NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

SINGLE TECHNOLOGY APPRAISAL

Reconsideration of Strontium Ranelate

TA160/1 Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the primary/ secondary prevention of osteoporotic fragility fractures in postmenopausal women

Appraisal Committee Meeting – 20 October 2010

Background

This reconsideration is in response to a court order and is focussed on one particular issue and one technology, strontium ranelate.

Servier, the manufacturer of strontium ranelate, one of the drugs appraised in TA160 and 161, applied for a judicial review following publication of the guidance. One of the points raised was related to the approach that the Appraisal Committee took to a particular subgroup analysis; this point was not upheld at the Judicial Review stage. Servier applied to the Court of Appeal to challenge the ruling on the subgroup analyses point.

Servier claimed that

1. NICE had not adequately explained its reasons for rejecting the post hoc subgroup data, particularly in the light of the fact that the same data had been accepted by the EMA (the 'reasons' ground).
2. the Appraisal Committee's decision to reject the post hoc subgroup data was not rational (the 'rationality' ground).

The Court of Appeal ruled in favour of Servier on the reasons ground, and the judges ordered NICE to reach a fresh decision and issue fresh guidance in respect of strontium ranelate. The Appraisal Committee will therefore reconsider the relative effectiveness of strontium ranelate and, if they consider appropriate, review their consideration of its cost effectiveness.

Therefore, the committee will not have to look at the whole guidance, only to decide the relative risk for the hip fracture efficacy of Strontium ranelate, and to look at any consequences of utilising that relative risk in the existing model used in TA160/1.