Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	B14X06		
Policy Title	Urethroplasty for benign urethral strictures in adult men		
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Section K - Activity Impact			
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1. 1 This policy proposes to set out a **routine commissioning** position for the treatment of benign urethral strictures. Urethral strictures are estimated to affect about 62,000 men in the UK, or c. 52,000 in England[i], at any one time.[ii] Prevalence of urethral strictures varies worldwide[iii] and prevalence estimates from the United States are c. 200 per 100,000 for men in their 20s rising to 900 per 100,000 for men in their 70s.[iv]	

	K1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	K1.2 Under the policy it is proposed that urethroplasty will be routinely commissioned for the treatment of benign urethral strictures in patients following an assessment by a multi-disciplinary team (MDT), and specifically[v]: i. Patients with urethral strictures longer than 3cm in length; or ii. Patients with lichen sclerosis and lengthy penile urethral strictures which are unlikely to respond to first-line treatment (urethrotomy); or iii. Patients with short bulbar urethral strictures following at least one urethrotomy, unless after counselling about treatment options the patient would prefer to undergo primary urethroplasty and is aware of the risks and benefits of surgery. Repeat procedures for patients who have recurrent urethral strictures following urethral dilation, urethrotomy or urethroplasty will be funded. It is estimated that every year over 3,360 men in England require surgery for recurrent bulbar urethral strictures.[vi] This corresponds to c. 6% of the prevalent population.
	K1.3 What age group is the treatment indicated for?	K1.3 This treatment is indicated for adults (18 years and over).
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 The mean age of treatment is 39 with the majority of adult patients receiving surgery ages 40-60. [vii]

	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 It is estimated that in 2014/15 c. 730 men received a **urethroplasty**[viii]. Those currently not receiving an urethroplasty are expected to instead receive multiple **urethrotomies**, and it is estimated that c. 3,000[ix] men underwent an urethrotomy for recurrent stricture in 2014/15. Data from HES show c. 4,660 episodes relating to urethrotomies in 2014/15.[x]
	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 The most common cause of urethral strictures is injury or damage to the urethra or infection (see K2.2). Therefore, no specific factors affecting the growth of urethral strictures other than demographic factors were identified. Future prevalence is thus estimated in the region of[xi] • ~ 53k in 2016/17 (year 1) • ~ 53k in 2017/18 (year 2) • ~ 54k 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 proposed policy (under a do nothing scenario) – it is anticipated that the historic growth trend would continue. Based on historic growth in the number of episodes relating to urethroplasties between 2009/10 and 2014/15, a Compound Average Growth Rate (CAGR) of c. 1.1% was identified.[xii] If this growth rate continues, the number of urethroplasties in future are estimated in the region of:[xiii] • ~ 745 in 2016/17 (year 1) • ~ 755 in 2017/18 (year 2) • ~ 780 in 2020/21 (year 5)

	K1.8 How is the population currently distributed geographically?	K1.8 Across England – no geographic differences have been identified in the sources reviewed.
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 This policy aims to routinely commission urethroplasties for men with benign urethral strictures. This procedure is already commissioned however there is no national commissioning policy in place.
	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 As urethral strictures are mainly due to trauma or infections[xiv], no specific factors affecting growth were identified other than demographic factors.
	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 were identified.
	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 Under a routine commissioning position, it is expected that number of urethroplasties being undertaken could double over the next five years.[xv] Assuming this is spread proportionately over the next five years[xvi], the net increase in the number of urethroplasties undertaken is estimated to be in the region of:

