National Institute for Health and Care Excellence

Medical technologies evaluation programme

MT241 UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia
Consultation comments table

Guidance update meeting date: 19th February 2021

There were 111 consultation comments from 14 consultees:

- 1 company representative
- 9 healthcare professionals
- 3 professional organisations
- 1 comparator company

The comments are reproduced in full, arranged in the following groups:

- General comments (comments 1-3, n=3)
- Population (comments 4-12, n=9)
- Procedure setting (comments 13-29, n=17)
- Anaesthetic use (comments 30-42, n=13)
- Flexible Cystoscopy (comments 43-45, n=3)
- Number of implants (comments 46-53, n=8)
- Obstructive median lobe (comments 54-61, n=8)
- Procedure follow up (comments 62-66, n=5)

- MRI scans (comments 67-70, n=4)
- Device usage (comments 71-73, n=3)
- Failure rate (comments 74-81, n=8)
- Clinical evidence (comments 82-90, n=9)
- Economic evidence (comments 91-106, n=6)
- Wording (comments 107-111, n=5)

#	Consultee ID	Role	Section	Comments	NICE response FINAL
General Comments					
1	2	Healthcare Professional	General	Is it only a temporary intervention as the prostate can keep on enlarging any way. Apart from cost and a day case procedure, how is it better than HolEP which is done once and for all to remove the Prostate in toto. Comparitively QUALY is better with HoLEP. Overall the patient long term outcome must be a permanent solution .	Thank you for your comment. The medical technologies evaluation programme methods guide state that a cost-consequence analysis is most appropriate for these technologies. QALY analysis of the two treatment options is therefore outside of the scope for this guidance review process. The committee discussed re-intervention rates for UroLift, please see comment 71 for NICE's response. The clinical experts did agree that the prostate can keep growing and that people with UroLift may need further treatment in the future.
2	3	Healthcare Professional	General	I have carried out over 200 Urolift procedures since 2017. Overall I agree with the guidance, but I have a few points:	Thank you for your comment. Please see the individual comments for NICE's response.

3	7	Professional Organisation	General	Three clinical experts reviewed the document on behalf of BAUS and overall they agreed the guidance was positive and accurate.	Thank you for your comment.
Population					
4	7	Professional Organisation	2.3	It is our understanding that very little of the research was done on prostates up to 100cc and it has been previously suggested to NICE that this should be 70-80cc max.	Thank you for your comment. The device instructions for use state that the device can be used for prostates less than 100ml in volume. The external assessment centre explained to the committee that the evidence for using UroLift in prostates sized between 80 and 100ml is limited. As a result, the committee changed the recommendations in section 1.2 to cover prostates sized between 30 and 80ml in alignment with the evidence available
5	8	Healthcare Professional	1.2	The upper prostate volume (PV) limit of 100cc has no high level evidence to support it. Of the 2 RCTs for urolift: 1)The LIFT study included men with prostate volumes 30-80cc 2) The BPH6 study included men with prostates 60cc and less. The European Association of Urology and American Urological Association guidelines both recommend an upper PV limit of 80cc for urolift. This is an evidence based limit that should be used by NICE also in the absence of any high quality evidence to support 100cc.	Thank you for your comment. Please see NICE's response to comment 4.
6	8	Healthcare Professional	2.3	See comment in section 1 regarding upper prostate volume limit of 80cc rather than 100cc	Thank you for your comment. Please see NICE's response to comment 4.
7	9	Healthcare Professional	1.2	Many in UK have done patients aged between 40 to 50. UroLift needle is compatible up to 150cc in early trials. In UK many have performed sussesful UroLifts up to 120cc.	Thank you for your comment. NICE can only make recommendations within the population defined by the company's instructions for use. The instructions for use (UK version) state that the device can be used in people aged 50 and over with prostates up to 100ml. This means that NICE cannot make recommendations in the use of the

					device in people aged 40 to 50 or in those with prostates over 100ml.
8	12	Company	2.3	*urethral conditions that prevent the delivery system being inserted into the bladder, urinary incontinence caused by an incompetent sphincter, or current gross haematuria.* The contraindications cited here are incorrect and do not accurately reflect the Instructions for Use (IFU) in the UK/EU; please refer to link https://cdn2.hubspot.net/hubfs/2618738/L00174-02%20Rev%20A,%20Artwork,%20UroLift%20System,%20Instructions%20for%20Use,%20OUS.pdf The IFU states “The UroLift® System should not be used if the prostate volume is >100 ml or the patient has a urinary tract infection”. Please delete “urethral conditions that prevent the delivery system being inserted into the bladder, urinary incontinence caused by an incompetent sphincter, or current gross haematuria” as this is inaccurate as per the IFU.	Thank you for your comment. The wording in section 2.3 was changed in response to this comment to reflect the UK instructions for use.
9	9	Healthcare Professional	4.13	*The clinical experts explained that TURP and HoLEP are unsuitable for some people with lower urinary tract symptoms, because of frailty or comorbidities. However, they considered that although UroLift is minimally invasive, it may be unsuitable for some people in poor health.* UroLift is suitable for patients with frailty or comorbidities not suitable for GA.	Thank you for your comment. The committee heard that some people who are frail or have comorbidities can have UroLift. The choice of treatment option and anaesthetic use will be made on a case by case basis. The wording in this section has been clarified to reflect this.
10	9	Healthcare Professional	4.14	There's a publication in Journal of Endoluminal Endourology describing UroLift in a male patient with a penile implant.	Thank you for your comment. The committee considered this comment and decided not to make a change to the text.
11	9	Healthcare Professional	3.2	HoLEP is a different approach to prostates. It's better to be reserved for larger prostates more than 100cc, once the surgeon crossed the learning curve.	Thank you for your comment. The committee heard the clinical experts agree that HoLEP may be more suitable for larger prostates.

					However, HoLEP was identified as a relevant comparator in the scoping process and so was included alongside other standard care treatments for lower urinary tract symptoms caused by benign prostatic hyperplasia.
12	1	Healthcare Professional	4.20-4.21 (Further Research)	I would encourage further evidence on long-term clinical outcomes and re-intervention rates following UroLift. Also, uncertainties currently remain regarding the eligibility criteria for UroLift - further research is needed to establish the suitability of patients with a median prostate lobe, but also patients with very enlarged prostates (>80g).	Thank you for your comment. The committee discussed these uncertainties and decided to add them to further research considerations (section 4.22).
Procedure Setting					
13	3	Healthcare Professional	2.1	2.1 I carry out the majority of Urolift procedures in a day case theatre. A treatment room would be sufficient, but not a normal out patient clinic. Urolift is not an in-patient procedure, in my experience.	Thank you for your comment. The committee heard that the majority of UroLift procedures are done as a day-case. The clinical experts did agree that there are a small number of NHS trusts which do UroLift as an outpatient procedure, where appropriate facilities are available to do the procedure in a sterile and safe manner. The committee heard that the reference to inpatient procedures reflect instances where doing UroLift as an inpatient procedure may be more appropriate, irrespective of the procedure itself, such as for social reasons or comorbidities. As a result of the discussion the UroLift guidance document has been clarified to reflect the focus on doing UroLift as a day-case or outpatient procedure with only occasional instances of inpatient use.
14	7	Professional Organisation	2.1	It is increasingly rare these days to do Urolift as an inpatient procedure. The mention of inpatient here may possibly be a hangover to the original guidance where the day case pathway had not yet been established and is therefore no longer relevant to current practice. Urolift is an outpatient or day case	Thank you for your comment. Please see NICE's response to comment 13 on procedure setting.

				procedure done mainly under local or local +sedation.	
15	6	Healthcare Professional	2.1	It is vanishingly rare to do Urolift as an inpatient procedure. This is an outpatient or day case procedure done mainly under local or local + sedation	Thank you for your comment. Please see NICE's response to comment 13 on procedure setting. Please see NICE's response to comment 31 regarding anaesthetic use.
16	12	Company	2.1	Although Urolift can be done on an inpatient basis, the vast majority of patients are treated on a day-case basis. This is supported by HES data from the past 3 years, showing 84-86% of procedures (OPCS M68.3) were recorded as zero length of stay (day case). Urolift is also listed in the BADS Directory of Procedures as a day case procedure. Any mention of treating patients with Urolift as an inpatient should be put into context that Urolift is a day case procedure.	Thank you for your comment. The committee considered statistics in their consideration of the guidance wording. Please see NICE's response to comment 13 on procedure setting and changes to the guidance text.
17	4	Professional Organisation	2.1	*The procedure can be done under local or general anaesthetic on an inpatient or day-case basis.* 2.1 The last sentence is incorrect. This procedure would not require inpatient stay. Please amend to "The procedure can be undertaken under local anaesthetic in an outpatient clinic, or local, spinal or general anaesthetic on a day case basis.	Thank you for your comment. Please see NICE's response to comment 13 on use of UroLift as an inpatient procedure. Please see NICE's response to comment 31 on anaesthetic use.
18	4	Professional Organisation	4.9	*There are potential limitations for doing UroLift as an outpatient procedure* Suggest change this heading to: UroLift can be undertaken as an outpatient procedure	Thank you for your comment. NICE has changed the heading to reflect changes in the text of section 4.9.
19	4	Professional Organisation	4.9	*The clinical experts explained that they do not currently offer UroLift as an outpatient treatment. They expressed concerns about a lack of operational and recovery space in an outpatient environment and the increased potential for infection. The clinical experts stated that if these limitations were overcome, they would consider doing UroLift as an outpatient procedure but this is not current*	Thank you for your comment. The committee heard that doing UroLift as an Outpatient procedure is feasible and done in a small number of NHS trusts. The text in section 4.9 has been changed to reflect this.

