

Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B14X10		
Policy Title	Penile prosthesis surgery for end stage erectile dysfunction		
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Section K - Activity Impact			
Theme	Questions	Comments (Include source of info made and any issues with the data	rmation and details of assumptions
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1.1 This policy proposes to routin prostheses implants for men with e The prevalence of erectile dysfunc it is thought to have a high prevale affect c. 4.8m - 5.2m men in Engla transient erectile dysfunction as we estimated that only 33% of these m healthcare professional ^V . The incidence of erectile dysfunction aged 40 to 70 ^{vi} . Therefore, in Engla	nely commission penile and stage erectile dysfunction. tion is difficult to estimate, although nce worldwide ⁱ and is estimated to nd. ^{II, III, IV} This estimation includes all as that of all severities. It is nen are likely to seek advice from a on is reported as 26 in 1,000 men and it is estimated that there were

	$\sim 201,000$ new second of exactly during the in $201,1/45^{\text{VII}}$
	c. 261,000 new cases of erectile dysfunction in 2014/15.
K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 This policy looks specifically at men with end stage erectile dysfunction (ESED), for which no other treatment options remain ^{viii} . Of the c. 261,000 new cases of erectile dysfunction, it is expected that c. 5,165 men will have ESED ^{ix} .
	In addition, erectile dysfunction affects c.50% of all adult patients who have undergone pelvic surgery, and c. 100% of adult patients who have undergone an intervention for bladder cancer. Of these additional patients, it is estimated that c. 20% will progress to ESED, numbering 1,900 – 2,000 per year. ^x
	Of the c 7,115 ^{xi} adult patients with ESED, it is estimated that between 5% and 7.5% ^{xii} might require a new penile prosthesis implant each year. Applying this to patient estimate of men with ESED results is a target population group of c. $355 - 535$ in 2014/15. ^{xiii}
K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for adults (aged 18 and over).
K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Erectile dysfunction appears to be more prevalent in older patients ^{xiv} . As such, the population taking up this procedure could usually be expected to be aged over 40 ^{xv} . However, patients aged above 75 are less likely to receive treatment. ^{xvi}

K1.5 What is the current activity associated with currently routinely commissioned care for this group?	 K1.5 A penile prosthesis implant is the last line of treatment for this patient group. There are estimated to be currently c. 500 episodes relating to penile prostheses in 2014/15^{xvii}. This includes activity for the implant of, and attention to, penile prostheses. Attention to penile prostheses relates to all non-implant activity and would include revisions^{xviii}. The dataset includes two main procedures^{xix}: Implantation of prosthesis into penis (331 or 66% of total activity) Attention to prosthesis in penis (170 or 34% of total activity) It is to be noted that currently the procedure is commissioned locally by CCGs based on the local commissioning practice for the treatment. This has led to differences in access across the country and as such, significant variation in activity (relative to population).
K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	 K1.6 No specific factors affecting the incidence rate (as described in K1.1) were identified. As such, it is assumed that the number of new cases grows in line with the aged 40-70 male population in England. The incidence is thus expected to be:^{xx} ~ 262k in 2016/17 (year 1) ~ 261k in 2017/18^{xxi} (year 2) ~ 263k in 2020/21 (year 5)
K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	 K1.7 In the absence of the new policy, activity would continue to be commissioned locally. Based on the recent trend in penile prosthesis procedures^{xxii}, future activity could be in the region of: ~ 510 in 2016/17 (year 1)

		 ~ 515 in 2017/18 (year 2) ~ 530 in 2020/21 (year 5) This includes activity for both new implants and attention to prosthesis in penis, which includes revision surgery. This is the 'donothing' activity.^{xxiii}
	K1.8 How is the population currently distributed geographically?	K1.8 As noted in K1.4, the target population typically includes men aged over 40 so the geographic distribution of patients is expected to be in line with this.
		Moreover, as noted in K1.5, due to differences in local commissioning practices there is variation in access across the country. As such, there is observed variation in the rates per thousand population across the country, when controlling for gender and age.
K2 Future Patient Population & Demography	K2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	K2.1 The policy proposes that the new implantation of a penile prosthesis is routinely commissioned for the specific cohort identified in K1.2. Currently there is no national commissioning policy on this treatment and there is significant variation in local commissioning. ^{xxiv}
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	K2.2 It is estimated that over 70% of erectile dysfunction cases due to physical factors are caused by vascular diseases and diabetes ^{xvv} . As such, lifestyle factors such as smoking and alcohol may affect future growth rates by influencing the prevalence of these conditions. ^{xvvi}

