Dear Kate,

Thank you for the opportunity to provide comment on the ACD for the above mentioned appraisal.

Overall recommendation by NICE:
1) for primary prevention of OP fractures: denosumab is recommended as a treatment option for women who cannot tolerate bisphosphonates and meet criteria of T-score, age and risk factors;

2) for secondary prevention: denosumab is recommended as a treatment option for women who cannot tolerate bisphosphonates.

In section 3.34, the ERG (Evidence Review Group) mentioned that "Based on the assumptions in the manufacturer's base-case analysis, a comparison of denosumab with oral bisphosphonates carried out by the ERG suggested that denosumab may be a cost effective option for women who cannot take alendronate (ICERs of £21,189 per QALY gained compared with risedronate and £8680 per QALY gained compared with oral ibandronate in the lower-risk cohort - that is, 70-year-old women with no prior fragility fracture and a T score of -2.5 SD). Therefore,for women who cannot take oral alendronate, denosumab might be considered cost effective compared with risedronate and/or oral ibandronate"

As we have data to the contrary we would be obliged if the following 3 questions can be addressed:-

- How does the overall recommendation of the STA fit with TAG 160 & 161 in terms of order of treatment i.e. generic alendronate followed by risedronate or etidronate?
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- What was the thinking behind classing bisphosphonates all together as this appears not to acknowledge the different efficacy, tolerability and safety profiles?

- How was the "ICERs of £21,189 per QALY gained compared with risedronate" derived?
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If there is anything else you need from me for these questions to be considered please let me know

Best Wishes,
[redacted]

[redacted]

Warner Chilcott UK Ltd.
[redacted]