		• ~ 225 in 2016/17 (year 1) • ~ 340 in 2017/18 (year 2) • ~ 670 in 2020/21 (year 5) In the absence of the policy (do nothing), it is expected that these patients would have instead received multiple urethrotomies, so by having the urethroplasty the probability of a recurrence is expected to fall. Recurrence rates for repeat urethrotomies are estimated to range between 50 and 100%, with a median of 80% within 24 months.[xvii] It is also estimated that in the UK, men undergoing a urethroplasty will have undergone a median of 3 to 5 previous urethrotomies.[xviii] Urethroplasties on the other hand have been found to have recurrence rates ranging from 11 to 24% over 1 to 4 years.[xix] Under the assumption that by having a urethroplasty the need for an average of 3 urethrotomies could be removed[xx], the increase in urethroplasties above could be associated with the following **decrease in urethrotomies**: • ~ 680 (for urethroplasties undertaken in 2016/17) • ~ 1,020 (for urethroplasties undertaken in 2017/18) • ~ 2,035 (for urethroplasties undertaken in 2020/21) The year in which these procedures would be avoided is not known, however there could be a lag up to 24 months per repeat procedure.[xxi]
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 activity is described 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 described in K2.4, there is expected to be an increase in urethroplasties under the policy. The total number undertaken each year is estimated to be in the region of: • ~ 970 in 2016/17 (year 1) • ~ 1,095 in 2017/18 (year 2) • ~ 1,455 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 The activity under the 'Do Nothing' is as described 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 activity	K4.1 Patients who see their local GP or present at A&E with urinary symptoms, infection or poor flow will be referred to a general urologist. The urologist will investigate with a flexible cystectomy under local anaesthetic. The standard treatment for newly diagnosed strictures is urethrotomy or dilatation (both endoscopic treatment modalities), which can be carried out by general urologists in most urology departments. The narrowed diseased segment of urethra is widened by either incising longitudinally with a cold steel blade (endoscopic urethrotomy) or stretching the urethra with serial dilators of increasing diameter (urethral dilatation). If this initial treatment fails, the options are either to repeat the urethrotomy / dilatation followed by intermittent self-dilation, or carry out a urethroplasty, an anastomotic procedure or an augmentation using a buccal graft. Current guidelines suggest that after any failed urethrotomy an open urethroplasty should be considered and discussed with the patient, or

		to have a repeat urethrotomy.
	K4.2. What are the current treatment access criteria?	K4.2 The treatment decision is taken by a urologist following a flexible cystectomy.
	K4.3 What are the current treatment stopping points?	K4.3 Some patients decline urethrotomy or are not suitable or have significant comorbidities. Of the 15,000 patients who undergo urethrotomy in the UK, 50% of patients with short bulbar strictures respond successfully and do not require repeat urethrotomy.
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 Patients would follow the same pathway and instead of urethrotomy, patients may opt for comparator treatments including observation, intermittent self-dilation, or repeated stretching using metal/plastic dilators.
	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 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.	K5.2 Same stopping points as K4.3

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 Having identified an anterior urethral stricture, a urethrogram should be carried out to identify the length of the stricture and its exact relationship to the rest of the urinary tract. The alternative to this would be the use of ultrasound of the corpus spongiosum. Treatment options are considered as part of an MDT, and all patient will also undergo further investigation with an urethrogram or flexible cystectomy to confirm the stricture and before a decision is made about the going onto surgery. Urethroplasty should be considered for strictures longer than 3cm in length and for patients with lichen sclerosis and lengthy strictures and penile urethral strictures which are unlikely to respond to urethrotomy. Patients with a lengthy stricture who have significant comorbidities should consider perineal urethrotomy as a primary approach. Traumatic anterior urethral strictures require open surgical resolution. Urethrotomies and/or urethral dilation should be considered for strictures shorter than 3cm in length as first-line treatment, unless patients are contraindicated and/or after counselling about treatment options the patient would prefer to undergo urethroplasty. Where patient shows incomplete response to first-line treatment, urethroplasty is proposed. Patients will receive information from a urologist explaining the risks and benefits of the procedure, outlining the potential side effects of urethroplasty which include: a low incidence of impotence (no more than 2-6% at six months); a risk of failure which is highest with augmentation urethroplasty; a risk of post-micturition dribbling following urethroplasty although this is often present previously with a stricture. If patients do not want to have urethroplasty, alternative treatment includes intermittent self-dilation for at least six months following a urethrotomy.
	K6.2 Where there are different stopping points on the pathway please indicate	K6.2 Some patients decline urethroplasty or are not suitable or have

	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.	significant comorbidities. Urethrotomies and/or urethral dilation should be considered for strictures shorter than 3cm in length as first-line treatment, unless patients are contraindicated and/or after counselling about treatment options the patient would prefer to undergo urethroplasty.
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 o Community setting o Homecare delivery	K7.1 This treatment is delivered as a surgical inpatient procedure under general anaesthetic.[xxii]
	K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	K7.2 Delivery setting will not change. There may be an increase in capacity requirements as patients more patients are prescribed urethroplasty as a first line treatment option, although these patients are likely to eventually receive urethroplasty as a second line treatment in the existing patient pathway.
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 is an inpatient procedure; activity is recorded within the Secondary Uses Services (SUS) 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 could be identified by specific ICD-10 code[xxiii] and OPCS codes relating to the procedures. [xxiv]
K9 Monitoring	K9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	K9.1 No
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 N/A
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 N/A
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 N/A
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 Surgeons should participate in the national clinical audit administrated by BAUS.
	K9.6 Are there any directly applicable	K9.6 No

	NICE quality standards that need to be monitored in association with the new policy?	
	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
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions 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 Urethroplasty is usually carried out in specialist centres.
	L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.2 No change in organisation.
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 Patients who see their local GP or present at A&E with urinary symptoms, infection or poor flow will be referred to a general urologist.
	L2.2 Will the new policy change / restrict / expand the sources of referral?	L2.2 Sources of referral will not change.