K 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details	K2.3 No changes to the underlying patient population are expected – though there will be more consistent access to the service across the country which may increase activity in certain regions.
K2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	K2.4 As noted in K1.5, due to differences in local commissioning practices there is variation in access across the country. With the policy in place, there would be consistency in commissioning position across England and hence all those clinically eligible would be able to access the service. As such, there is expected to be an increase in activity over time.
	Based on 2014/15 activity data ^{xxvii} , when controlling for gender and also age (aged 40 and over, as specified in K1.4), the London Area Teams reflect the upper decile of activity rates per thousand of the population nationally. ^{xxviii} These have been fairly consistent over the last few years and the view of the policy working group is that this reasonably reflects the policy ambition. If all areas in the country were to reach the upper decile then overall activity levels could increase by c.75%. ^{xxix}
	However, there are some immediate structural barriers to meeting this increased demand (as covered in the service specification) – particularly around the capacity in the designated specialist centres to undertake the increased volumes of activity. As such, the increase in activity would not be immediate and may take $4 - 5$ years to reach full year effect.
	 Based on the above, the net increase estimated future activity (including both new implants and revisions), could be in the region of: ~ 90 in 2016/17 (year 1), assuming 25% phasing

		 ~ 180 in 2017/18 (year 2), assuming 50% phasing ~ 350 in 2020/21 (year 5), assuming 100% phasing
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet	K3.1 Current annual activity is identified in K1.5.
	K3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet	 K3.2 As noted in K2.4, the policy is expected to lead to an increase in overall activity with the new in activity expected to be phased in over time. New activity is expected to be in the region of^{xxx}: ~ 605 in 2016/17 (year 1) ~ 695 in 2017/18 (year 2) ~ 880 in 2020/21 (year 5)
	K3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet	K3.3 If the policy is not adopted, current trends in penile prosthesis implants are expected to continue. This is outlined in K1.7.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated	K4.1 Currently, only drug therapies and intraurethral injections are commissioned but the patients requiring penile prosthesis will have already trialled these interventions and found them to be ineffective. These patients will first see their GP when experiencing erectile

	activity	dysfunction. GPs will advise on lifestyle changes and may start medications such as sildenafil (Viagra). GPs refer to specialist urological teams if these initial therapies and lifestyle changes are ineffective. The specialist urological team can also trial intraurethral injections and external devices such as vacuum pumps. If none of the above are effective, penile prosthesis is considered. Current variation in the commissioning of penile prosthesis across CCGs (with most CCGs requiring IFRs) leads to inequality of access.
	K4.2. What are the current treatment access criteria?	K4.2 Patients with erectile dysfunction who fail lifestyle changes, pharmacotherapies or external vacuum devices, as described in K4.1 will have access to penile prosthesis. In addition, patient's undergoing pelvic surgery (for example for bladder cancer) will be considered for penile implant.
	K4.3 What are the current treatment stopping points?	K4.3 Currently, patients will leave the pathway if the lifestyle changes or initial pharmacotherapy is effective. Some patients will also leave the pathway despite being eligible for penile prosthesis after undergoing preoperative counselling and choosing not to undergo the procedure.
K5 Comparator (next best alternative treatment) Patient Pathway	K5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity.	K5.1 There is no 'next best' alternative to penile prosthesis in patients with end stage erectile dysfunction. All comparators would have already been tried and found ineffective.
	K5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected	K5.2 Estimated 80% of erectile dysfunction patients will respond to oral medications. Of the remaining 20%, 70% will then achieve symptomatic relief through intraurethral injection or external devices. The remaining patients will go on to be defined as 'End Stage Erectile

	to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	Dysfunction' and, as discussed in K1.2, between 5% and 7.5% are estimated to require a new penile prosthesis each year.
K6 New Patient Pathway	K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy	K6.1 As K4.1, however the specialised urological MDT can then decide to go ahead with penile prosthesis if initial treatment options were ineffective.
	K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	K6.2 As K.5.2, in addition, those who are contraindicated to penile prosthesis (due to allergy to device components or untreated lower urinary tract symptoms) would not continue to penile prosthesis. Some patients will also leave the pathway despite being eligible for penile prosthesis after undergoing preoperative counselling and choosing not to undergo the procedure.
K7 Treatment Setting	 K7.1 How is this treatment delivered to the patient? o Acute Trust: Inpatient/Daycase/ Outpatient o Mental Health Provider: Inpatient /Outpatient 	K7.1 This treatment is an inpatient surgical procedure and includes an average hospital stay of one overnight ^{xxxi} .