				Again this is incorrect a number of centres are now undertaking this in an outpatient setting and this is supported by BADS and GIRFT. Suggested amendment: UroLift is offered as an outpatient procedure in a number of centres. This confers additional benefits including a more efficient service for the patient and lower cost for the NHS provider.	
20	12	Company	2.1	*The procedure can be done under local or general anaesthetic on an inpatient or day-case basis.* It is important to add to this statement that the procedure can be also be done in an outpatient setting. This is strongly supported by the recent report by BADS/GIRFT (National Day Surgery Delivery Pack, Sept 2020; https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2020/10/National-Day-Surgery-Delivery-Pack_Sept2020_final.pdf) which listed Urolift as one of 9 procedures where the focus should be to develop an outpatient rather than day surgery pathway. Recommendations from this report primarily reflected the need to find new ways of working due to the COVID-19 pandemic.	Thank you for your comment. The committee heard that UroLift can be done in an outpatient setting. Please see NICE's response to comment 13.
21	6	Healthcare Professional	4.8	At our NHS trust, we have moved this procedure successfully into an outpatient setting using topical local anaesthesia only. Other units, eg NHS Fife in Scotland, have been doing Urolift using topic local anaesthesia for more than a year. General anaesthesia does not make the procedure quicker. There is time in the anaesthetic room and recovery to factor in - the delivery of the implants takes the same time regardless of the anaesthesia	Thank you for your comment. The committee considered these comments and discussed the feasibility of doing UroLift as an outpatient procedure. Please see NICE's response to comment 13 for the changes made in response to these comments. Please see NICE's response to comment 31 on anaesthetic use.
22	6	Healthcare Professional	4.9	Doing Urolift as an outpatient procedure is NOT associated with an increased risk of infection. In US and EU, this is an office procedure . Recovery space not needed as there is no anaesthesia. Patients can	Thank you for your comment. Please see comment 13 for NICE's response on doing UroLift as an outpatient procedure.

				put their outside clothes back on and just need to void before going home, just as with flexi cystoscopy. So only a seating area is needed. IT IS CURRENT UK PRACTICE!!	
23	7	Professional Organisation	4.8	One of our clinical experts commented that his unit now undertake this procedure in an outpatient setting using topical local anaesthesia only. Other units, eg Fife have been doing this for more than a year. It is not accepted that general anaesthesia enables the procedure to be done quicker. There is time in the anaesthetic room and recovery to be factored in and delivery of the implants takes the same time regardless of the anaesthesia. He disagrees that sedation and more tme are needed to place the Urolift implants without causing unacceptable discomfort to the patient. This is not his experience.	Thank you for your comment. Please see comment 13 for NICE's response on doing UroLift as an outpatient procedure. Please see NICE's response to comment 31 on anaesthetic use.
24	7	Professional Organisation	4.9	A surgeon experienced in undertaking the procedure in an outpatient setting does not agree that doing Urolift in an outpatient setting carries an increased risk of infection, especially if the procedure is carried out in an appropriate treatment or procedure room. In the US and EU, Urolift is an office procedure. In some units Urolift as an outpatient procedure is current clinical practice.	Thank you for your comment. The committee and clinical experts considered whether outpatient procedures led to an increased risk of infection. They felt that if the procedures were done in an appropriate treatment room, there was no increased infection risk. The wording of the guidance was changed to reflect this.
25	9	Healthcare Professional	4.9	*There are potential limitations for doing UroLift as an outpatient procedure* UroLift is suitable for Walk-in clinics. Appropriate training and infrastructure will make this possible.	Thank you for your comment. Please see NICE's response to comment 13 on outpatient procedures. The clinical experts agreed that appropriate infrastructure was needed to facilitate doing UroLift as an outpatient procedure.
26	11	Healthcare Professional	4.9	In our practice in NHS Fife, we do offer the Urolift procedure as an outpatient procedure and additionally, we offer it under local anaesthetic without the presence of an anaesthetist. We have set up clear guidelines and standard of practice for all our nursing staff. We perform a flexible cystoscopy in order to assess the prostatic urethra anatomy and the patient's pain threshold. In our cohort, we haven't recorded a higher rate of	Thank you for your comment. The committee considered your experiences of doing UroLift as an outpatient procedure. The guidance reflects that flexible cystoscopy is useful to judge suitability for doing the procedure using local anaesthetic. The committee and clinical experts have considered the infection risks associated with doing the procedure as an outpatient. They felt that if the appropriate treatment rooms and procedures

				infections when performing the Urolift in an outpatient setting.	were used that there was not an increased risk of infection. The wording to section 4.9 has been amended as a result.
27	12	Company	4.9	This statement needs to be set in the context of the current COVID-19 pandemic where NHS trusts are adopting new ways of working. The transitioning of Urolift into an outpatient setting is strongly supported by the recent report by BADS/GIRFT (National Day Surgery Delivery Pack, Sept 2020; https://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2020/10/National-Day-Surgery-Delivery-Pack_Sept2020_final.pdfhttps://www.gettingitrightfirsttime.co.uk/wp-content/uploads/2020/10/National-Day-Surgery-Delivery-Pack_Sept2020_final.pdf) which listed Urolift as one of 9 procedures where the focus should be to develop an outpatient rather than day surgery pathway. Recommendations from this report primarily reflected the need to find new ways of working due to the COVID-19 pandemic.	Thank you for your comment. Please see NICE's response to comment 13 on the use of UroLift in an outpatient setting.
28	14	Healthcare Professional	4.9	*4.9 The clinical experts explained that they do not currently offer UroLift as an outpatient treatment. They expressed concerns about a lack of operational and recovery space in an outpatient environment and the increased potential for infection. The clinical experts stated that if these limitations were overcome, they would consider doing UroLift as an outpatient procedure but this is not current clinical practice.* Comments: This opinion is dated. Centres around the UK have demonstrated Urolift as a total ambulatory procedure, similar to flexible cystoscopy, aided with the use of a transperineal biopsy chair. This should be recognised by NICE. There is also no evidence for increased infection risk.	Thank you for your comment. Please see NICE's response to comment 13 on outpatient procedures and comment 26 on infection risk.
29	14	Healthcare Professional	4.11	*4.11 The clinical experts agreed that on average, the UroLift procedure takes 10 to 15 minutes per person to do. However, they noted that this does not take into account variations in time taken for the*	Thank you for your comment. Although there are variations in procedure times and length of stay, as noted in section 4.11, UroLift has

				administration of local or general anaesthetic or for changeover time between procedures. The clinical experts also noted that the length of hospital stay can vary because of local hospital procedures, the time taken to recover from the anaesthetic and for the person to empty their bladder Comments: But in the main, Urolift is a true daycase procedure.	been considered in this guidance review as a day case procedure.
Anaesthetic Use					
30	4	Professional Organisation	2.2	*The procedure can be done under local or general anaesthetic on an inpatient or day-case basis* This sentence is incorrect as this procedure does not require inpatient stay. Suggested revision: "The procedure can be undertaken under local anaesthetic in an outpatient clinic, or local, spinal or general anaesthetic on a day case basis."	Thank you for your comment. Please see NICE's response to comment 13 on procedure setting. The text has been changed to reflect the preference for day-case and outpatient use. The committee discussed the use of spinal anaesthesia. They decided that although it can be used for these procedures, a change to the text was not needed.
31	3	Healthcare Professional	4.8	Section number 4.8 I have not found that doing Urolift under local anasthetic, with or withour sedation prolongs the procedure. I very rarely use General Anaesthesia for Urolift now	Thank you for your comment. The committee heard from clinical experts that they use either local anaesthetic or general anaesthetic. This decision was based on the needs of the person having the procedure. The clinical experts agreed that the procedure length of time did not change based on anaesthetic use. The text in section 4.8 was changed to reflect this.
32	4	Professional Organisation	4.8	4.8 is incorrect. An anaesthetist is not required when this is undertaken under local anaesthetic the procedure is quicker under local than general anaesthesia. Suggested revised text: Heading: UroLift can be done using Local anaesthesia, sedation, spinal or general anaesthesia. A large number of patients tolerate this procedure under local anaesthesia, enabling it to be moved out	Thank you for your comment. The committee heard that UroLift procedures can be tolerated with local anaesthetic and that UroLift can be done as an outpatient procedure. However, it was heard that the use of outpatient procedures are currently limited by the availability of appropriate facilities. The committee acknowledged that if general anaesthesia or spinal anaesthesia is needed then day surgery was more appropriate. Section 4.8

