ETHICON ENDO-SURGERY
a Johnson & Johnson company

TRANSFORMING PATIENT CARE THROUGH INNOVATION

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23rd May 2007

Dear Reetan,

Response to Appraisal Consultation Document:
Stapled Haemorrhoidopexy for the Treatment of Haemorrhoids

Thank you for the opportunity to respond to the above preliminary recommendations. We recognise this is a positive outcome for the procedure, and concur with the Committee's conclusions. We do consider that:

I. all relevant evidence has been taken in to account
II. The summaries are reasonable interpretations of the evidence, and
III. The recommendations constitute a sound basis for guidance to the NHS

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Specifically, we wish to note the following points:

- We concur with the wording of Section 1. We believe this to be a positive outcome for patients and surgeons.
- We appreciate that the procedure name has now been recognised; being '–pexy' recognising haemorrhoidal tissue is conserved, rather than the traditional method of complete removal, or '-ectomy'.
- We support the comments in paragraph 4.3.10. We recognise the principal recommendation is related to the procedure, however we appreciate that the committee has recognised that the success of the general procedure is in part determined by the specific devices used, and these therefore require their own evidence base.
- That the Committee recognised the value of our utility estimates (4.3.7).

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We have one textual change to suggest for paragraph 3.2, clarifying the device currently available. Only PPH03 is currently marketed for this procedure in the UK, as implied in Paragraph 3.3. A suggested amendment is attached in the Annex, Section A.

Finally, we have one comment on the response to our comments on the Assessment Report. We recognise these do not impact the ACD, so they are in the Annex, Section B. However they are included as they may be relevant to any subsequent monograph produced, and request they be passed to the Assessment Team.

We thank the Committee for their recommendation and look forward to receiving the Final Appraisal Determination in due course.

Yours sincerely,

Adrian Griffin

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Annex: Section A

Suggested amendment to Paragraph 3.2 & 3.3

3.2 Two devices were listed in the scope for this appraisal: the HCS33 device, ~~of which the~~ **(models** PPH01 and PPH03**)** ~~models are currently in use~~, developed by Ethicon Endo-Surgery (**a** Johnson & Johnson **company**); and the Autosure stapler, developed by Tyco Healthcare, which can be used in conjunction with the STAM kit adaptor to perform haemorrhoidopexies.

3.3 The cost of the HCS33 PPH03 stapling device**, the model currently in use,** is £420.00, based on the submission from Ethicon Endo-Surgery. Costs may vary in different settings because of negotiated procurement discounts. The cost of the Autosure stapler with the STAM kit adaptor was not available.

Section B

We thank the Assessment Group for their responses to our comments. We consider one of our comments may not have been well communicated as it appears to have been misunderstood in the comments. We are flagging it at this time as it might warrant comment in any future monograph or publication.

Our comment relates to the use of the HODaR data to estimate the quality of life impact, and hence QALYs. Our key issue was that the HODaR data based on the SF36 elicits responses from patients over their experiences during weeks 3 to 6 post surgery (it has a four week recall period, and is asked after week 6). It therefore does not include any contribution from weeks 1 and 2 – when the pain from the traditional haemorrhoidectomy is at its greatest. Therefore, using SF36 data from HODaR as the baseline estimate under-estimates the impact of pain following conventional haemorrhoidectomy. This is important as the Assessment Team then use a relative reduction for the benefit of the stapled procedure. Applying a relative reduction to a baseline that already under-estimates the actual impact of the traditional surgical approach can only under-estimate the relative benefit of the stapled procedure.

This issue is not recognised in the Assessment Report or in their follow up comments. We request that the group consider at least mentioning this issue qualitatively if not quantitatively in the discussion of any future publication.