	 Community setting 	
	• Homecare delivery	
	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what?	K7.2 No anticipated change in delivery. Estimated increase in service capacity requirements to meet the estimated demand identified in K3.2.
	e.g. service capacity	
K8 Coding	K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 As this treatment is delivered as an inpatient procedure; this is recorded within the SUS central data repository.
	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 Activity would be identified by procedure codes ^{xxxii} within SUS.
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 As per L1.2
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 Not applicable.
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 All centres undertaking penile prosthesis will be required to report outcomes (including patient-partner satisfaction, infection rates and mechanical failure rates) into the British Association of Urological

	Surgeons (BAUS) national penile prosthesis audit.
K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 Activity should be delivered in penile centres; there will be a need in some localities to increase contracted activity levels. Further guidance will be given to local contracting teams within a specialised commissioning circular.
K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 Not applicable
K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 No
K9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. See also linked question in M1 below	K9.7 No – Blueteq is not proposed
Section L - Service I	mpact
Questions	Comments (Include source of information and details of assumptions

Theme

		made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	L1.1 There is currently one centre undertaking the majority of penile implants. Three other centres undertake approximately 20 implants per year and there are many other smaller centres undertaking 5-10 implants per year, or less.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	 L1.2 Upon commissioning of this policy, NHS England will need to produce a service specification to dictate how the service is organised. This will include details on: (1) The number of centres commissioned to implant penile prosthesis (2) The route of referrals to the specialised urology service (3) To what extent activity shifts to larger centres and therefore how service capacity will change year on year (4) Changes in provider staffing and support services
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 GPs refer to local urology departments who refer on to specialised urological MDT for prosthesis consideration.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 As per L1.2, with no expected increase in the sources of referrals.
	L2.3 Is the new policy likely to improve equity of access	L2.3 The new policy is expected to improve equity of access
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 The new policy is expected to improve equality of access and improve outcomes by ensuring penile prosthesis is carried out at

		larger volume implant centres.
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 No lead time.
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No change anticipated
	L3.3 Is there a change in provider staffing required?	L3.3 As per L1.2
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 As per L1.2
	L3.5 Are there changes in the support services that need to be in place?	L3.5 As per L1.2, including access to psychosexual counselling services at centres commissioned to implant penile prostheses.
	L3.6 Is there a change in provider / inter- provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 As per L1.2

	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 As per L1.2	
	L3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	L3.8 As per L1.2, publication of new service specification	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 No	
	Section M - Finance Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)	
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	 M1.1 The procedures fall under national prices with the corresponding HRG codes from the 2014/15 national tariff: For 'Implantation of prosthesis into penis' the corresponding HRG code is LB74Z - Implantation of Penile Prosthesis with a tariff listed as £7,694^{xxxiii}. This includes the device cost. 'Attention to prosthesis in penis' refers to the HRG codes LB47Z – Penis Major Open Procedures and LB48Z – Penis Intermediate Open Procedures. The weighted average tariff for these two HRG codes is estimated to be £2,448.^{xxxiv} 	

	 It should be noted that the for HRG LB74Z '<i>Implantation of prosthesis into penis</i>', the tariff price in 2015/16 is significantly lower, at: HRG LB74Z - Implantation of Penile Prosthesis has a tariff^{xxxv} of £4,009. This includes the device cost.^{xxxvi} HRG codes LB47Z - Penis Major Open Procedures and LB48Z - Penis Intermediate Open Procedures have a weighted average tariff estimated to be £2,476. In the 2016/17 shadow tariff this is proposed as: HRG LB74Z - Implantation of Penile Prosthesis has a proposed tariff^{xxxvi} off £8,479. This includes the device cost. HRG codes LB47Z - Penis Major Open Procedures and LB48Z - Penis Intermediate Open Procedures the device cost. HRG codes LB47Z - Implantation of Penile Prosthesis has a proposed tariff^{xxxvii} off £8,479. This includes the device cost. HRG codes LB47Z - Penis Major Open Procedures and LB48Z - Penis Intermediate Open Procedures have an estimated weighted average tariff of £2,331. This is discussed in M6.1.
M1.2 Is this treatment excluded from national prices	M1.2 Not applicable.
M1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	M1.3 Not applicable.
M1.4 If a new price has been proposed	M1.4 Not applicable.