				of the operating theatres into an outpatient environment. This provides a more efficient service with more rapid turn over of cases and more cases undertaken within a session. A few patients require anaesthetic input (sedation, spinal or general anaesthesia), these should be undertaken within a day surgery environment.	was changed to reflect that the choice of anaesthesia needed should be specific to the needs of the person having the procedure.
33	4	Professional Organisation	4.8	*UroLift can be done using general anaesthesia, or local anaesthesia with sedation* Suggest change this heading to: UroLift can be done using local anaesthesia, sedation, spinal or general anaesthesia.	Thank you for your comment. The title was changed to reflect that sedation can be optionally used alongside local anaesthesia. Please see NICE's response to comment 30 on the use of spinal anaesthesia.
34	13	Healthcare Professional	4.8	The nice guidance on your lift has been brought to my attention. I would like to state that we carry out urolift under local anaesthetic as the default position. We do not have an anaesthetist present. We have been doing this for the last year. We perform 8 to 12 urolifts on a three hour day surgery unit list. I would be happy to provide the data to support this if you wish.	Thank you for your comment. The committee acknowledged that an anaesthetist does not need to be present if the procedure is done under local anaesthetic.
35	4	Professional Organisation	4.8	*The clinical experts stated that in clinical practice, UroLift is done under either general anaesthesia or local anaesthesia with an anaesthetist present. They stated that the advantages of general anaesthesia are that the procedure can be done more quickly with less discomfort to the individual. When local anaesthetic is used, sedation and more time are needed to place the Urolift implants without causing unacceptable discomfort to the person.* This is incorrect - see comment below with revision A large number of patients tolerate this procedure under local anaesthesia, enabling it to be moved out of the operating theatres into an outpatient environment. This provides a more efficient service with more rapid turn over of cases and more cases undertaken within a session. A few patients require anaesthetic input (sedation, spinal or general	Thank you for your comment. Please see NICE's response to comments 32.

				anaesthesia), these should be undertaken within a day surgery environment.	
36	6	Healthcare Professional	4.8	*When local anaesthetic is used, sedation and more time are needed to place the Urolift implants without causing unacceptable discomfort to the person.* I disagree with this statement. In our (extensive) experience with Urolift, when local anaesthetic is used, sedation and more time are NOT needed to place the Urolift implants without causing unacceptable discomfort to the person	Thank you for your comment. The committee heard that the local anaesthetic does not lead to a longer procedure time or lead to unacceptable discomfort. The clinical experts stated that the used flexible cystoscopy can be used to judge suitability for local anaesthetic use. Section 4.8 has been changed to reflect this.
37	11	Healthcare Professional	4.8	The experts express the view that the Urolift procedure cannot be offered under local anaesthetic without sedation due to the unacceptable discomfort to the patient. Our data from NHS Fife in Scotland, do not indicate that. When performed under local anaesthetic, with no sedation, the procedure is neither longer nor unacceptably painful to the patient.	Thank you for your comment. Please see NICE's response to comment 36.
38	12	Company	4.8	*UroLift is done under either general anaesthesia or local anaesthesia with an anaesthetist present.* The way this statement is worded does not reflect the vast majority of current NHS practice where Urolift is performed under a local anaesthetic with or without sedation.	Thank you for your comment. Please see NICE's response to comment 31.
39	12	Company	4.8	*They stated that the advantages of general anaesthesia are that the procedure can be done more quickly with less discomfort to the individual. When local anaesthetic is used, sedation and more time are needed to place the Urolift implants without causing unacceptable discomfort to the person.* Statements around the relative benefits of using general anaesthetic vs local anaesthetic are not consistent with the clinical evidence (Shore 2014, NHS Fife 2020) and the experience of a significant number of NHS clinical users, who have either transitioned or are transitioning to local anaesthetic due to the patient benefits and operational gain afforded by following a local anaesthetic pathway.	Thank you for your comment. Please see NICE's response to comment 31.

40	4	Professional Organisation	4.8	*The clinical experts explained that doing flexible cystoscopy in the outpatient clinic to plan treatment is a good opportunity to assess tolerance and suitability for doing the procedure under local anaesthesia.* This sentence should remain	Thank you for your comment. The committee agreed with this comment and have retained this sentence.
41	9	Healthcare Professional	2.3	*light sedation* It's better to avoid sedation. Nitrous is a better choice.	Thank you for your comment. The committee heard that the choice of anaesthetic or sedation techniques should be chosen on an individual basis. The text has been rephrased to reflect this.
42	14	Healthcare Professional	4.7-4.8	*4.7 A clinical expert confirmed that UroLift is widely used in the NHS since the publication of the original NICE guidance. However, there are now other minimally invasive procedures available to treat the condition in the same population, such as Rezum.* *4.8 The clinical experts stated that in clinical practice, UroLift is done under either general anaesthesia or local anaesthesia with an anaesthetist present. They stated that the advantages of general anaesthesia are that the procedure can be done more quickly with less discomfort to the individual. When local anaesthetic is used, sedation and more time are needed to place the Urolift implants without causing unacceptable discomfort to the person. The clinical experts explained that doing flexible cystoscopy in the outpatient clinic to plan treatment is a good opportunity to assess tolerance and suitability for doing the procedure under local anaesthesia.* Comments: There is no evidence to support quicker operative time under GA – it is entirely dependent on anaesthetist and medical history of the patient. My own experience (observational and actual hands on) is that LA is quicker for obvious reasons (no anaesthetic time). Sedation is not always necessary,	Thank you for your comment. The committee heard that here time referred to procedure time rather than anaesthetic time. The clinical experts acknowledged that procedure time would be similar between local and general anaesthetic use. The committee heard that local anaesthetic use without sedation was an appropriate option for this procedure. Please see NICE's response to comments 31, 32 and 36 for text changes to this section.

				and the procedure is tolerable under LA alone, as is widely practised in Europe and the USA.	
Flexible Cystoscopy					
43	1	Healthcare Professional	4.15	As the clinical experts noted, and also in my experience, a significant proportion of patients undergo flexible cystoscopy to establish the suitability for Urolift (many urologists would not proceed with Urolift if there is a middle prostate lobe). The cost of this additional investigation may need to be considered in the cost modelling.	Thank you for your comment. The cost of flexible cystoscopy was considered in scenario analysis done by the external assessment centre and reflected in section 4.19 of the guidance document. The committee heard that flexible cystoscopy was used for determining most appropriate treatment options. As this was independent of final treatment decision it could be considered across all care options. As a result, the committee decided to not include flexible cystoscopy in the base case analysis.
44	7	Professional Organisation	4.10	A flexi-cystoscopy allows an assessment of the prostate with regards to the presence or absence of a middle lobe, although it is not essential if the patient has had an accurate prostate volume measurement.	Thank you for your comment. The variability of flexible cystoscopy use is captured in 4.11 of the guidance document.
45	9	Healthcare Professional	1 (rationale)	*flexible cystoscopy is used before the procedure* Not all patients require flexible cystoscopy before UroLift	Thank you for your comment. The committee heard that there was variability in flexible cystoscopy use. This is reflected in section 4.11 of the guidance.
Number of Implants					
46	8	Healthcare Professional	3	Please consider using published data from a level 1 study for the number of implants. This is available in the LIFT study where:an average of 4.9 implants were used with a range of 2-11. 85% had 6 or less implants	Thank you for your comment. The committee considered the evidence for the number of implants needed. They deemed that the NHS audit data submitted by the company, with an average of 3.5 implants used, was an appropriate figure to use.
47	8	Healthcare Professional	2.5	See comment in section 1 about average number of implants in the LIFT study and note that LIFT excluded men with enlarged median lobes who would be expected to require more than the average number of implants	Thank you for your comment. Please see NICE's response to comment 46 on the average number of implants used. Further to this, the external assessment centre used an additional 1.3 implants (based on the Rukstalis et al., 2019

