

## 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  |

| Section                                | Consultees      | Comments  | Action  |
|--|-----------------|---|---|
|  | 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

| Section                                 | Consultees      | Comments  | Action  |
|---|-----------------|---|---|
|   | EE / JJ         | Pain and time taken to return to normal activities are the two key differences between stapled Haemorrhoidopexy and the standard techniques.<br>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.<br>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<br><br>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**