satisfied in the prostatectomy group and 90.1% in the vasculogenic ED group.

Overall high satisfaction rates have been reported in numerous case series. A recent prospective multicentre case series (Ohl et al, 2012) reported an overall satisfaction at 12 months of 90%, with one third of patients having diabetes mellitus. In addition, evaluation of quality of life after penile prosthesis implant questionnaire (Caraceni et al, 2014) reported high levels for functional domains (89.6%) and personal domain (87%).

Mechanical failure and infection of penile prosthesis have been commonly described in the literature. Common organisms cultured include; Coagulase negative Staphylococcus (CONS), Enterococcus faecalis, Pseudomonas Aeruginosa, Escherichia coli and Enterobacter aerogenes. Recently Chung et al (2013) showed Kaplan-Meier penile prosthesis infection free rates at 5 and 10 years of 98% and 96.5% respectively. The Kaplan-Meier estimates of penile prosthesis mechanical failure free rates at 5 and 10 years were 79.4% and 72.8% respectively. Common causes of mechanical failure include fluid loss and device auto-inflation (although newer prostheses have a lock-out valve to prevent auto-inflation). Henry et al (2012) demonstrated the majority of patients undergoing revision surgeries were a result of mechanical failure (65%), with combined erosion or infection at 29%. The study observed incorporating a washout procedure increased the Kaplan-Meier

estimated 5 year survival from 60% with no washout to 94% ( $P=0.002$ ). Enemchukwu et al (2013) evaluated revision rates current generation girth expanding and length and girth expanding IPP. They found equivalent survival rates (7 years) between the two groups, 88.7% and 89.5% respectively, and found approximately 50% of revision cases were a result of mechanical failure.

To date studies evaluating outcomes between antibiotic and non-antibiotic coated implants are of low evidence (Grade -2 to 3). Katz et al (2012) conducted a survey among experience and high volume penile prosthesis surgeons in the US, and found a great variation in perioperative strategies to prevent postoperative penile implant infection. There is currently a lack of uniform evidence based practice guidelines.

A recent systematic review (Christodoulidou et al, 2015) with a total of 38 case series (Grade 3) evaluated the risk of infection in penile prosthesis in patients with diabetes mellitus, a group perceived to be at high infection risk. They found 15 predominantly small studies dating back to 1970s which supported the hypothesis of diabetes mellitus as a risk factor for infection. However these studies were conducted in an era where both malleable and inflatable prosthesis were associated with high complication risks. In addition Charles et al (2003), found the risk of infection in the paraplegic cohort to be high, with a 15% rate, compared to 10.6% in the diabetic group. Wilson et al (1995) conducted a retrospective review of 823 primary prostheses and found infection rate requiring prosthesis removal to be 50% in those patients receiving steroids, 9% spinal cord and 3% diabetic mellitus cohort Minervine et al (2005), found patients with pelvic trauma had a 21% and those with diabetes mellitus had 10% infection rate. Recent studies have evaluated antibiotic and non-antibiotic coated implants, with further stratification of diabetes mellitus patients, and/or primary versus revision implants.

Carson et al (2011) reviewed infection related revisions of minocycline HCL rifampicin impregnated ( $n=35,737$ ) and non-impregnated implants ( $n=3,268$ ), and found the seven year life table survival analysis revision events to be lower in the impregnated group ( $P<0.001$ ), with patients requiring revision secondary to infection, 1.1% in impregnated and 2.5% in non-impregnated group. They also found the rate of infection at seven years was greater in the diabetes mellitus cohort overall 1.88% compared to 1.53%. The largest series by Eid et al (2012)  $n=2,347$  reported a decrease in infection from 5.3% (2002) to 2% (2003-2005) when an infection-retardant-coated prosthesis in a mixed patient cohort ( $P<0.001$ ). Rate was reduced further to 0.46% when a no touch technique was adopted from 2006-2010. They found the diabetic cohort did not influence the rate of infection. Chung et al (2013),  $n=955$  reported over three decades with infection occurring in 0.8% with an equal incidence between diabetic mellitus (2%) and pelvic trauma patients (3.6%). This study also found no difference in prosthesis infection rate between men who received Inhibizone coated and non-coated inflatable prosthesis ( $P>0.05$ ). However, Serefoglu et al (2012) found over a 11 year follow-up rate of revision due to device infection was reduced to 69.56% in patients with hydrophilic-coated IPPs ( $P<0.001$ ). Kava et al (2011) in a single surgeon cases series found no difference in infection rate between antibiotic coated prosthesis (3%) and non-coated implants (8.4%).

Gross et al (2015) recently evaluated the Mulcahy salvage (MIST, Malleable Implant Salvage Technique) with malleable prosthesis insertion following removal of infected IPP. Of the 42 patients with primary IPP infections, 38 underwent MIST procedure with no

subsequent complications. The use of salvage therapy remains low following a prosthesis infection. Zargoff et al (2014) showed salvage therapy in 17.3% of over the past decade, with preference towards explantation with delayed re-implantation (82.7%).

To date no studies have evaluated the cost effectiveness of penile prosthesis implantation.

## 7. Proposed Criteria for Commissioning

Primary penile prosthesis will be routinely commissioned for patients who have been assessed by the specialist andrology multi-disciplinary team (MDT) and fulfil all of the following criteria:

1. Males with end stage erectile dysfunction of all aetiologies including; vasculogenic (including priapism), neurogenic, hormonal, anatomical (e.g. secondary to pelvic surgery, radiotherapy for cancer, or cases of buried penis), drug-induced, psychogenic or traumatic (e.g. Peyronie's disease and pelvic or spinal cord trauma).
2. Any males who fulfil criterion (1) and for whom lifestyle modifications, medicinal management, psychosexual counselling, intraurethral or intracavernous vasoactive agents (e.g. Alprostadil), and external devices such as a vacuum pump have been ineffective.
3. Males who fulfil criteria (1) and (2) who have been appropriately risk-assessed by the specialist MDT with attention to diabetes, BMI and steroid use.

Exclusions:

1. Males with contraindications to penile prosthesis (including allergy to device components, or untreated lower urinary tract symptoms)
2. Males with risk of anaesthesia deemed too high

## 8. Proposed Patient Pathway

Penile prosthesis is a final treatment option for end stage erectile dysfunction.

Patients who experience problems with erectile dysfunction will first see their GP who will consult the patient regarding lifestyle modifications, ensure conditions that could be causing erectile dysfunction are appropriately managed (e.g. diabetes) and review all medications as erectile dysfunction can be a side effect of medications.

First line therapy:

Some GPs will commence first-line oral medicinal therapies such as a PDE5 inhibitor (e.g. sildenafil, tadalafil). PDE5 inhibitors are not suitable for patients with moderate - severe cardiovascular disease, or those taking nitrate medications. Most cases of erectile dysfunction can be successfully treated with lifestyle changes and medications. Patients will be referred to a specialist urological team if lifestyle modifications and initial treatments are ineffective and at this stage be introduced to second-line therapies. If a hormonal condition is causing erectile dysfunction, patients are referred for hormonal treatment and investigation. Psychosexual counselling including sensate focus and cognitive behavioural therapy (CBT) will also be offered to patients with psychogenic causes of erectile dysfunction.

Second line therapy:

Second line therapies include intracavernous and intraurethral vasoactive agents (Alprostadil) or external vacuum devices, which are contraindicated in men at risk of priapism (e.g. those with sickle cell anaemia) and those taking anticoagulant medication.

End stage erectile dysfunction:

If none of these treatments are effective at allowing penetrative intercourse, patients are considered to have end stage erectile dysfunction and will be referred for consideration of penile prosthesis in a tertiary urology centre. Patients who present with refractory priapism or patients who have undergone treatment for pelvic cancers (including radiotherapy and surgery) are also classed as end stage erectile dysfunction as the first and second line therapies described are unlikely to be effective. These patients will also be referred to the specialist MDT for management of erectile dysfunction. Their care will be managed by a specialist MDT, at the implanting centre, that includes an andrology service, psychological support, andrology nurse specialists and urological surgeons specially trained in penile prosthesis implantation. Patients suitable for a penile prosthesis will receive pre-operative counselling regarding the likely outcome of penile prosthesis as well as the common complications ensuring full management of the patient's surgical expectations.

The MDT will identify and manage patients at higher risk of complications and those patient groups that have been shown in the evidence review to have a lower satisfaction rate due to post-operative complications. These include diabetic patients, who will be required to display good diabetic control (HbA1c measurements), patients with a raised BMI, who will be given support to aid weight loss and patients taking steroids, who will need further counselling as to the greater risk of complications whilst taking steroids. Clinicians estimate that in current practice only one patient in each centre undergoing penile prosthesis each year is also receiving steroid therapy.

