The Alliance for Better Bone Health

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Dear Carole

Appraisal Consultation Documents: primary and secondary prevention of osteoporotic fragility fractures in postmenopausal women

Thank you for the above ACDs. The comments from the Alliance for Better Bone Health on behalf of sanofi-aventis and Procter & Gamble (The Alliance) are below.

The committee has delivered a set of recommendations for alendronate and risedronate that suggest distinctions between these products which are not supported by the clinical evidence.

The Alliance proposes that the Committee should recommend the use of oral bisphosphonates as the first line treatment option with the decision on which bisphosphonate to prescribe taking account of both cost of acquisition and suitability for the patient. A recommendation made in this way is consistent with previous recommendations for product classes, and will ultimately result in a similar outcome that NICE seeks to achieve.

Furthermore, the advantage of this approach is that it does not require overly complex recommendations that will be difficult to implement and it avoids potentially discriminatory rules that deny women who cannot take alendronate, the opportunity to take an equivalent alternative treatment.

- For example, some women who cannot tolerate alendronate will not be able to receive risedronate until their T-score worsens under the more restrictive recommendation of Paragraphs 1.2 in both ACDs. These patients will be denied an equally effective treatment on the basis of cost, despite having been initiated on alendronate.

- For those patients not able to comply with the administration instructions, or who are contraindicated to alendronate, the guidance further fails them since the committee already recognised in section 4.3.23 (primary prevention) and 4.3.22 (secondary prevention) that it would unfairly disadvantage patients if first-line treatment were denied until reaching a higher age or lower T-score, but then fails to fully rectify this imbalance by only providing access in line with the more restrictive T-scores for those unable to tolerate alendronate.

P&G Pharmaceuticals

sanofi aventis
Because health matters

- In addition to the potentially discriminatory rule-set outlined above, the guidance regarding women aged 75 and over should be clarified with respect to the need for DXA scanning before treatment. It is recommended in Section 1.1 that women aged over 75 can be initiated on alendronate without the need for a DXA if clinically appropriate. However if any of these women are intolerant to alendronate they need to wait for a scan before initiating risedronate. This is incorrect as in section 4.2.25 risedronate is demonstrated as being cost effective at all osteoporotic BMD levels. The Alliance recommends that the committee remove the need for DXA for risedronate if a patient has not received a DXA before initiation with alendronate. We recommend that no further BMD measurement is required in the over 75 years population.

Paragraph 4.3.33 (primary) and 4.3.34 (secondary) makes reference to the Committee's consideration of a concern raised by Servier Laboratories on the concomitant use of bisphosphonates with acid-suppressing medications. Elsewhere in these ACD documents (paragraph 4.1.35 Primary prevention) and in the Evaluation report the data used to assess this question is described as tentative, being of generally poor quality, open to confounding or not able to distinguish cause and effect and with several observations indicating usage is associated with both increased and decreased risk of fracture depending on the fracture site. In addition we would like to bring to the Committees attention that there is evidence for risedronate that PPI usage does not effect fracture risk.

In light of the evaluation of this evidence, we believe that the part of Paragraph 4.3.33 (primary) and 4.3.34 (secondary) in which the Committee recommends caution before co-prescription of acid-suppressing medications and bisphosphophonates requires deletion, or at least, revision as it gives greater weight to this evidence than it currently warrants.

The Alliance trusts that the Committee will appreciate the concerns expressed in this response. We hope that the Committee will be minded to make the necessary revisions in order to provide clear, pragmatic and implementable guidance for the NHS.

Yours sincerely,