

20th December 2007

Dear Consultee,

Health Technology Appraisal

Continuous positive airway pressure for the treatment of obstructive sleep apnoea/hypopnoea syndrome

Final Appraisal Determination

Please find enclosed/attached a revised Final Appraisal Determination (FAD) for your consideration. This replaces the document that was sent to you on 16th Nov. Exceptionally we have taken the step of issuing a second FAD to enable to the incorporation of an important comment that was missed at an earlier stage in the process. Section 1 of the guidance has undergone some minor revisions and there have been some small changes and additions to the body of the document. We have also amended the comments table to incorporate these comments and our responses in full.

Whilst no appeals were received on the original FAD in accordance with our appraisal process we are offering you a further period in which you have the opportunity to lodge an appeal against the guidance or request any factual changes to the revised FAD should you wish.

In addition to the revised FAD, which will form the Guidance to the NHS, Comments on the Appraisal Consultation document (ACD) from consultees and commentators, and those received via the Institute's web site, are also enclosed, together with a revised summary table of these comments and the action taken in response to them.

The revised FAD and comments table will be posted on the Institute's website on **Wednesday 2nd January. I must emphasise that the documents enclosed with this letter, and their contents, are confidential until they are published on the Institute's website.** Accordingly, neither the documents nor their contents should be divulged to anyone other than those individuals within your organisation who need to see them. You must ensure that anyone to whom you show the documents is aware of their confidentiality.

If you have any queries regarding this correspondence please contact Chris Feinmann on email: Christopher.feinmann@nice.org.uk or telephone: 0161 209 3856

On the NICE web site this appraisal is listed as Sleep Apnoea – continuous positive airway pressure (CPAP)

You have the right to appeal against the revised Final Appraisal Determination. The procedure for making an appeal is summarised below, and described more fully in the 'Guidance for Appellants' attached with this letter.

Grounds for appeal

The Institute will hear an appeal based on one or more of the following grounds.

1. The Institute has failed to act fairly and in accordance with the Appraisal Procedure set out in the 'Guide to the Technology Appraisals Process'.
2. The Institute has prepared guidance that is perverse in the light of the evidence submitted.
3. The Institute has exceeded its powers.

Appealable sections of the FAD

ACDs and FADs are prepared in two parts. The first part, sections 1-4, is produced by the Appraisal Committee, and is guidance directed to the NHS. The second part, the remainder of the ACD or FAD, is prepared by a variety of authors and contains a range of material consequent on the content of the first part (for example research recommendations and an analysis of the impact on the NHS if the guidance is implemented).

All parts of an ACD are subject to consultation. But for a FAD, the position is slightly different. NICE's procedures allow for an appeal on guidance to be issued to the NHS. It is always possible, subject to NICE's published procedures, to appeal against any part of sections 1-4 of a FAD. It would not normally be possible to appeal against the remainder of a FAD alone. This is because that material is not guidance to the NHS, but instead flows from the guidance contained in sections 1-4.

Appellants may find it useful to have guidance on cases where an appeal against the second part of a FAD is more likely to fall within NICE's appeal process. The most common will be where an appeal against the first part necessarily calls related elements of the second part into question. Less common will be the case where the second part of the FAD can be read as itself containing guidance to the NHS. (An example might be if a technology is recommended only in the context of a trial, and the second part of the FAD contains further detail of the sorts of trial being recommended). Other examples may arise and each case would be considered on its merits.

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Making an appeal

You may appeal individually or jointly with any other organisation that was invited to make a submission to the Appraisal Committee. You must submit your appeal to the project manager by Thursday 17th January; the Institute will confirm receipt shortly after that deadline.

The appeal documents must contain the following information.

- The aspect(s) of the guidance to the NHS or appraisal process being appealed against.
- The ground(s) of appeal.
- The basis for the appeal.

Please note that copies of your appeal will be made available on the day of the appeal to the general public attending and will also be published on the NICE website. Therefore, you should ensure that if your appeal contains commercial in confidence or academic in confidence information that the information is clearly labelled or that you submit a second version of your appeal with the commercial in confidence or academic in confidence information removed.

Appeal hearing

You will be able to make oral representations to the Appeal Panel unless the Chair decides that the appeal can be dealt with fairly on the basis of written submissions only. If the Chair decides not to allow oral representations, you will be notified within 7 days of submitting your appeal.

If the Chair decides that oral representations should be made, the Appeal Panel intends to hold a hearing in March 2008. You will receive further details of the Appeal Panel membership and confirmation of the Appeal date.

Please let me know the names of the people who would represent your organisation at such a hearing. If you intend your oral representation to expand significantly on your written submission, please help the Appeals Panel by providing a written outline of your oral submissions before the hearing. (This outline need be no more than a skeleton argument.)

Correcting factual errors in a Final Appraisal Determination

The Final Appraisal Determination has been prepared after a process of consultation. Other than changes, which may follow from an appeal panel

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decision, changes can be made **only** to correct factual inaccuracies. If you believe there is a factual inaccuracy in this guidance, please inform the project manager. The Technical and Executive Leads for this appraisal will discuss the proposed changes with the Chair of the Appraisal Committee. If they consider that it is appropriate to make changes, they will send the amended FAD to the Institute's Guidance Executive for ratification. Corrections will only be made after the end of the appeal period (in the event that no appeals are made) or following completion of any action arising from an appeal panel decision. Before the guidance is issued, the Institute will notify all consultees of any change to the FAD that has been made to correct a factual inaccuracy. All consultees will be informed at the same time, 48 hours prior to publication of the guidance on our website.

Confidentiality and misuse of information

The enclosed revised Final Appraisal Determination is confidential. If you use any information contained in the revised Final Appraisal Determination, before it is published by the Institute, to make investment decisions regarding any shares or other securities, or if you pass on information to another person for such use, you may be carrying out insider dealing, which is a criminal offence under section 52 of the Criminal Justice Act 1993. It may also be an offence to encourage another person to deal in shares or securities the price of which would be affected by the disclosure to the public of any information contained in the Final Appraisal Determination.

We remain committed to publishing guidance as speedily as possible.

Yours sincerely

Dr Carole Longson
Director, Centre for Health Technology Evaluation

Enclosed:
Revised Final Appraisal Determination
Revised Comments tables
Guidance for Appellants

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