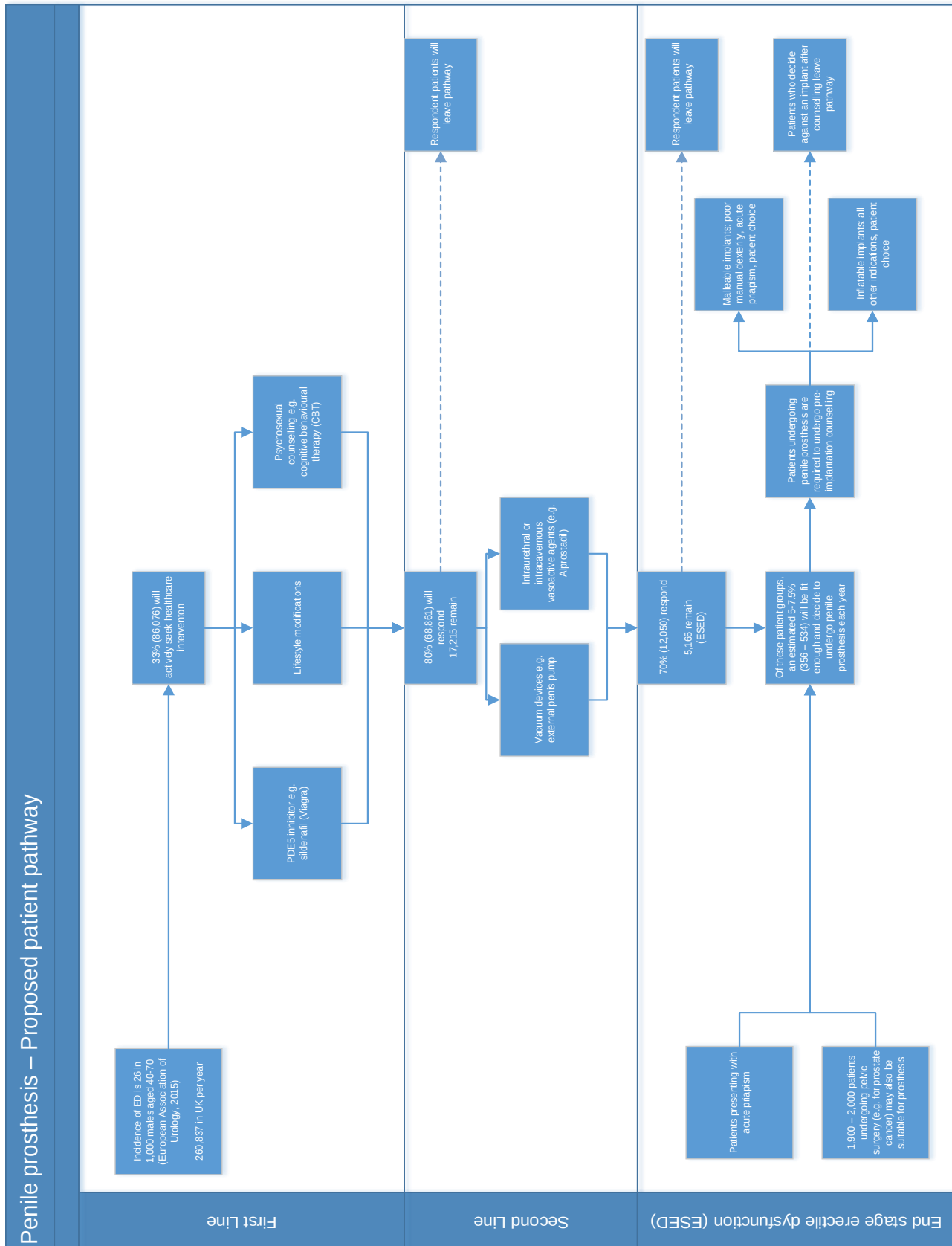
The MDT, together with the patient, will decide which prosthesis is most suitable; inflatable or malleable.

Inflatable prostheses are preferred as they provide patients with the most realistic replacement for natural erections and inflatable prostheses result in higher patient and partner satisfaction rates (when compared to malleable prostheses) as demonstrated in the evidence review. Both antibiotic coated and non-antibiotic coated inflatable implants can be used, usually at the surgeons discretion.

Malleable prostheses can be used in patients with acute priapism, Peyroine's disease (where significant deformity requires simultaneous grafting) and patients who do not have the dexterity to manipulate the pump used for inflatable implants. However they are harder to conceal and patients report less satisfaction.

Penile implant surgeries are typically performed as a day case or overnight stay. After treatment, there will be a post-operative check-up, and the patient is again taught how to use the inflatable device. There is a further follow-up up to one year after surgery.

Potential complications are mechanical failure, erosion or infection. If mechanical failure or erosion occurs, further surgery is usually required to correct the problem and the patient may be required to travel nationally for this as this will only be undertaken in the highest volume implant centres. Infection will be treated as per usual care depending on the severity of infection.



## 9. Proposed Governance Arrangements

(1) Penile prosthesis should only be provided under the care of a specialist MDT including urologists, andrologists, nurse specialists and appropriate psychological support.

(2) Primary Penile prosthesis should only be performed in penile implant centres with urology and andrology services on-site. Centres should align themselves with service specifications, where they exist.

## 10. Proposed Mechanism for Funding

NHS England will fund the implantation of penile prosthesis in patients fulfilling the above criteria only via local commissioning teams.

First and second line treatments for erectile dysfunction will continue to be funded by CCGs.

## 11. Proposed Audit Requirements

All centres undertaking penile prosthesis will be required to report outcomes (including patient-partner satisfaction, infection rates, mechanical failure rates) into the British Association of Urological Surgeons (BAUS) national penile prosthesis audit.

## 12. Documents That Have Informed This Policy Proposition

British Society for Sexual Medicine, Guidelines on the management of erectile dysfunction, September 2013.

## 13. Date of Review

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned (expected by June 2016)