					study) in the base case and an extra 2 implants in the scenario analysis for obstructive median lobe treatment.
48	8	Healthcare Professional	3.23	It seems the number of implants used per case in the draft document is partly based on self reported audits from 6 centres of excellence in the NHS where the urolift service is led by urolift enthusiasts who have potential conflicts of interest as they have all done paid work for Neotract/Teleflex. It would be more transparent and appropriate to use the implant numbers from the peer reviewed and published randomised trials for urolift (even though these too were industry sponsored). In LIFT, which excluded men with enlarged median lobes and those with PV > 80cc, an average of 4.9 implants were used with a range of 2-11. 85% had 6 or less implants. In the era of increased indications for urolift (i.e. used now in some patients with enlarged mobile median lobes and it seems some are offering urolift to men with PV= 80-100cc) the number of implants used can be expected to rise rather than fall.	Thank you for your comment. NHS audit data from 550 UroLift cases formed the basis of the economic model. The external assessment centre also added in additional implants for obstructive median lobe treatment as mentioned in NICE's response to comment 47.
49	9	Healthcare Professional	2.1	My average implants for my initial 42 patients is 2.92. Less implants are needed in many patients.	Thank you for your comment.
50	10	Comparator Company	2.5	*An average of 4 implants is used per procedure and so the typical cost per person is £1,600.* This statement conflicts with the Recommendations in section 1.3. The cost modelling assumptions were based on a per patient cost of 3.5 implants per procedure (smaller glands). As per our previous comments, the cost of the UroLift procedure is very sensitive to changes in the number of implants used. Therefore we would suggest that the committee recalculate the per patient cost based on the treatment of different prostate glands (</> 80g) and the presence of an Obstructing Median Lobe (OML), because the cost of the other procedural comparators in scope are unaffected by changes in the prostate gland size and the presence of an OML. There is no patient who has 3.5 implants, this is not a realistic clinical scenario - any more than 3 clips	Thank you for your comment. The committee heard that the cost model is sensitive to the number of implants and that the model is based on an average number of implants from NHS audit data collected over a 3-year period. The committee concluded that the varying of implant number did not affect the cost saving conclusions compared to TURP and HoLEP. This is reflected in 4.18. 4.19 of the guidance highlights the uncertainty compared to Rezum, with reference to the threshold number of implants. The committee felt that after hearing the evidence around the cost compared to Rezum that there was still uncertainty in the cost difference between the two treatments. The cost of treating obstructive median lobe was also considered by the external assessment centre who used an additional 1.3 implants (based on the

				does not demonstrate a saving, as previously stated. Evidence shows that for larger glands up to 80g at least 4 clips are needed.	Rukstalis et al., 2019 study) in the base case and an extra 2 implants (based on expert opinion) in the scenario analysis.
51	10	Comparator Company	4.15	As we described before we believe some of the assumptions that are used in the model are inaccurate. Average number of Urolift implants should be updated to 4 implants to reflect the minimum requirement needed to treat a prostate up to 80g, in addition to adjusting the costs to account for the additional resource use needed to treat the OML which will require a further 2 clips in addition	Thank you for your comment. Please see NICE's response to comment 50.
52	10	Comparator Company	4.17	The clinical experts thought this was an underestimate and that an average of 4 implants was more appropriate, with a range of between 2 and 6 implants depending on prostate size. As mentioned in our previous comments before, we strongly agree with this statement and it should be reflected as a clear statement earlier in the guidance. Currently the document is confusing and non-cohesive.	Thank you for your comment. Please see NICE's response to comment 50. The economic model was based on average NHS data from 550 UroLift procedures. The committee viewed that this was the most appropriate value to include in the economic evaluation. Sensitivity analysis explores the variation in the number of implants used which is reflected in section 4.18 and 4.19.
53	12	Company	2.5	The company submitted evidence from an audit of over 550 NHS patients to show the average implant utility to be 3.5 per patient. The EAC base case and the cost savings described in section 1 are based on an average of 3.5 implants. Therefore, we suggest the costs in subsection 2.5 should reflect this to state: An average of 3.5 implants is used per procedure and so the typical cost per person is £1,400	Thank you for your comment. NICE have rephrased the sentence in section 2.5. It was deemed more appropriate to quote a whole number of implants here.
Obstructive Median Lobe					
54	3	Healthcare Professional	4.19	Section number 4.19 My experience is that one implant is usually sufficient to treat a median lobe, occasionally 2.	Thank you for your comment. The committee heard that between 1 and 2 extra implants were needed to treat obstructive median lobe. The cost of treating obstructive median lobe was considered by the external assessment centre who used an additional 1.3 implants (based on the Rukstalis et al., 2019 study) in the base case and an extra 2 implants (based on expert opinion) in the

					scenario analysis. This is discussed in section 4.20 of the guidance.
55	6	Healthcare Professional	4.19	In my experience treatment of a middle lobe requires only one extra implant	Thank you for your comment. Please see NICE's response to comment 54.
56	7	Professional Organisation	4.19	A unit with quite an extensive experience of Urolift stated that, in their experience, the treatment of an obstructive median lobe requires only one extra implant, not an average of 2 as stated.	Thank you for your comment. Please see NICE's response to comment 54.
57	10	Comparator Company	1.3	*There is uncertainty about whether UroLift is cost saving when treating benign prostatic hyperplasia with an obstructive median lobe because of the need for more UroLift implants.* This statement is misleading and inaccurate. We believe a more accurate statement would be "When using UroLift for treating benign prostatic hyperplasia with an obstructive median lobe, because of the need for more Urolift implants, the procedure is no longer cost saving to Rezum and the incremental cost vs Rezum is -£968 on average". This is evidenced by the EAC report, where it states that if UroLift is used as a daycase procedure for OML, all sensitivity analyses demonstrate that the incremental cost of Urolift vs Rezum was -£968, because the main cost driver is the cost of device or implant. One of the main reasons for updating the guidance is to consider UroLift in treating OML. As such the cost difference should be clearly stated in the guidance in the first section to support providers and clinicians to make accurate choices. The procedure cost of using UroLift is extremely sensitive to changes in the number of implants used, in contrast to Rezum where the cost is not affected by the presence of an OML as only one device is used per procedure. If Urolift is used in the OML, on average a patient requires 2 additional clips, this drives up the total treatment cost for a daycase procedure to £3,357 as stated in the EAC report. Therefore stating that the savings are 'uncertain' is not accurate. It is certain that there are no savings as it is £400 per clip.	Thank you for your comment. The committee heard that for the base case analysis, where 1.3 extra implants were used in instances where there was an obstructive median lobe, UroLift was cost saving compared to all comparators. If obstructive median lobe was considered separately with 2 extra implants and with flexible cystoscopy use, UroLift was found to cost more than Rezum but still be cheaper compared to monopolar TURP and HoLEP. The difference between these two economic models and the sensitivity of the model to the number of implants used led to the uncertainty highlighted in section 4.20 of the guidance. The committee concluded that no change to the text was needed.

58	10	Comparator Company	1 (rationale)	*More implants are needed when UroLift is used for obstructive median lobe treatment, which means that additional cost may be incurred when compared with Rezum.* The additional cost of treating the OML incurs an incremental cost -£968 favouring Rezum. We believe a more accurate statement is "More implants are needed when UroLift is used for obstructive median lobe treatment, which means that additional cost will be incurred when compared with Rezum	Thank you for your comment. Please see NICE's response to comment 57.
59	10	Comparator Company	4.19	The EAC reports highlight that UroLift is not cost saving to Rezum in treating the OML. This should be clearly stated.The cost of Urolift is very sensitive to changes in procedure duration and number of UroLift implants used. In contrast to Rezum where the price is not affected by treating the OML. The UK clinical experts advised on average in the OML, 2 additional UroLift implants are required (additional £800).	Thank you for your comment. Please see NICE's response to comment 57.
60	12	Company	4.19	*The base case for treatment of an obstructive median lobe included an average of 1.3 additional implants whereas the clinical experts believed the average to be 2 additional implants.* Evidence presented by the company (Rukstalis et al 2018), referred to in Section 3.19, showed that the average additional impact use for obstructive median lobe (OML) was 1.3. Clinical experience in the NHS from centres with significant experience of treating middle lobes show that surgeons will use either 1 or 2 extra implants to treat OML (average 1.5). Use of more than 2 extra implants to treat middle lobe is not consistent with common clinical practice.	Thank you for your comment. The committee considered these comments and concluded that there is variability in the number of implants used for obstructive median lobe treatment. Both the base case, using an additional 1.3 implants, and scenario analysis, using an additional 2 implants, were considered.
61	14	Healthcare Professional	4.10	*4.10 Two of the clinical experts stated that they used flexible cystoscopy routinely before deciding whether to offer UroLift. This allows them to see whether there is an obstructive median lobe and estimate the number of implants needed. They can also assess whether there are any other conditions, including bladder stones or bladder cancer, which might affect*	Thank you for your comment. The committee heard that UroLift can be used to treat prostates with an obstructive median lobe. Flexible cystoscopy allows identification of these obstructive median lobes to help procedure decision making.

				whether the procedure is done. One expert stated that they do not routinely use flexible cystoscopy before UroLift because of the added time and cost implications. There is some uncertainty about the proportion of flexible cystoscopies routinely carried out before the procedure. Comments: Once again, this opinion is slightly out of date. Obstructing median lobes are now being tackled successfully and large volume centres in the UK are offering training in this technique (mobilisation and lateral fixation).	
Procedure Follow Up					
62	5	Healthcare Professional	3.24	2. Face to face versus remote follow-up. All BPH therapies can undergo remote follow-up. This has been clearly shown during the Covid pandemic therefore this asymmetrical cost saving is incorrect.	Thank you for your comment. The committee heard that all BPH therapies discussed can undergo remote follow up, as reflected in 4.13. These costs were reflected in 4.17 where it was shown that UroLift remained cost saving when all treatments had a telephone follow up instead of an outpatient appointment.
63	8	Healthcare Professional	3.24	Since covid, follow-up by phone consultation after BPH surgery of all kinds has become standard practice in the NHS. This is not urolift specific	Thank you for your comment. Please see NICE's response to comment 62.
64	10	Comparator Company	4.16	We would like to refer the committee to MTG49 where expert advisors confirmed that patients have TWOC in community following Rezum, and do not routinely return as an outpatient admission. In addition, the evidence supported by the shared learning examples highlight that UroLift follow up is routinely done as an outpatient.	Thank you for your comment. The committee heard that trial without a catheter in the community can be done after Rezum. Section 4.17 demonstrates that Rezum and UroLift are cost neutral when there was a trial without a catheter in the community (instead of as an outpatient) after Rezum. Clinical experts stated that all treatment options now routinely have telephone follow ups as mentioned in NICE's response to comment 62.
65	9	Healthcare Professional	3.14	*45% of the UroLift group* Nowadays the rate of catheterisation post-UroLift is much lower around 10%.	Thank you for your comment. The 45% catherization rate is the reported rate from the Sonksen et al. (2015) study. The committee heard that the catherization rate for UroLift was low.