	how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes	
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 Not applicable.
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	M1.6 No
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	 M2.1 The total cost^{xxxviii} per patient is usually comprised of the following components: Patients receive a "pre-assessment"^{xxxix}, which has a cost of c. £168 per patient.^{xl} a) New patients are expected to take up the implantation procedure^{xli}, which has a tariff of £8,328^{xlii}. b) Revisions and replacements to existing penile implants will fall under attention to penile prosthesis^{xliii} and have an average tariff of £2,650^{xliv}. After treatment there will be a check-up where the patient is taught how to use the device. This has a tariff of £76.^{xlv}
		has a tariff of £76 ^{xivi} . Costs per patient in year one could therefore range from c. £2,969 ^{xivii} (for revisions) to c. £8,647 ^{xiviii} for new implants ^{xiix} . Were both a new implant and a revision required in the same year then the annual cost

		would be c. £11,616 (for new implant plus revision).
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Some patients may have long term follow-up plans, however these are determined on an individual basis and are difficult to quantify. These could cost c. £76 per follow-up attendance as mentioned in M2.1. Moreover, revisions or replacements of the implants may be needed in the future. These could cost £2,969 as described in M2.1. Apart from follow-ups and potential revisions, there are no further
		ongoing costs of the treatment identified.
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England	M3.1 Under the policy it is assumed that the funding for penile prosthesis implants would transfer from CCGs to NHS England. Given the current activity in K1.7 and the costs per patient in M2.1, the current spend on penile prosthesis expected to transfer to NHS England would be in the region of:
		 ~ £3.4m in 2016/17 (year 1) ~ £3.4m in 2017/18 (year 2) ~ £3.5m in 2020/21 (year 5)
		As discussed in K2.4, there is estimated to be an increase in the volume of activity following implementation of the policy, however, this may take a few years to implement. Based on the policy achieving full year effect by year 4 or 5, the additional cost pressure could be:
		 £0.6m in 2016/17 (year 1, assuming 25% effect) £1.2m in 2017/18 (year 2, assuming 50% effect) £2.3m in 2020/21 (year 5, assuming 100% effect)

		This is the cost of servicing the additional activity increase presented in K2.4. ^{li}
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured	M3.2 Not applicable.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	M4.1 This is likely to be cost neutral to CCGs as it is assumed that their budget for penile prosthesis implants would transfer to NHS England under the policy.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole	M4.2 Whilst estimates of future activity are uncertain, they are likely to increase. This would represent an overall cost pressure to the NHS, borne by NHS England. This is identified in M3.1.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured	M4.3 Not applicable.
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 Not anticipated.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified <i>e.g.</i> <i>decommissioning less clinically or cost</i> -	M5.1 To be discussed at CPAG.

	effective services	
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 Given the variation in how this is currently commissioned locally, a national policy could lead to increased activity if there is unmet need in the system. The potential costs of these are outlined in K3.1.
		Moreover, in the 2015/16 Enhanced Tariff Option, the price of a new penile prosthesis implant is significantly cheaper than the one identified within the 2014/15 National Tariff. ^{III} Were the 2015/16 tariff to prevail, the cost pressure indicated in M.4.2 is estimated to be:
		 ~ £0.4m in 2016/17 (year 1) ~ £0.7m in 2017/18 (year 2) ~ £1.5m in 2020/21 (year 5)
		In the 2016/17 tariff proposals, however, the price for the new penile prosthesis implants increases to around 10% greater than in 2014/15 ^{liii} . In the case, the cost pressure indicated in M4.2 is estimated to be:
		 ~ £0.7m in 2016/17 (year 1) ~ £1.3m in 2017/18 (year 2) ~ £2.6m in 2020/21 (year 5)
	M6.2 Can these be mitigated, if so how?	M6.2 Not applicable.
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	M6.3 The impact modelled assumes a phasing of the transition towards more consistent access across the country. The following phasing assumptions are used to arrive at a best estimate:
		• Year 1, 25%

