

Decision Support Unit Project Specification

Decision Support Unit Project Specification Form	
Project Number	
Appraisal title	<p>Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women.</p> <p>Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (update of TA 87).</p>
Synopsis of the technical issue	<p>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 Servier¹²³⁴ that was discussed at the appeal hearing requires independent assessment.</p>

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	<ol style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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.

	<ul style="list-style-type: none"> ○ Results expressed as previously done, including a cost per QALY per strategy (and age band). ○ 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. ○ Critical review the information supplied by Servier on the increased fracture risk associated with proton pump inhibitors. If required, update the model inputs.
<p>Relevant existing evidence</p> <ol style="list-style-type: none"> 1. In the TAR (if applicable) 2. Other evidence presented to NICE 	<ul style="list-style-type: none"> ○ Existing economic model. ○ Information supplied by Servier on the increased fracture risk associated with proton pump inhibitors.
Relevant new evidence requested by DSU	