66	9	Healthcare Professional	3.18	*time to discharge 1.0 days* Only rarly patients stay overnight. Average hospital stay should be in hours, not one day.	Thank you for your comment. The discharge time of 1.0 days is the reported from the Sonksen et al. (2015) study. The length of stay used in the economic model was 0.125 days.
MRI Scans					
67	5	Healthcare Professional	4.13	5. The Committee need to give due regard and concern for the impact of the implants on MRI image artefact. Many men with BPH will present with elevated PSA and need investigation for prostate cancer. The pathway for these men is to undergo an MRI scan. Men with implants have poorer image quality and anterior areas of the prostate are more likely to be affected. Usually a non-suspicious MRI confers a higher probability of avoiding an invasive biopsy test. The artefact from the implants that there will lesser confidence in avoidance of a biopsy so men must be counselled about this and that there is a higher probability of undergoing an invasive biopsy following an MRI scan due to a an elevated PSA result that they might have in future. If physicians are carrying out an MRI BEFORE Urolift then the cost of the MRI (~£200-250 on Tariff) and the burden on limited scanning and reporting facilities for the NHS to conduct these needs to also be modelled into the health economics model.	Thank you for your comment. The committee heard that any misinterpretation of artefacts on the MRI scans, seen as a result of UroLift implants, can be overcome if the radiologists interpreting the scans are aware of the presence of these implants. The committee agreed that no additional cost considerations were necessary.
68	9	Healthcare Professional	4.13	*leave traces on MRI scans,* Radiologists in Australia have developed MRI protocols to circumvent this issue.	Thank you for your comment. Please see NICE's response to comment 67.
69	10	Comparator Company	4.6	The UroLift™ surgical retreatment rate is likely understated, as it does not include all surgeries for removal of implants that had become encrusted or were exposed to the bladder. The clinical experts noted that the implants can sometimes leave traces on MRI scans, which may be confusing when people are being investigated for possible prostate cancer. Has the committee taken into account the additional costs incurred over five years when assessing men	Thank you for your comment. Please see NICE's response to 67 regarding MRI scan interpretation.

				for prostate cancer, given the increased difficulty of assessing the prostate with MRI scan alone in men with foreign body material in the prostate causing scatter of the image?	
70	10	Comparator Company	4.13	*The clinical experts noted that the implants can sometimes leave traces on MRI scans, which may be confusing when people are being investigated for possible prostate cancer.* Are these additional costs for implant removal considered in the economic model?	Thank you for your comment. Please see NICE's response to 67 regarding MRI scan interpretation. The committee heard that implants would be partially removed using if re-intervention was needed. This was factored into the cost of a re-intervention procedure.
Device Usage					
71	8	Healthcare Professional	3	There is one glaring omission in the draft urolift recommendations, and that is, the durability data for urolift. This is important as it has significant implications for cost effectiveness which is prominently featured in this document. Durability should be included in the cost modelling over 5 years which is mentioned in 1.3. There is level 1, 5-year durability data published for the LIFT study. 13.6% of men had a salvage surgical procedure for failed urolift within 5 years and another 10.7% went back on to BPH medications because of failed urolift. 7.1% of those who had urolift needed a subsequent secondary procedure to remove encrusted implants and a further 2.1% had subsequent prophylactic removal of implants that were exposed to the bladder. The costs of these corrective/salvage treatments should be included in the cost modelling to give a fair comparison with the other procedures mentioned (rezum, TURP and HoLEP). It should also be noted that the costs of HoLEP and TURP when performed as salvage procedures after failed urolift are often more expensive than normal as the urolift implants can damage bipolar resection loops and morcellator blades which are expensive to replace. In comparison, the 5-year durability data for rezum is significantly better that for urolift (4.4% required a salvage procedure within the first 5 years) and it is rare for recommencement of BPH	Thank you for your comment. The committee heard that surgical re-intervention was included in the economic modelling. This was listed as 13.6% over 5 years, based on the Roehrborn et al. (2015) study. The Rezum re-intervention rate was considered to be 4.4% and 4.1% for HoLEP. The committee heard from the clinical experts that TURP and HoLEP as re-intervention procedures were not more expensive, provided clinicians were careful not to damage resection loops and morcellator blades.

				medication or salvage BPO surgery to be required even 10 years after HoLEP (salvage surgical treatment = 0.7% over 10 year follow-up after HoLEP in published data).	
72	8	Healthcare Professional	2.2	*adjustable, so the procedure is reversible* Please consider removing this statement. The implants can be removed but not in their entirety (they are removed by grasping the urethral endplate and pulling to break the suture ie the endplate can be removed but not the capsular tab on the other end of the suture). Once the implants have been in place for more than around 6 moths it is not possible to see them endoscopically so therefore not possible to remove them without doing a HoLEP or TURP. The implants are not adjustable in any way. They can either be implanted or partially explanted as above but not adjusted.	Thank you for your comment. The committee decided to change the wording of this sentence to reflect that the implant is partially removal and not adjustable.
73	10	Comparator Company	4.5	We would ask the committee to investigate the MAUDE database in addition to the other adverse events reported in the Urolift MTG update. This database has several adverse events which were not considered in the updates. For e.g One injury event reported on May 24, 2008, of a patient who had bacterial prostatitis following UroLift. In 2019 it was reported that this patient was retreated with TURP and had all implants removed, the pain and swelling persists after the removal of their clips. We would also suggest that the committee could interrogate social media for the many reports of adverse events from clinicians directly.	Thank you for your comment. The committee heard that there were 155 reported MAUDE adverse event reports for UroLift since February 2015. The committee noted that MAUDE adverse event reports are limited by the information available and the nature of the database. The committee viewed that it was inappropriate to review social media posts.
Failure Rate					
74	3	Healthcare Professional	4.6	4.6 Failure rate: I would say that a failure rate of 10% would be realistic, not 10-30%.	Thank you for your comment. The committee heard that the surgical reintervention rate could be up to 20%. The clinical experts also noted that there would be an early failure rate of less than 5%. The external assessment centre economic model included a surgical re-intervention rate of

					13.6% over 5 years, based on the Roehrborn et al. (2015) study. Section 4.6 was re-worded for clarity.
75	6	Healthcare Professional	4.6	The distinction needs to be made between failure and retreatment. Retreatment rate is 7% in our unit. 5% in Real world data . 30% is a ridiculous figure to state.	Thank you for your comment. Please see NICE's response to comment 74.
76	7	Professional Organisation	4.6	One of the clinical experts BAUS consulted stated that a distinction needs to be made here between failure and retreatment. His units retreatment rate was 7% and real world data shows a rate of 5%. He felt the 30% figure was too high.	Thank you for your comment. Please see NICE's response to comment 74.
77	12	Company	4.6	*However, they considered that people should expect a failure rate of between 10% and 30%.* The guidance needs to qualify what 'failure' means in this context, which is the requirement for retreatment at some point in time following discharge, not procedural failure during the episode of care or device failure. % failure rate actually refers to the need for retreatment following surgery. The failure rate cited in the guidance should reflect the evidence, 13.6% at 5 years, or 2-3% per year (Roehrborn 2017), as well as the experience of NHS users of Urolift who have a large cohort of patients with long-term follow-up. 30% is not supported by the evidence.	Thank you for your comment. Please see NICE's response to comment 74. The device failure rates were clarified in section 4.6 of the guidance.
78	8	Healthcare Professional	4.6	Please consider deleting the statement that treatment failure is low with urolift. As previously mentioned the urolift failure rate in the only level 1 study with published 5 year follow-up (LIFT) was 33.5%. This is not a low rate. I would suggest defining failure in the same way that LIFT does: 1) Starts/restarts medical BPH treatment = 10.7% during the first 5yr after urolift 2) Salvage BPH procedure for recurrent LUTS =13.6% during the first 5yr after urolift 3) Secondary procedure to remove encrusted implants =7.1% within the first 5yr after urolift	Thank you for your comment. The committee discussed the re-intervention procedures and early failure rates. Please see NICE's response to comment 74.

