From: Jeremy Powell
Sent: 11 February 2008 12:37
To: Jeremy Powell
Cc: Natalie Bemrose
Subject: Osteoporosis Appraisals - Specification of Additional Work

Attachments: Osteo DSU spec to C&C 11 02 08.doc

Osteo DSU spec to C&C 11 02 08...

11 February 2008

Sent via email

Dear Consultee/Commentator

Health Technology Appraisals

Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary and secondary prevention of osteoporotic fragility fractures in postmenopausal women

and

Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women

Please find attached the specification of the additional work carried out in preparation for the next Appraisal Committee meeting for these appraisals on 6 March 2008.

If you have any questions about these appraisals, please contact Ms Natalie Bemrose, Technology Appraisal Project Manager (email: Natalie.bemrose@nice.org.uk or 020 7045 2245).

Yours sincerely,

Jeremy Powell

Technology Appraisals Administrator
Centre for Health Technology Evaluation

National Institute for Health and Clinical Excellence (NICE)
MidCity Place
71 High Holborn
London WC1V 6NA

Website: www.nice.org.uk

PLEASE NOTE THAT MY CONTACT DETAILS HAVE CHANGED TO:

Direct line: 0207 045 2248
Fax: 0845 003 7784

PLEASE ALSO NOTE THAT THE INSTITUTE'S MAIN CONTACT NUMBERS HAVE CHANGED TO:

- NICE reception - 0845 003 7780
- NICE enquiries - 0845 003 7781
- NICE press office - 0845 003 7782
- NICE publications - 0845 003 7783

NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

Decision Support Unit Project Specification Form	
Project Number	
Appraisal title	Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women. Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (update of TA 87).
Synopsis of the technical issue	Following the appeal decisions for the above appraisals, the Appraisal Committee has been requested to reconsider the recommendations. Because of changes in the price of one of the drugs included in this appraisal, the modelling needs to be updated. Additionally, information supplied by Servier[1][2][3][4] that was discussed at the appeal hearing requires independent assessment.

[1] De Vries F, Cooper AL, Logan RF, Cockle SM, van Staa TP, Cooper C. Fracture risk in patients receiving concomitant bisphosphonate and acid- suppressive medication or bisphosphonates alone. Osteoporosis Int. 2007; 18(Suppl 3):S261

[2] Vestergaard, P., L. Rejnmark, L. Mosekilde. 2006 Proton Pump Inhibitors, Histamine H2 Receptor Antagonists, and Other Antacid Medications and the Risk of Fracture Calcified Tissue International Vol 79:76-83

[3] Yang Y-X, J.D. Lewis, S. Epstein, D.C. Metz. 2006, Long term proton pump inhibitor therapy and risk of hip fracture, JAMA, 296:2947-2953.

[4] Yu E W, Shinoff C, Blackwell T, Ensrud K, Hillier T, Bauer D C. Use of acid-suppressive medications and risk of bone loss and fracture in postmenopausal women. J Bone Min Res 2006; 21 (Suppl. 1), S281

Question(s) to be answered by DSU	1. What is the effect on the cost effectiveness modelling if the current lowest acquisition cost of alendronate is used? 2. What would be the ICERs for the other drugs in this appraisal for the age-group and T-scores that could be considered cost-effective for alendronate at the lowest acquisition cost? 3. How does the information supplied by Servier regarding the increased fracture risk associated with proton pump inhibitors affect the model outputs? 4. How robust is the information supplied by Servier on the increased fracture risk associated with proton pump inhibitors?
Why are these questions important	To provide analysis to define the subgroups of women for which treatment for the prevention of osteoporotic fractures is cost effective, following the decisions made by the appeal panel.
In what way does this project extend the content of the TAR	Update latest alendronate price to address appeal panel decisions.
How will the DSU address these questions	o All aspects of the modelling will be the same as in the analysis carried out for the November 2006 Committee meeting. The following scenario analysis will be used: 50% efficacy for fractures related to risk factors other than age, BMD and previous fracture; overall disutility of side effects assumed to be 10 times higher than reported in patient event monitoring study (from ScHARR systematic review of adverse events; 2006) . o Using the scenario analysis, alter the annual cost of alendronate to reflect the January 2008 prescription pricing authority drug tariff i.e. £53.56 for the once weekly (70 mg) tablets and £108.20 for the once daily (10 mg) tablets. o Using the scenario analysis, report the cost per QALY per strategy (and age band) for when risedronate and strontium ranelate become cost effective. o Results for primary prevention to be presented for £20K per QALY gained. o Results for secondary prevention to be presented to cover the range of £20k to £30k per QALY gained.

	o Results expressed as previously done, including a cost per QALY per strategy (and age band). o Present the results by age and T-score: in 5 year age bands for women aged from 50–74, with a single age band for women aged 75 and above (the latter based on the results for women aged 75–79); each age band in graduations of T-score at intervals of 0.5 standard deviations. o Critical review the information supplied by Servier on the increased fracture risk associated with proton pump inhibitors. If required, update the model inputs.
Relevant existing evidence 1. In the TAR (if applicable) 2. Other evidence presented to NICE	o Existing economic model. o Information supplied by Servier on the increased fracture risk associated with proton pump inhibitors.
Relevant new evidence requested by DSU	