		 Year 2, 50% Year 3, 75% Year 4, 100% Year 5, 100% However, the actual activity may vary. Using the 2014/15 tariff, costs could be up to c. £2.4m if full year effect were to be achieved in the Year 1 or 2.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i>	M7.1 The evidence review has not provided any literature on cost effectiveness of the intervention
	M7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i>	M7.2 No evidence available
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i>	M8.1 None expected
	M8.2 If so, confirm the source of funds to meet these costs	M8.2 N/A

ⁱ NICE clinical knowledge summaries. Erectile dysfunction. [Online] Available from <u>http://cks.nice.org.uk/erectile-dysfunction#!backgroundsub:2</u> [Accessed: 26/11/2015].

ⁱⁱ Prevalence has been estimated to be c. 26% for UK men aged 18-75 [Source: British Society for Sexual Medicine Guidelines on the Management of Erectile Dysfunction, 2007]. This is applied to the relevant age group for 2014 from the ONS (2012) population projections.

ⁱⁱⁱ In men over 40 it is estimated that c. 40% could have a degree of erectile dysfunction (Based on information received from the policy working group). This is applied to the relevant age group for 2014 from the ONS (2012) population projections.

^{iv} It has further been estimated that c.50% of men aged 40-70 will have a degree of erectile dysfunction [Source: NHS Choices. Erectile dysfunction. [Online] Available from http://www.nhs.uk/conditions/Erectile-dysfunction/Pages/Introduction.aspx [Accessed: 26/22/2015]]. This is applied to the relevant age group for 2014 from the ONS (2012) population projections.

^v UK Health Centre. Statistics on Erectile Dysfunction. [Online] Available from <u>http://www.healthcentre.org.uk/pharmacy/erectile-dysfunction-statistics.html</u> [Accessed: 21/11/2015].

^{vi} European Association of Urology (2015). Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation.

vii Based on population estimates for men in England between the ages of 40 and 70 in 2014/15 [Source: ONS (2012). Population projections].

^{viii} Specifically men having failed pharmacological treatment, men with end stage Peyronie's, men with buried penises, men with erectile dysfunction after surgery/radiotherapy for pelvic cancer/secondary to vascular disease/penile cancer surgery/diabetes/neurological disease, and patients undergoing penile reconstruction. (Based on discussions with the policy working group).

^{ix} This assumes that 33% of the 261,000 incident population with erectile dysfunction identified for 2014/15 seek advice from a healthcare professional. Clinical view suggests that c. 80% will respond to oral medication and of the remaining 20%, around 70% are likely to be successfully treated by other methods. The remaining c. 5,165 patients would be classified as having ESED (based on discussions with the policy working group).

^x Based on discussions with the policy working group

^{xi} Please note this uses 1,950, the mid-point for the number of patients who would have ESED after having undergone pelvic surgery or an intervention for bladder cancer.

^{xii} Assumption from the clinicians in the policy working group.

^{xiii} See policy proposition.

x^{iv} Guidelines on Male Sexual Dysfunction: Erectile dysfunction and premature ejaculation. K. Hatzimouratidis (chair), I. Eardley, F. Giuliano, D. Hatzichristou, I. Moncada, A. Salonia, Y. Vardi, E. Wespes © European Association of Urology 2014.

^{xv} Based on discussions with the policy working group, and NHS Choices, Erectile Dysfunction. [Online] Available from <u>http://www.nhs.uk/conditions/Erectile-dysfunction/Pages/Introduction.aspx</u> [Accessed: 26/11/2015].

^{xvi} Based on discussions with the policy working group.

^{xvii} Hospital Episode Statistics (HES) 2014/15 for the procedure codes N291and N292.