				4) Subsequent prophylactic removal of implants that were exposed to the bladder = 2.1% within the first 5yr after urolift OVERALL FAILURE RATE WITHIN 5YR OF UROLIFT = 33.5%	
79	8	Healthcare Professional	3.7	In section 3 it should be made clear that long term symptoms, urinary flow and retention symptoms and QoL improve over 5 year follow-up, but only in those who do not fail urolift and subsequently elect to restart BPH medication or to have a corrective or salvage procedure. As stated in my comments in Section 1, the LIFT study reported that 33.5% either restarted BPH medication or had a revision or salvage surgical procedure over the 5 year period post-urolift. These patients should be regarded as urolift failures who clearly did not have durable improvements in urinary symptoms, QoL or urinary flow over the 5 years after urolift.	Thank you for your comment. The committee discussed surgical re-intervention and early failure rates. Please see NICE's response to comment 74.
80	14	Healthcare Professional	4.6	*4.6 The clinical experts explained that UroLift has a good success rate in adequately relieving lower urinary tract symptoms. However, they considered that people should expect a failure rate of between 10% and 30%.* Comments: There is no definition here of "Failure rate". Is it fall in IPSS greater than 4, Rise in Qmax or re-operative rate. Studies (Real Life and LIFT) have shown a re-treatment rate of 2-3% a year for a maximum of 5 years follow-up (cf with 1% for TURP). The figure of 30% may therefore be a misprint and certainly has no evidence base. My own audit of patients was also consistent with the larger studies with patients opting for re-Urolift due to initial success and tolerability.	Thank you for your comment. The definition of failure rate was clarified in response to consultation comments. Please see NICE's response to comment 74.
81	5	Healthcare Professional	ARU	4. Relapse rates. The updated 5 year data for the LIFT study (Roehrborn et al, Can J Urol 24(3): 8802-13) demonstrates not a 0% relapse at 3 years but 13.6% relapse. A brief review of Pubmed demonstrates that relapse rates for other interventions are lower in the long term. For example, from Elshal et al BJUI Int 126(6): 731-738,	Thank you for your comment. A 13.6% re-intervention rate for UroLift was included in the economic model, please see NICE's response to comment 74.

				an RCT of TURIS TURP (n=62) vs Greenlight laser (n=60) vs HOLEP (n=60), 3 year relapse rates were 9.7% vs 6.7% vs 0% (p=0.04). Other data from Rieken et al (Curries Opin Urol 26: 22-27) review shows 5 year relapse rates of 9% for TURP and close to zero for HoLEP. Another recent RCT of Urolift vs TURP showed after 2 years, the re-treatment rate due to failure to cure was 13.6% in the Urolift arm (6 patients) and 5.7% after TURP (2 patients) (Sonksen et al, Eur Urol, 68: 643). Further, an expert commentary by Professor McNicholas states that, "A third of patients do not find the treatment as effective, often due to: some need for removal/repositioning of implants; about a third of this subgroup (±10% overall) require more invasive treatments such as bladder neck incision (BNI), TURP or holmium laser enucleation of the prostate (HoLEP). The need for more invasive treatment becomes evident within the first few weeks post-UroLift system procedure; these are men to consider for urodynamic testing; in this author's experience, these patients are often more reconciled to the need for, and complications of, more invasive treatments as they feel that at least they have tried the lesser procedure first." Therefore, assumptions of 0% relapse for Urolift in the long-term are therefore incorrect and have no validity. This should be corrected in the cost-effectiveness analysis as it is a key factor that needs incorporation.	
Clinical Evidence					
82	12	Company	3.2	*In the original guidance, there was no published evidence directly comparing the UroLift System with the comparator technologies highlighted in the scope.*	Thank you for your comment. The committee heard that the inclusion of the initial results from the BPH6 trial were made available during the consultation period of the original guidance. Section 3.2 was rephrased to reflect this.

				This statement is misleading. Although it is in a section of the current guidance that relates to the original guidance, it is written in the present tense. To state that there is no published comparison of Urolift to the comparator is incorrect. The BPH6 study which compares Urolift with TURP is widely cited (Sonksen et al. 2015; Gratzke et al. 2016) throughout the current consultation document. It is also incorrect to state that “In the original guidance, there was no published evidence directly comparing the UroLift System with the comparator technologies”. As stated in MTG26, “during consultation, the results of the BPH6 trial (Sønksen et al. 2015) became available as an in process document (Clinicaltrials.gov identifier: NCT01533038). This study most closely matches the scope for this evaluation because it directly compares UroLift with TURP as part of a randomised, multicentre clinical trial. The original guidance also states (3.29) “After consultation, the Committee noted that the results of a recent comparative trial (BPH6) of UroLift against TURP were similar to those in the External Assessment Centre's evidence synthesis, and supported its interpretation of the comparative effectiveness of UroLift and TURP.”"	
83	10	Comparator Company	3.6	*2 non-randomised, comparative, prospective studies (Tutrone and Schiff 2020;* Part 1: This study should not be considered as a comparative analysis, but only as a reporting case series selected retrospectively. The only appropriate conclusion to draw is that the outcomes cannot be meaningfully compared between UroLift and Rezum due to the following reasons. There were several methodological limitations that we would like to highlight to the committee. Firstly, because of the non-randomised nature of the trial, any efficacy comparisons are limited, due to a high	Thank you for your comment. The External Assessment Centre was asked to comment on their evaluation of the Tutrone and Schiff (2020) study. They stated that the study was assessed using the Joanna Briggs Institute Checklist for Quasi-Experimental Studies. It showed minimal concerns as the study groups were similar at baseline (no statistically significant differences) for age, prostate size and IPSS score. The measures being compared were the same in each group and the statistical analysis was correct for the comparisons made. As the study is not an RCT and

				risk of selection bias. It is not stated how its subjects were selected other than that it was done retrospectively. It is not known how many patients were treated, but never included in the study results. This design opens the door to bias in the selection of subjects. It is stated in the article, that prostate volume appears to have been larger in the Rezum group (63 vs. 49) than in PUL. The assessment of symptom severity (IPSS) at baseline was available for only 63.3% (19/30) of PUL and 52.2% (12/23) of Rezum subjects. The article presented no baseline data for the other variables on which the treatments were compared post-operatively (IPSS-QoL, SHIM, MSHQ-EjD function, MSHQ-EjD bother). It is stated in Table 2 in the paper that at baseline the proportion of men currently or previously on BPH medications was at least 84% in Rezum and 27% in PUL. The lack of baseline assessments makes it impossible to know whether the two arms were comparable at baseline. Thus, there is a high risk of confounding bias in the comparison of treatment outcomes.	does not have a control group, efficacy comparisons may be limited but they are not incorrect or unusable. Where there is limited evidence that is not from an RCT will be considered. Alternative types of studies can still provide meaningful comparative analysis, and the limitations are highlighted by the external assessment centre in its critique. The committee considered the comments and concluded that although this study did have limitations, it was still valid and should be included in the clinical evidence.
84	10	Comparator Company	3.6	Part 2: PUL was performed by different surgeons than those who performed Rezum. As the prior experience of each urologist has not been described in the paper, it will be important for the committee to consider the impact on outcomes of inter-surgeon variability in their experience of each procedure. It is not stated whether the surgical techniques and post-operative care were performed to appropriate standards at both study centers. Catheters were placed per physician protocol. No uniform criteria for catheter removal were noted in the article and the decision of when to remove the catheter apparently was not made blind to the treatment. Thus, the pre-requisites for an unbiased comparison of the treatments on catheterisation were not in place. In addition, conducting the assessments only during the peri-operative period (post-operative day 30, on	Thank you for your comment. The External Assessment Centre was asked to comment on their evaluation of the Tutrone and Schiff (2020) study. They state that all of the included papers have different surgeons completing procedures. The level of control over surgeons performing procedures is not feasible in real life settings. Although the 30 day follow up period is a limitation of the study, the study does report its planned outcomes of 30-day (average) results. The committee heard that a 30 day follow up is a limitation to this study, however this is the only published study comparing the two technologies. The committee concluded that this study should remain in the guidance.

				average) implicitly fixed the comparison to a time point that would favor PUL (clips/no ablation) to Rezum (an ablative procedure) and fails to obtain any data on durability of the treatments. Resolution of the immediate inflammatory response post-procedure, following steam ablating the tissue, is usually observed around 3 months. This 3-month improvement has been consistently reported in other BPH RCTs. Conversely, PUL has immediate effects as it is a mechanical non-ablative procedure. Consequently, reporting 3-month follow-up outcomes would have allowed for more meaningful conclusions against all other comparators.	
85	10	Comparator Company	3.8	*Compared with Rezum, people having Urolift reported greater improvements in IPSS scores at 30 days after the procedure (Tutrone and Schiff, 2020).* This statement is not accurate, same comment as above. Due to the non-randomised nature of the study, any efficacy comparisons are limited, due to a high risk of selection bias. Therefore, the committee should not make any comparative claims comparing UroLift to Rezum. In addition, conducting the assessments only during the peri-operative period (post-operative day 30, on average) implicitly fixed the comparison to a time point that would favor PUL to Rezum and fails to obtain any data on durability of the treatments. The resolution in the immediate inflammatory response post-procedure, following steam ablating the tissue are usually observed around 3 months. This 3-month improvement has been consistent reported in other BPH RCTs. On the contrary, PUL has immediate effects as it is a mechanical non-ablative procedure. Therefore, reporting 3-month follow-up outcomes would have allowed for more meaningful conclusions. There is no protocol in the study to ensure any consistency between clinicians, and in addition the IPSS scores at 30 days also includes a period of time where a	Thank you for your comment. Please see NICE's responses to comment 83 on selection bias and comment 84 on length of study follow up.

