Professional organisation statement template

Thank you for agreeing to give us a statement on your organisation's view of the technology and the way it should be used in the NHS.

Healthcare professionals can provide a unique perspective on the technology within the context of current clinical practice which is not typically available from the published literature.

To help you in making your statement, we have provided a template. The questions are there as prompts to guide you. It is not essential that you answer all of them.

Please do not exceed the 8-page limit.

About you

Your name: [redacted]

Name of your organisation

Society and College of Radiographers

Are you (tick all that apply):

Specialist in the treatment of people with the condition for which NICE is considering this technology?

A specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)?

An employee of a healthcare professional organisation that represents clinicians treating the condition for which NICE is considering the technology? If so, what is your position in the organisation where appropriate (e.g. policy officer, trustee, member etc.)?

Other? (Please specify)

✓ Specialist involved in Education of Clinicians in the practice of Bone Densitometry, the reporting of scans and the treatment recommendations made in clinical practice.

What is the expected place of the technology in current practice?

DENOSUMAB, as a 60 mg twice yearly subcutaneous injection will be an added tool in the armoury of options for treatment of osteoporosis in the postmenopausal woman, providing another avenue for those patients for whom the current alternatives are not applicable.
It will be easier to use for those who suffer from upper GI tract symptoms who find that ingestion of a daily or weekly medication is contra indicated.

This is a good example of devolving total care to the primary sector.

The advantages and disadvantages of the technology

Denosumab is a fully human monoclonal antibody administered by subcutaneous injection 60 mgs twice yearly, this is in contrast to teriparatide which is a synthetic version of PTH and needs a daily injection.

Denosumab prevents the interaction of RANKL with RANK, its receptor, on osteoclasts and their precursors, thereby blocking the formation, function and survival of osteoclasts. In contrast, bisphosphonates chemically bind to calcium hydroxyapetite in bone; they decrease bone resorption by blocking the function and survival, but not the formation, of osteoclasts.

Researchers reported a 35% risk reduction with Denosumab compared with placebo (17% vs 49%), with new vertebral fractures in this subset of only 31% for those taking Denosumab versus 71% receiving the placebo.[1]

Denosumab has the same risk reduction of vertebral fracture as IV Zoledronate but it appears to have a greater risk reduction than that reported for oral bisphosphonate preparations. [2, 3]

At least 50% of patients stop bisphosphonate treatment within 1 yr after receiving prescription for an oral agent. Twice yearly subcutaneous injections might improve adherence.

<u>Evidence Base</u>

The evidence base trial Fracture Reduction Evaluation of Denosumab every 6 months (FREEDOM) was an international, randomised, placebo controlled trial which covered 7868 women subjects over 3 yrs, using 6 monthly injections. This mirrors the intended clinical use of Denosumab.

The outcomes of this were primarily new vertebral fractures and secondarily new non vertebral and hip fractures; this again is relevant to the clinical scenario where efficacy is measured in fracture reduction.

A small subset (441) was used to study changes in Bone Mineral Density BMD as against placebo but this is an outcome that can be misleading due to potential for error by confounding external factors.

Potential side effects

There is a suggestion of increased potential risk of poor fracture healing, infections and cancer but no significant difference was demonstrated in the first 3yrs against the placebo group, longer follow up is under way.

References

1 Cummings SR et al Denosumab for the prevention of fractures in postmenopausal women with osteoporosis. N Engl J Med2009;361:756-65
2 Chestnut CH III et al Effects of oral ibandronate administered daily or intermittently on fracture risk in post menopausal osteoporosis. J Bone Miner Res 2004;19:1241-9
3 Cummings SR et al Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the Fracture Intervention Trial JAMA 1998; 280:2077-82

Any additional sources of evidence

None

Implementation issues

NICE guidance would, if it did not support the use of Denosumab, inhibit the quality of care that physicians are able to offer to patients who are intolerant of the first line option for the treatment of osteoporosis and the prevention of future fractures.

Use of Denosumab may have a positive effect on treatment compliance and adherence because of its ease of administration.

There will be little need for extra staff education and training as subcutaneous injection is already in use with parathyroid hormone treatment (Teriparatide), the advantage is that Denosumab is twice yearly not daily