	L2.3 Is the new policy likely to improve equity of access	L2.3 Yes, all patients across England will have access to treatment through specialised commissioning.
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 Should ensure consistent access and improve consistency of outcomes due to patients receiving most suitable treatment.
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 in time
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No. Although the patient pathway will change to consider urethroplasty as first line treatment, the infrastructure is already in place.
	L3.3 Is there a change in provider staffing required?	L3.3 No change expected.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No change expected.
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No change expected.

	L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 Specialist urology MDT will have a greater role in the governance arrangements.
	L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	L3.7 No change expected.
	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 This treatment is paid under tariff with the following HRG codes and prices: • For urethroplasty – LB29A: Urethra Major Open Procedures 19 years and over, £2,698.[xxv] • For urethrotomy – LB55A: Urethra Intermediate / Minor

		Procedures 19 years and over, £618.[xxvi]
	M1.2 Is this treatment excluded from national prices	M1.2 No, please refer to M1.1.
	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 No, please refer to M1.1.
	M1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes	M1.4 Not applicable
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 Yes.
	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 cost in year 1 for a urethroplasty would comprise:

		1. **Pre-assessment and investigation.** Every patient's case is first considered at an MDT meeting with an estimated cost of c. £168[xxvii]. The patient would then undergo further investigation with an urethrogram or flexible cystectomy to confirm the stricture and before a decision is made about the going onto surgery. This costs an estimated £137.[xxviii] 2. **The procedure.** a) Urethrotomy should be considered for strictures shorter than 3cm, in length as first-line treatment.[xxix] This would cost c. £670.[xxx] b) The cost of an urethroplasty is estimated in the region of c. £2,920.[xxxi] 3. **Follow-up costs.** Patients are expected to be followed-up every 3 months. This could cost c. 76 per follow-up attendance, or £305 in total. This leads to a revenue cost per patient in year one in the region of c. £1,280 for a urethrotomy, or £3,530 for a urethroplasty. In both cases where a catheter is required, this would be removed after c. 2 weeks. Where patients undergo a urethrotomy, where the stricture recurs then they could choose to self-catheterise, and these would be provided on a prescriptions basis from the GP.[xxxii] Where patients are managed with repeat urethrotomies, it is expected that these patients would have increased interactions with the health service, so the cost impact may not just be that of the repeat itself.[xxxiii]
	M2.2 What is the revenue cost per patient in future years (including follow up)?	M2.2 Patients would likely be followed-up once per year[xxxiv] and this could cost c. £76 as identified in M1.1.
M3 Overall Cost Impact of this Policy to	M3.1 Indicate whether this is cost saving,	M3.1 The proposed policy is expected to have the following cost

<table>
<tr>
<td>NHS England</td>
<td>neutral, or cost pressure to NHS England</td>
<td>impacts to NHS England:

1. An increase in urethroplasties undertaken (and therefore potential repeats); and
2. A corresponding decrease in the number of urethrotomies undertaken.

This could have the following financial impact:

<table>
<tr><th>Year</th><th>Cost from additional urethroplasties</th><th>Cost of repeat urethroplasties *</th><th>Avoided cost of urethrotomies*</th></tr>
<tr><td>2016/17 (year 1)</td><td>c. £0.8m</td><td>c. £0.1 to £0.2m</td><td>c. -£0.9m</td></tr>
<tr><td>2017/18 (year 2)</td><td>c. £1.2m</td><td>c. £0.1 to £0.3m</td><td>c. -£1.3m</td></tr>
<tr><td>2020/21 (year 5)</td><td>c. £2.4m</td><td>c. £0.3 to £0.6m</td><td>c. -£2.6m</td></tr>
</table>
*These costs / savings are likely to be spread over a number of years.

The policy is therefore expected to be broadly cost neutral to NHS England. The extent to which this could be a cost pressure, or even cost saving, would depend on how the additional cost of repeat urethroplasties and the avoided costs of urethrotomies are likely to be spread over future years.