				catheter was used for Rezum, where IPSS scores cannot be collected.	
86	10	Comparator Company	3.12	*The amount of change in SHIM scores did not differ significantly between UroLift and TURP (Sonksen et al. 2015; Gratzke et al. 2016) but was better with UroLift than Rezum (Tutrone and Schiff, 2020).* This statement is not accurate, same comment as above- unable to make efficacy comparison	Thank you for your comment. Please see NICE's responses to comment 83 on selection bias and comment 84 on length of study follow up.
87	10	Comparator Company	3.13	*In 1 study there was no significant difference in scores between people who had UroLift or Rezum at 30 days follow up (Tutrone and Schiff, 2020).* This statement is not accurate, same comment as above- unable to make efficacy comparison	Thank you for your comment. Please see NICE's responses to comment 83 on selection bias and comment 84 on length of study follow up.
88	10	Comparator Company	3.15	*Catheterisation time after UroLift was statistically significantly less than with Rezum (1.2 days compared with 4.5 days; Tutrone and Schiff, 2020).* This statement is not accurate, same comment as above- unable to make efficacy comparison	Thank you for your comment. Please see NICE's responses to comment 83 on selection bias and comment 84 on length of study follow up.
89	10	Comparator Company	4.3	*The committee noted that there is only 1 study comparing Rezum with UroLift, in which the follow-up period was only 30 days. The results showed that UroLift was better than Rezum for the short-term relief of lower urinary tract symptoms and for improving erectile dysfunction, but any comparative benefits beyond 30 days were uncertain* This statement is inaccurate, as described previously the study was non-randomised, therefore any efficacy comparison is limited and subject to bias.	Thank you for your comment. Please see NICE's responses to comment 83 on selection bias and comment 84 on length of study follow up.
90	9	Healthcare Professional	3.5	*sexual function is not negatively affected after using UroLift* One publication showed improvement of sexual function scores after UroLift.	Thank you for your comment. Section 3.5 refers to the evidence available for the original guidance. For the UroLift guidance update, sections 3.12 and 3.13 discuss the recent publications showing improved sexual function scores.
Economic Evidence					

91	5	Healthcare Professional	3.23	1. Urolift time. The change from the EAC recommendation of 30 minutes (they even state it could be as high as 60 minutes) to 14 minutes based on audit data seems incorrect. First, the audits as summarised use differing terminology. Northampton NHS Trust use 'operating time' of 20.1 minutes (n=20), St Helens summarise their data as 'theatre time ' of 10-30 minutes (excluding anaesthetic time) (n=7) and Frimley NHS as 'theatre time' of 25 minutes (n=75). Operating time (or surgical time) is shorter than actual time in theatre. Nonetheless, with these summaries of data, it is implausible that the mean is 14 minutes when the dominant series is n=75 of 25 minutes. The time for Urolift needs correction as a result.	Thank you for your comment. The committee heard that the procedure time used in the economic model was based on NHS audit data from 550 procedures over the past 3 years. The clinical experts agreed that a procedure time of around 14 minutes was acceptable. The committee decided that the data source used was appropriate.
92	5	Healthcare Professional	ARU/3.23	3. Number of implants. On page 78 the EAC state that 4.4 implants per procedure is "more representative" and the base case is 4 implants. Indeed, in the Sunken et al RCT sponsored by the manufacturer Neotract (Eur Urol, 2015) there were 4.7 implants on average. It is therefore incorrect for the Committee discussion on 4.17 for the cost effectiveness analysis to assume 3.5 implants per case. This either needs clarification that 4.4 implants was indeed used in the analysis, or corrected so that 4.4 implants are incorporated into the analysis and the results updated.	Thank you for your comment. This value of 4.4 implants is from the original guidance assessment report. The number of implants used in the updated guidance is derived from NHS audit data. As a result 3.5 implants were used in the updated base case for the economic analysis.
93	8	Healthcare Professional	3.25, 4.15	Please note that it is now standard practice in the NHS for TURP and HoLEP to also be done as daystay procedures. It seems that this fact has not been included in the cost analysis comparison and therefore artificially inflates the stated cost savings for urolift when compared to TURP and HoLEP	Thank you for your comment. The committee heard that HoLEP and TURP are routinely done as an inpatient procedure, with limited instances of day-case use. The external assessment centre modelled the cost of doing TURP or HoLEP as a day-case procedure. The committee heard that UroLift was still cheaper than TURP and HoLEP in these instances and decided that no corrections to the guidance were needed.

94	8	Healthcare Professional	Economic analysis	The following assumptions/omissions should be corrected as they have implications for the cost modelling of all the procedures mentioned in the report: a) In 1.3 it is stated that the cost savings for urolift are partly ""because of reduced length of stay"". Acknowledgement should be made that it is now standard practice in the NHS for TURP and HoLEP to also be done as daystay procedures. It seems that this fact has not been included in the cost analysis and therefore artificially inflates the stated cost savings for urolift when compared to TURP and HoLEP b) It seems the number of implants used per case in the draft document is based on self reported audits from 6 centres of excellence in the NHS where the urolift service is led by urlolift enthusiasts who have potential conflicts of interest as they have all done paid work for Neotract/Teleflex. It would be more transparent and appropriate to use the implant numbers from the peer reviewed and published randomised trials for urolift (even though these too were industry sponsored). In LIFT, which excluded men with enlarged median lobes, an average of 4.9 implants were used with a range of 2-11. 85% had 6 or less implants. In the era of increased indications for urolift (i.e. used now in some patients with enlarged mobile median lobes) the number of implants used can be expected to rise rather than fall. c) In 4.17 it is stated that ""varying the number of implants used was unlikely to affect the cost saving conclusions when compared with TURP and with HoLEP"" should be removed in my opinion because every implant costs £400 exc VAT. When taken in isolation, the use of 4 implants might be cheaper than the cost of HoLEP/TURP, however when all costs are taken into account (i.e. costs of corrective/salvage surgery and restarting medications post-urolift, costs of pre-urolift flexible	Thank you for your comment. Please see NICE's response to comment 93 on the cost of TURP and HoLEP as a day-case procedure. The number of implants used were derived from NHS audit data of 550 UroLift procedures. The committee decided that the data source used was appropriate. Re-intervention costs, at a rate of 13.6% over 5 years, was included in the UroLift economic model. Flexible cystoscopy was included in the scenario analysis for UroLift and was deemed to still be cost saving compared to TURP and HoLEP. The committee viewed that HoLEP and TURP were more routinely done as an inpatient procedure. The committee concluded that no further changes were needed to the economic analysis.

				cystoscopy (not necessary for rezum, TURP, HoLEP), and the fact that HoLEP/TURP are now also routinely done as daystay procedures, it could be that rather than being cost saving, urolift is actually more expensive overall when compared to rezum, TURP and HoLEP.	
95	9	Healthcare Professional	1.3	If performed as "Walk-in" procedure, UroLift is more cost effective. Many patients require only two implants, which is more economical than the quoted values. Is Rezum's generator costs and HoLep Laser machine investment costs, included?	Thank you for your comment. The committee heard that Rezum generator costs and HoLEP laser costs are not included in the economic model. The external assessment centre stated that the (MTG49) Rezum assessment removed the capital costs for HoLEP, as it was considered an established device used for other procedures. HoLEP capital costs were not included in the company submitted model for the UroLift update, and this was accepted by the external assessment centre. MTG49 (Rezum) assessment states that the generator and annual servicing costs are provided free of charge (the cost being included in the purchase of consumables) for Rezum.
96	9	Healthcare Professional	3.24	*£72.33 per consultation. This was based on an EAC cost of £37 for 20 minutes* Telephone consultantion by LUTS nurse should not cross 20 mins. Hence total cost will be less than £37.	Thank you for your comment. The committee heard that a time between 10 and 20 minutes was reasonable for a telephone follow up appointment.
97	9	Healthcare Professional	3.26	*£1,006 compared with bipolar TURP£1,267 compared with monopolar TUR* Bipolar is costlier than monopolar TURP due to disposable loops and usage of normal saline.	Thank you for your comment. Although Bipolar TURP is more expensive, the cost difference is a result of reduced procedure times and length of stay.
98	9	Healthcare Professional	3.28	*UroLift is cost saving compared with Rezum* TWOC clinic expenses and initial generator costs will make Rezum costlier than UroLift.	Thank you for your comment. TWOC clinic expenses for Rezum were considered in the base case. Please see NICE's response to comment 95 on Rezum generator costs.
99	10	Comparator Company	3.22	We would ask that the EAC be consistent in the methods used between different BPH treatment MTEP's. In this instance, the EAC removed the following costs from the model: pre procedure	Thank you for your comment. The External Assessment Centre was asked to comment on the exclusion of these costs. They

