

Memo

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From: [REDACTED]
Office/Location: London - Fetter Lane
Extension: 6572
Date: 19 August 2010
Matter: Reconsideration of subgroup analyses of Strontium Ranelate

Meindert

1. The purpose of this note is to guide the appraisal committee as to the correct approach to take when considering whether or not to amend the guidance in TA 160/161 as it relates to Strontium Ranelate in the light of information received on the subgroup analyses put forward by Servier.
2. It is very important that the committee consider and act on this advice. Failure to do so may make any subsequent decision more likely to be subject to further legal challenge, merited or otherwise.
3. The first point to consider is what information and evidence need to be taken into account. The criticism of NICE upheld in the Court of Appeal related to the committee's previous approaches around Servier's sub group analyses when determining the most appropriate RR value for Strontium Ranelate on which to base guidance. Any new information and evidence not related to that issue may be ignored. All information and evidence related to that issue must be considered.
4. When reconsidering the guidance the committee should approach the question of any possible change with an open mind. The Committee must not have a preconceived view as to any particular RR value. Whilst the Committee cannot be asked to forget their background knowledge and experience on the strengths and weaknesses of subgroup analyses generally, it must be open to considering these particular analyses on their own merits.
5. When considering the appropriate scientifically justifiable value the Committee should not have in mind its likely effect on cost effectiveness or on the guidance. Having selected the RR value the committee feel most confident with based on the information and evidence, it should only then explore what the consequences of that value may be for the subsequent assessment of cost effectiveness and development of recommendations. The Committee must conclude this exercise with a fresh decision on the recommended use of Strontium Ranelate. For this the Committee needs to use the existing economic model for TA160/1, as this has already been the subject of consultation with all interested parties. No parameters other than the RR for hip fracture for strontium ranelate should be adjusted, as only this is under re-consideration. This fresh decision may be to adopt new recommendations, or it may be to re-adopt the current recommendations, but either way a new decision must be taken. As part of the process of writing up the decision as guidance, the committee's reasons will be recorded in detail in the considerations section of the guidance document.

6. In directing that NICE reconsider this issue, the court does not have any expectation as to what the committee's decision will be. In the court's mind there is no presumption either for or against making a change. So long as the committee properly consider the issue, it is perfectly entitled to decide that the guidance should remain as it was, or be changed in whole or in part (as it relates to Strontium Ranelate). The committee do not need to be seen to change their mind to have reconsidered the issue, but it does need to demonstrate to have turned their mind to the new issues raised.
7. I would not suggest that the Committee read the Court of Appeal judgement. It may be it would find the views apparently expressed on scientific matters in that judgement unexpected and/or at variance with their own expert perspective. My advice is that it will not be conducive to an open minded reconsideration to risk some members of the Committee being provoked by disagreement with the Court of Appeal on matters that they might well feel are outside that Court's expertise. The issue is not whether the Committee agrees with the Court or not. The Court has ruled and that is final. The reasons for its ruling are, for present purposes, irrelevant. The issue is compliance with the ruling. This means that having been instructed to look again at the subgroups and the RR value, the Committee must do so fairly and properly.
8. The Committee must not take any negative account of the fact that Servier and others have challenged NICE or have engaged in litigation on this issue, or of any press coverage there may have been. Nor should it take any account of the fact that NICE has already published guidance with a particular set of recommendations. Instead, it must take a fresh decision, as if it had itself decided that it should look at this matter another time.