Given these are likely to be spread over a number of years; this policy is likely to represent a cost pressure to NHS England in early years.</td>
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	M3.2 Where this has not been identified, set out the reasons why this cannot be measured	M3.2
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 expected to be broadly cost neutral to other parts of the NHS. As discussed in M2.1, it is expected that being managed unsuccessfully with urethrotomies could lead to more interactions with the health service, however this cannot be quantified.
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole	M4.2 Please refer to 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 expected.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified *e.g. decommissioning less clinically or cost-effective services*	M5.1 To be discussed at CPAG.

M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy?	M6.1 No material financial risks have been identified.
	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 scenario presented in M3.1 assumes that for every additional urethroplasty undertaken, three future urethrotomies would be avoided. The financial impacts are based on the net change in activity identified in K2.4 and the costs per patient in M2.1.
M7 Value for Money	M7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	M7.1 & M7.2 Studies looked at comparative cost effectiveness of direct vision internal urethrotomy (DVIU) and urethroplasty as the primary methods of managing bulbar urethral strictures. In summary, although the direct and indirect cost of a single urethrotomy episode is much lower than urethroplasty, due to significantly high rate of recurrence after these procedures, urethroplasty is likely to be more cost effective as a primary procedure in cases where the chances of recurrence are high such as longer strictures. A combination approach with single urethrotomy followed by urethroplasty for any future intervention could be more cost effective in small bulbar strictures with low chances of recurrences. Greenwell et al (2004) reported a strategy of initial urethrotomy or urethral dilation followed by urethroplasty in patients with recurrent stricture proves to be financially most cost-effective. United Kingdom medical and hospital costs were applied to management of urethral stricture to 126 patients treated in a general urological setting. Urethrotomy/urethral dilation £2,250, simple 1-stage urethroplasty

		£5,015, complex 1-stage urethroplasty £5,335 and 2-stage urethroplasty £ 10,370. Of the 126 patients assessed 60 (47.6%) required more than one repeat urethrotomy (mean 3 procedures/ person). The total cost per patient for all 126 patients for stricture treatment during follow-up was £6,113. This cost was calculated by multiplying procedure cost by the number of procedures performed. A strategy of urethrotomy or urethral dilation as first line treatment, followed by urethroplasty for recurrence yielded a total cost per patient of £5,866. Two US-based analysis also reported similar findings. Wright et al (2006) used a decision tree with the number of planned possible urethrotomy before attempting urethroplasty using published success rates. Costs were based on United States data and estimated from a societal perspective and included the costs of the procedures and office visits and work absenteeism during recovery. This study reported that the best most cost-effective approach for 1-2 cm bulbar strictures was single urethrotomy followed by urethroplasty, if a revision was required. The incremental cost of performing a second urethrotomy before attempting urethroplasty was $141,962 for each additional successfully voiding patient. For longer strictures for which the success rate of DVIU is expected to be less than 35%, urethroplasty as primary therapy was likely to be more cost-effective. Rourke et al (2005) developed a cost minimisation decision analysis model for the costs of urethrotomy and open urethral reconstruction for 2 cm bulbous urethral strictures, taking into account clinical probability estimates for complications and recurrence. Direct third party payer costs were determined in 2002 United States dollars. The model predicted that treatment with urethrotomy was more costly than immediate open urethral reconstruction with an incremental cost savings of $1,304 per patient, favouring urethral reconstruction. Treatment with urethrotomy became more favourable when the long-term risk of stricture recurrence after urethrotomy was less than 60%.

	M7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? *e.g. Transitional costs, periodical costs*	M8.1 None identified.
	M8.2 If so, confirm the source of funds to meet these costs	M8.2 Not applicable.

[i] Based on the population for England accounting for c. 84% of the UK.

[ii] Please refer to the policy proposition.

[iii] Jackson, M. et al. (2014). "Intermittent self-dilatation for urethral stricture disease in males." *Cochrane Database of Systematic Reviews*. 12.

[iv] Santucci RA, et al. (2007). "Male urethral stricture disease". *Journal of Urology*; **177**(5):1667-74.

[v] Please refer to the policy proposition.

[vi] Based on 4,000 men in the UK requiring surgery for recurrent strictures [Source: UK Clinical Research Network (2015). *Portfolio Database. The OPEN Trial: Open Urethroplasty versus Endoscopic Urethrotomy*. [Online] Available from: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=13507 [Accessed: 30/11/2015]], corrected to cover only men living in England (based on ONS population estimates).

[vii] Based on Hospital Episodes Statistics (HES) data from 2014/15 for all procedures and OPCS code M73.6 - *Urethroplasty NEC*.

[viii] Based on episodes relating to "all procedures and interventions" within HES from 2014/15 for the procedure code M736-*Urethroplasty NEC*. This is adjusted for only males as well as those aged 18 and over. It is unclear from the data what fraction of these episodes were due to recurrent strictures and first strictures.

[ix] Based on a reported 3,075 men receiving an urethrotomy for recurrent stricture in 2010 [Source: Open trial. *Clarifying the management of men with recurrent urethral* stricture: a pragmatic, randomised, multicentre superiority trial of open urethroplasty versus endoscopic urethrotomy. [Online] Available from:

http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0015/81123/PRO-10-57-23.pdf [Accessed: 30/11/2015], which is grown with the Compound Annual Growth Rate (CAGR) in urethrotomies and dilation of urethra between 2009/10 and 2014/15(based on HES data for primary procedures, a CAGR of -0.3% was identified).

[x] Based on episodes relating to "all procedures and interventions" within HES from 2014/15 for the procedure codes M75.3 – External urethrotomy, M76.3 – Optical urethrotomy and M79.4 – Internal urethrotomy NEC. This is adjusted for only males as well as those aged 18 and over. It is unclear from the data what fraction of these episodes were due to recurrent strictures and first strictures.

[xi] Based on a prevalence of c. 52,000 described in K1.1, grown by demographic growth of the male population in England [Source: ONS (2012). Population projections].

[xii] Based on finished consultant episodes for primary procedures for the OPCS code M73.6 - *Urethroplasty NEC* identified within HES data from 2009/10 and 2014/15.

[xiii] These numbers are based on c.730 urethroplasties in 2014/15 grown by ca. 1.1% per year.

[xiv] The Pennine Acute Hospitals NHS Trust (2014). *Urethral Strictures - An information guide*. [Online] Available from http://www.pat.nhs.uk/downloads/patient-information-leaflets/urology/499%20Urethral%20Strictures.pdf [Accessed: 03/12/2015].

[xv] Based on discussions with the policy working group.

[xvi] Based on discussions with the policy working group.

[xvii] Source: UK Clinical Research Network (2015). *Portfolio Database. The OPEN Trial: Open Urethroplasty versus Endoscopic Urethrotomy*. [Online] Available from: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=13507

[xviii] Source: UK Clinical Research Network (2015). *Portfolio Database. The OPEN Trial: Open Urethroplasty versus Endoscopic Urethrotomy*. [Online] Available from: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=13507

[xix] Please refer to the policy proposition.

[xx] Based on discussion with the policy working group.

[xxi] Based on 80% of repeat urethrotomies recurring within 24 months. Source: UK Clinical Research Network (2015). Portfolio Database. The OPEN Trial: Open Urethroplasty versus Endoscopic Urethrotomy. [Online] Available from: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=13507.

[xxii] The British Association of Urological Surgeons. Proximal Urethroplasty – Information for patients. [Online] Available from http://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Urethroplasty_proximal.pdf [Accessed: 30/11/2015]; and The British Association of Urological Surgeons. Distal Urethroplasty – Procedure-specific information for patients [Online] Available from http://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Urethroplasty_distal.pdf [Accessed: 03/12/2015].

[xxiii] Expected to be N35: *Urethral stricture*

[xxiv] The relevant OPCS codes are expected to be: M73.6 – *Urethroplasty NEC* for the main procedure, M75.3 – *External urethrotomy*, M76.3 – *Optical urethrotomy* and M79.4 – *Internal urethrotomy NEC* for the comparator treatments.

[xxv] 2014/15 national tariff for combined day case / ordinary elective spell.

[xxvi] 2014/15 national tariff for combined day case / ordinary elective spell.

[xxvii] Based on the cost of an outpatient appointment for "Urology" - First Attendance Multi Professional (with a cost of £155) obtained from 2014/15 National Tariff to which a MFF uplift of 10%, efficiency gains of -3.5% and inflation of 1.9% are applied.

[xxviii] Based on the cost of an outpatient appointment for "Urology" - First Attendance Single Professional (with a cost of £127) obtained from 2014/15 National Tariff to which a MFF uplift of 10%, efficiency gains of -3.5% and inflation of 1.9% are applied.

[xxix] Please refer to the policy proposition.

[xxx] This takes the 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

[xxxi] This takes the 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

[xxxii] Based on discussions with the policy working group.

[xxxiii] Based on discussions with the policy working group.

[xxxiv] Based on discussions with the policy working group.