				outpatients consultation, pre and post procedure tests, fluids and other consumables during procedures, as they were assumed to be equal for all comparators. We would kindly ask the committee to be consistent in its reporting style and methods, as these costs were included in MTG49. Excluding these costs over- inflates the apparent savings received from UroLift. The difference in apparent costs are not inconsiderable (approximately £500). Anyone without health economic expertise would not immediately understand this, and it would appear that Urolift is more cost saving than it actually is.	stated that all pre and post procedure tests and consultations would be equivalent for all technologies and so inclusion would not effect comparative costs. Flexible cystoscopy prior to a UroLift procedure was also considered in scenario analysis. MTG26 included intravenous peri-operative antibiotic doses, post-operative irrigation fluid and analgesic doses. These were calculated at the same cost for each technology. The committee considered the comments and were satisfied that the exclusion of these parameters did not affect the cost outcomes.
100	10	Comparator Company	3.23	As mentioned in the previous comments, the cost of UroLift procedure is extremely sensitive to changes in the number of implants used, in contrast to the other comparators in scope that are not impacted by changes in different prostate morphologies. Therefore, we believe the above statement to be a misrepresentation of the overall treatment cost. We would suggest that the committee recalculate the per patient cost based on the treatment of different prostate glands (</> 80g) and the presence of an OML, because the cost of the other comparators is unaffected by changes in the prostate gland size and the presence of an OML.	Thank you for your comment. The committee considered these comments. The recommendations for UroLift have been changed to between 30 and 80ml as discussed in NICE's response to comment 4. The additional costs of treating obstructive median lobes have been considered in the base case and scenario analysis. The committee decided that no further analysis is needed.
101	10	Comparator Company	3.25	*In the model update the costs of bipolar TURP and monopolar TURP increased compared with the original guidance. This was because of an increase in consumables costs for bipolar TURP, and to a lesser extent for monopolar TURP. The cost of managing incontinence was also applied to the whole population who have treatment instead of only when treatment has failed.* Same comment as before, the assumptions used to arrive at this decision are inaccurate.	Thank you for your comment.
102	10	Comparator Company	3.26	*The revised EAC base-case analysis shows that UroLift is cost saving when compared with all comparators.*	Thank you for your comment.

				This statement is inaccurate, as described in our previous comments. Based on the published evidence and the shared learning case-studies, it is highlighted that the minimum number of UroLift implants to treat prostate size up to 80g is 4. Section 2.1 highlights that typically, 4 implants are used to ensure that the urethra is widened. Therefore, we believe that applying the weighted mean average of 3.5 clips is inappropriate for the purpose of this economic evaluation. It is clear from the EACs report, that Rezum is the most cost savings technology if the mean number of UroLift clips exceed 3.6. In addition, if you consider treating the median lobe, that on average requires 2 more UroLift implants, the procedure is no longer a cost-effective option. As per our recommendations before, we would suggest that the committee recalculate the per patient cost based on the treatment of different prostate glands (</> 80g) and the presence of an Obstructing Median Lobe (OML), because the cost of the other comparators is unaffected by changes in the prostate gland size and the presence of an OML.	The committee heard that the average of 3.5 implants was based on NHS audit data of 350 UroLift procedures. Costs of extra implants for treating obstructive median lobes were considered in the base case and scenario analysis.
103	10	Comparator Company	3.28	*The economic model was compared with the model used in NICE's medical technologies guidance on Rezum. The committee concluded that there were too many uncertainties to draw firm conclusions about the costs of using Rezum compared with UroLift. However, the base-case model results showed that Rezum was cost saving when compared with UroLift. The key parameters that were changed in the current model were theatre time, length of stay and type of consultation after UroLift. If length of hospital stay was the same for Rezum and UroLift, Rezum would be cost saving compared with UroLift. However, the EAC's sensitivity analysis concluded that UroLift was only cost saving compared with*	Thank you for your comment. Please see NICE's response to comment 50 on implant numbers and comment 43 on flexible cystoscopy use. The committee considered these comments and decided that no changes to the economic model were required. Sensitivity analysis explored changing the number of implants and procedure time, which concluded that the cost case for UroLift compared to Rezum were uncertain but that UroLift still remained cost saving compared to other BPH treatment options considered.

				Rezum if theatre time for the procedure was less than 16.7 minutes. We do not agree with this statement, as mentioned in our previous comments. The cost of UroLift is very vulnerable to changes in prostate morphology (requires more implants). In addition, if the procedure is to be considered in large prostates and the OML, then a flexible cystoscopy procedure is routinely done. Ignoring these costs of extra implants and cystoscopy from the modelling, underestimates the actual treatment cost per patient. In the shared learning, 3 of the 6 shared learning examples the teams performed flexible cystoscopies before Urolift procedures. Having a Rezum procedure does NOT usually require a flexible cystoscopy, therefore this would reduce the overall treatment cost. In addition, if we reference the OML, the EAC reported the incremental cost of Urolift vs Rezum was -£968 (favouring Rezum). Furthermore, recent UK abstract presentations at BAUS and EAU 2020 highlighted that in the UK the median procedure time for Rezum was currently in the range of 9-14 minutes. This reduction in procedure time further supports the case for Rezum being the overall less expensive comparator in scope.	
104	10	Comparator Company	4.10	The cost of a flexible cystoscopy should be included in the model, if UroLift is to be considered in treating prostates up to 100g and the OML. In these cases, a flexible cystoscopy is a requirement as stated previously and in the shared learning document.	Thank you for your comment. The committee heard that not all clinicians used flexible cystoscopy in their practice and that some clinicians would use flexible cystoscopy for more than just UroLift patients. This uncertainty is reflected in section 4.11 and 4.19. The committee agreed that no changes were needed to the economic model.
105	10	Comparator Company	4.11	Yes, we agree, so we believe that the guidance should clarify the resource use when treating different prostate morphology (up to 100g) including the OML. If UroLift is considered to treat a large prostate up to 100 g and/or the OML, then the	Thank you for your comment. The external assessment centre confirmed that no costs included for catheterisation where the catheter is removed prior to discharge from hospital. The

				procedure time and LOS would also increase. These additional increased resource use has not been accounted for throughout the guidance. In addition, the recent BAUS BOO audit reported that 11% of men received post-operative catheter after a UroLift procedure. Tutrone 2020 also reported high postoperative catherisation (57%) in the UroLift arm. These costs of catheterisation have not been included in the model.	committee heard that most procedures would take around 15 minutes unless the case is more complicated. The committee considered these comments and did not decide to update the economic model.
106	10	Comparator Company	4.18	*UroLift (if done as an outpatient procedure) was cost saving in the base case by £121 compared with Rezum for everyone who had treatment over a 5-year time horizon. However, the EAC's sensitivity analysis showed that Rezum would be cheaper if several parameters were changed individually, including:* *• if the procedure time was the same for both procedures* *• if the average number of UroLift implants exceeded 3.61.* *Further economic analysis was done to consider the use of flexible cystoscopy before UroLift treatment. It showed that Rezum was likely to be cost saving in this instance. However, there was uncertainty around whether only people being considered for UroLift would have flexible cystoscopy.* We believe that this statement is inaccurate, based on our previous comments. The EAC's sensitivity analysis is more reflective of what the base case assumption should reflect. It clearly demonstrated that Rezum was a more cost saving option than UroLift	Thank you for your comment. The committee considered the comments and decided that the base case analysis was appropriate.
Wording					
107	9	Healthcare Professional	1 (rationale)	*excess prostate tissue* Obstructing prostate tissue	Thank you for your comment. The committee decided to change the wording in the rationale in response to this comment.

108	9	Healthcare Professional	1 (rationale)	*unlikely to affect sexual function* Do not affect sexual function. Especially it preserves antegrade ejaculation.	Thank you for your comment. The committee decided to change the wording in the rationale to match recommendations in 1.1 in response to comment 109.
109	12	Company	1 (rationale)	*unlikely to affect sexual function* Suggest that this is changed to “avoids risk to sexual function” to be consistent with Recommendation 1.1	Thank you for your comment. The committee decided to change the wording in the rationale in response to this comment.
110	12	Company	2.1	Change "NeoTract" to "Teleflex Inc."	Thank you for your comment. The committee decided to change the wording in the rationale in response to this comment.
111	12	Company	3.28	*However, the base-case model results showed that Rezum was cost saving when compared with UroLift.* It is currently not clear from this statement that it is referring to the base case modelling in the Rezum guidance, not the current base case model	Thank you for your comment. The committee decided to change the wording in the rationale in response to this comment.

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