^{xviii} This is also expected to include activity such as scar revisions, replacements and glanspexy.

xix The OPCS code N291-Implantation of prosthesis into penis relates to the implantation of penile prostheses for a first time surgery, while N292 - attention to prosthesis in penis refers to the renewal/revision of a penile prosthesis.

x 2012-based Subnational Population Projections for England (ONS) with a CAGR of c.0.3% and c.0.02% from 14/15 to 16/17 and 19/20 respectively.

xⁱ Please note that a negative population growth is observed between 2016/17 to 2017/18 for men aged between 40 and 70.

x^{xii} Based on trends between 2009/10 and 2014/15 obtained from HES data for the implantation of, and attention to, penile prostheses [OPCS codes N291.1, N29.2 and N29.8], a CAGR of c. 1% was identified.

^{xxiii}This is the activity that is estimated to be serviced were the policy not to be implemented, and the current state continues to operate.

xxiv Based on discussions with the policy working group

^{xxv}Based on discussions with the policy working group and British Association of Urological Surge and British Association of Urological Surgeons. Erectile Dysfunction (Impotence). [Online] Available from. <u>http://www.baus.org.uk/patients/conditions/3/erectile_dysfunction_impotence</u> [Accessed: 26/11/2015].

^{xxvi} Based on NHS Choices (2014). *Erectile dysfunction (impotence) – Causes*. [Online] Available from <u>http://www.nhs.uk/Conditions/Erectile-dysfunction/Pages/Causes.aspx</u> [Accessed: 15/01/2016].

^{xxvii} 2014/15 activity data by Area Team, Source: NHS England

xxviii Based on 2014/15 data from NHS England.

xix This is based on data from 2014/15, however this is fairly consistent for the previous two years.

^{xxx} Please note that the figures in K1.7 and K2.4 may not sum exactly due to rounding.

^{xxxi} British Association of Urological Surgeons. Erectile Dysfunction (Impotence). [Online] Available from. <u>http://www.baus.org.uk/patients/conditions/3/erectile_dysfunction_impotence</u> [Accessed: 26/11/2015].

xxxii OPCS codes N29.1, N29.2 and N29.8

xxiii With a 10% MFF uplift this would be £8,463

^{xxxiv} This is based on the activity weighted tariff for the HRG codes LB47Z and LB48Z as well as the relative ratio of elective and non-elective spells obtained from HES 2014/15. Tariff numbers for the two HRG codes are obtained from 2014/15 Tariff. With a 10% MFF uplift this would be £2,693

^{xxxv} Combined daycase and elective

^{xxxvi} It was noted by the policy working group that this is lower than the cost of the prosthesis implant itself.

xxxvii Combined daycase and elective tariff

^{xxxviii} These take 2014/15 tariff price, and apply an average MFF of 10% and apply the 2015/16 efficiency (-3.5%) and inflation (1.9%) to determine 2015/16 prices. These are then assumed constant going forward.

^{xoxix} British Association of Urological Surgeons. Erectile Dysfunction (Impotence). [Online] Available from<u>http://www.baus.org.uk/patients/conditions/3/erectile_dysfunction_impotence</u> [Accessed: 26/11/2015]

^{xi} Based on 2014-15 tariff figures for first-attendance multi professional Urology.

^{xli} OPCS codes N291 and N298.

x^{lii} These take 2014/15 tariff price, and apply an average MFF of 10% and apply the 2015/16 efficiency (-3.5%) and inflation (1.9%) to determine 2015/16 prices. These are then assumed constant going forward.

xliii OPCS code N292.

x^{iv} These take 2014/15 tariff price, and apply an average MFF of 10% and apply the 2015/16 efficiency (-3.5%) and inflation (1.9%) to determine 2015/16 prices. These are then assumed constant going forward.

xlv Based on 2014/15 tariff for Urology Follow-up attendance (single professional)

x^{lvi} Based on 2014/15 tariff for Urology Follow-up attendance (single professional)

xivii Figures may not sum exactly due to rounding.

xiviii Figures may not sum exactly due to rounding.

xix It is likely that outpatient attendances remain to be funded by CCGs given that they are only identifiable under the urology treatment function code.

¹ Not controlling for inflation and potential efficiency gains in the future.

ⁱⁱ This assumes the same proportion of new implants and revisions as in K1.5.

ⁱⁱⁱ HRG LB74Z is listed as £4,009 in 2015/16 compared to £7,694 in 2014/15 for combined elective and day case tariff. This excludes an MFF uplift.

IIII HRG LB74Z is listed as between £8,479 and £8,502 in 2016/17, compared to £7,694 in 2014/15. This excludes an MFF uplift.