Decision Support Unit Project Specification

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 ACD consultation for the above appraisals, the Appraisal Committee requested further analysis.
Question(s) to be answered by DSU	1. a. What is the incremental cost per QALY gained of bisphosphonates for the prevention of osteoporotic fractures compared to no treatment, when treatment efficacy is assumed to be constant across all severities and is pooled for alendronate and risedronate? b. What is the incremental cost per QALY gained of strontium ranelate, raloxifene and teriparatide (where appropriate) relative to no treatment, and relative to pooled bisphosphonates? c. Including the cost of identification in the case of primary prevention, what is the incremental cost effectiveness of bisphosphonates for the prevention of osteoporotic fractures compared to no treatment, when treatment efficacy is assumed to be constant across all severities and is pooled for alendronate and risedronate? 2. How do adverse events in people who continue treatment affect the cost effectiveness of bisphosphonates? 3. Where efficacy data are available for osteopenic women, what is the incremental cost effectiveness of bisphosphonates compared to no treatment in this subgroup? What is the

	incremental cost effectiveness of bisphosphonates compared to no treatment for women with osteoporosis (excluding women with osteopenia), using efficacy data that are available for women in this sub-group.
	4. What is the impact on the cost effectiveness of bisphosphonates when alternative estimates are used for the following: fracture cost, nursing home entry, vertebral fracture utility, drug price and the efficacy of bisphosphonates on fracture reduction in people with risk factors other than low BMD or age.
Why are these questions important	To provide analysis to further define intervention levels at which treatment for the prevention of osteoporotic fractures is cost effective.
In what way does this project extend the content of the TAR	The new analysis will be expressed in cost per QALY
	The new analysis will explore the effect of updated model inputs.
	This new analysis will capture additional estimates about compliance and adverse events, and explore the impact of differential efficacy estimates in women with osteopenia and in women with risk factors other than low BMD or age.
How will the DSU address these questions	o Modify model to allow the expression of results as cost per QALY
	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 Vary the efficacy of bisphosphonates in women with risk factors other than age and BMD.
	o In the base case, include the disutility of adverse events. Source appropriate utility losses related to adverse events from therapy and the proportion of women to whom these will apply. If disutility data on drugs for osteoporosis cannot be derived from clinical practice, then explore the use of utility data derived from the use of other drugs that cause similar side effects.
	o Set the base case compliance rate to 50%

o Specifically

➢ Establish the incremental cost per QALY gained for bisphosphonates compared with no treatment for women with and without clinical risk factors other than age or BMD. Results to be presented by age and T-score as specified above.

➢ Establish the incremental cost per QALY gained for strontium ranelate, raloxifene, and teriparatide (the latter for secondary prevention only) compared with no treatment for women with and without clinical risk factors other than age or BMD. Results to be presented by age and T-score as specified above.

➢ Establish the incremental cost effectiveness (including identification) of alendronate compared to no treatment for osteopenic and osteoporotic women separately based on the FIT post-hoc subgroup analysis. Provide a commentary on the link between severity of osteoporosis and efficacy of alendronate.

➢ For each analysis, estimate the cost effectiveness versus no treatment including the costs of identifying women.

➢ Carry out one-way sensitivity analyses on the following parameters

  ➢ Fracture costs

  ➢ The proportion of women already in nursing home.

  ➢ Nursing home entry costs

  ➢ Vertebral fracture utility and hip fracture utility

  ➢ Prices for treatment

  ➢ Compliance rates, including an efficacy adjustment to account for the relative risks

	from the RCTs already incorporating compliance.

Relevant existing evidence
 	
   1. In the TAR (if applicable)
 	
   2. Other evidence presented to NICE
	a) Existing economic model
	
	b) Comments and analyses provided by NCC and GDG to the remodelling proposal

Relevant new evidence requested by DSU	