

National Institute for Clinical Excellence

Comment 1: the draft remit

Section	Consultees	Comments	Action
Remit size	RCN	There is concern that by including the treatment of 2nd degree haemorrhoids, this makes the remit too broad. As haemorrhoidectomy would not normally be the treatment of choice for these, it would be necessary to compare stapled haemorrhoidectomy against standard treatments e.g. banding or injection rather than the Milligan Morgan haemorrhoidectomy	Agreed
	RCN	If the remit were limited to the treatment of 3rd and 4th degree haemorrhoids then the wording would be adequate. By extending it to 2nd degree, there needs to be a fuller explanation of the other methods of treatment	There is no longer any reference in the patient group section as to degree of haemorrhoids; instead it states where surgery is indicated
	South Leeds PCT	Remit size is appropriate, but the title could usefully specify "Stapled haemorrhoidectomy for the treatment of second, third and fourth degree internal haemorrhoids	See above
	EE / JJ	Appears to be appropriate	
Wording	South Leeds PCT	See comment above: the wording could specify the restriction to second, third and fourth degree internal haemorrhoids	See above
Timing Issues	RCN	We support the review but do not believe this is a top priority at present.	Noted
	South Leeds PCT	Not urgent, unless this procedure is likely to become widely adopted over a short timescale	Noted

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	EE / JJ	<p>We do not consider that appraising "Stapled Haemorrhoidopexy" at this time to be ideal. Though we believe the technology offers advantages to both patients and providers, we are still developing the evidence base to support the UK. We would therefore proposed that if this technology is deemed appropriate for review, that it be deferred for approximately 12 months while the evidence base is strengthened. Furthermore, if an appraisal were undertaken at this time, and a positive recommendation made indicating wider use, the NHS is unlikely to be in a position to implement, and would most likely result in the guidance being issued with a 'non compulsory implemetation' note from the Department of Health. This is because the only training offered in this procedure at present is by EES. At present we have 4 training centres in the UK. These 4 centres provide all of the intial training in this procedure. Training is then followed up with a Preceptorship, and then in-theatre support from our technicians. The device in question is not actively sold by our traditional sales force, but is only distributed alongside our managed training and theatre support programme. The training programme is capacity limited, and would be unable to manage the demands of guidance that required rapid national expansion. In effect, we provide the training for the NHS in this procedure. Unless the NHS was in a position to provide training in response to a potential postive guidance, there would be little value in undertaking a review at this time. We have a managed training and implementation strategy in place working with Providers who see the benefits to themsleves and patients from this procedure. This is already working at capacity, and would not be able to accommodate a significant change in demand resulting from a potential postive NICE appraisal.</p>	The wording has not be changed, however, the issue will be addressed over the course of the appraisal
Additional comments on the draft remit	South Leeds PCT	Changes to the management of 2nd degree haemorrhoids will impact on nurse led services as these treatments are currently undertaken by nurse practitioners.	Noted
	EE / JJ	The name of the procedure should be changed to Stapled Haemorrhoidopexy rather than stapled haemorrhoidectomy, as'opexy' better describes the clinical procedure. In short, the anatomy is preserved, not removed.	The wording has not be changed, however, the issue will be addressed over the course of the appraisal

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	RCN	More information is required on standard treatments of sclerotherapy, banding and especially infrared coagulation for which there is little evidence	Where appropriate this will be covered within the appraisal
	RCN	It is minimal and requires expansion: complication rates etc	Noted
	South Leeds PCT	It is not made clear that the staples remain in-situ postoperatively	Scope amended
The technology/ intervention	South Leeds PCT	Yes, as far as we now, in the context of our Primary Care knowledge base	Noted
	EE / JJ	Procedure numbers: In 2003 there were estimated to be 2,100 Stapled Haemorrhoidopexy procedures in the UK.	Scope amended
Population	RCN	Fine	Noted
	South Leeds PCT	Our interpretation is that the remit is restricted to adult populations. Would the procedure be unsuitable for anyone who engages in anal intercourse given that staples remain in the rectal wall postoperatively ?	Noted
	EE / JJ	Stapled Haemorrhoidopexy is generally positioned for Grade 3, uncomplicated Grade 4 and selected Grade 2 where banding has failed.	The wording has not be changed, however, the issue will be addressed over the course of the appraisal
Comparators	South Leeds PCT	As far as we know, bearing in mind our Primary Care knowledge base.	Noted
	EE / JJ	Yes	Noted
Outcomes	RCN	Fine	Noted
	South Leeds PCT	Yes, provided that the fairly long list of postoperative complications which have been reported are all included in the phrase "peri- and post-operative complications of surgery", and that re-admission rates for haemorrhoidectomy are taken into account over, say, the following 2 years.	Noted

Summary form

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	EE / JJ	Pain and time taken to return to normal activities are the two key differences between stapled Haemorrhoidopexy and the standard techniques. With experience, Stapled Haemorrhoidopexy is often offered as a day case procedure.	Noted
Economic analysis	South Leeds PCT	At least 2 years post-operatively. NHS Trust Finance officer(s) should be involved to ensure all relevant factors are taken into account.	Noted
Other considerations	South Leeds PCT	? any possible complications from leaving staples in-situ long term	Where evidence allows, this will be covered within the appraisal.
	EE / JJ	In stage 2, Stapled Haemorrhoidopexy is confined to patients where rubber band ligation has failed. There is currently a study ongoing in grade 2 versus banding, but the results are not yet available. We are attempting to determine the timelines for this data.	Scope amended Noted
Additional comments on the draft scope.	South Leeds PCT	There are a number of international studies on this procedure - should comments from other organisations, eg the American College of Surgeons, be taken into account ?	Noted

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope