

## Appendix D – Clinical specialist statement template

### Denosumab for the treatment of bone metastases from solid tumours

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:**Dr.David Dodds

**Name of your organisation**  
Healthcare Improvement Scotland

#### Are you (tick all that apply):

- a 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)

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

How is the condition currently treated in the NHS? Is there significant geographical variation in current practice? Are there differences of opinion between professionals as to what current practice should be? What are the current alternatives (if any) to the technology, and what are their respective advantages and disadvantages?

Are there any subgroups of patients with the condition who have a different prognosis from the typical patient? Are there differences in the capacity of different subgroups to benefit from or to be put at risk by the technology?

In what setting should/could the technology be used – for example, primary or secondary care, specialist clinics? Would there be any requirements for additional professional input (for example, community care, specialist nursing, other healthcare professionals)?

If the technology is already available, is there variation in how it is being used in the NHS? Is it always used within its licensed indications? If not, under what circumstances does this occur?

Please tell us about any relevant **clinical guidelines** and comment on the appropriateness of the methodology used in developing the guideline and the specific evidence that underpinned the various recommendations.

The management of bones metastases secondary to metastatic prostate cancer involves both local and systemic therapies. Local treatments such as surgery and palliative radiotherapy are given in conjunction with systemic treatments in order to control the overall disease. Denosumab should be considered as a supportive systemic treatment in hormone relapsed metastatic prostate cancer. It should be considered as a supportive therapy as there is no evidence of a disease modifying effect unlike systemic chemotherapy. There would seem no specific indication for treatment off licence. In view of the above Denosumab should be considered for use within appropriate multidisciplinary clinics specialising in hormone relapsed metastatic prostate cancer. These clinics should be led by consultant clinical oncologists as they are the only group trained in all the therapeutic modalities indicated. This would be in preference to Urology led clinics. Once the decision to treat with Denosumab has been made there would seem no reason why this could not be delivered in a community setting. Patients not suitable for other systemic therapies or those who relapse despite systemic treatment might be most likely to benefit from Denosumab. There is a major question as to the exact placement of the drug within the current therapeutic armamentarium and specifically the timing of introduction with relation to chemotherapy in hormone relapsed disease.

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### **The advantages and disadvantages of the technology**

NICE is particularly interested in your views on how the technology, when it becomes available, will compare with current alternatives used in the UK. Will the technology be easier or more difficult to use, and are there any practical implications (for example, concomitant treatments, other additional clinical requirements, patient acceptability/ease of use or the need for additional tests) surrounding its future use?

If appropriate, please give your view on the nature of any rules, informal or formal, for starting and stopping the use of the technology; this might include any requirements for additional testing to identify appropriate subgroups for treatment or to assess response and the potential for discontinuation.

If you are familiar with the evidence base for the technology, please comment on whether the use of the technology under clinical trial conditions reflects that observed in clinical practice. Do the circumstances in which the trials were conducted reflect current UK practice, and if not, how could the results be extrapolated to a UK setting? What, in your view, are the most important outcomes, and were they measured in the trials? If surrogate measures of outcome were used, do they adequately predict long-term outcomes?

What is the relative significance of any side effects or adverse reactions? In what ways do these affect the management of the condition and the patient's quality of life? Are there any adverse effects that were not apparent in clinical trials but have come to light subsequently during routine clinical practice?

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The major benefit of Denosumab is the method of delivery ie.subcutaneous injection.The main competitor,Zoledronic Acid,involves a 15min intravenous infusion.Another advantage is the lack of necessity for renal function monitoring compared to Zoledronic Acid.The published evidence would seem suggest additional benefits for Denosumab as regards the reduction of skeletal related events compared with Zoledronic Acid.The conditions indicated in the clinical trial setting entirely in keeping with routine UK clinical practice.The side effect profile noted in the trial would be entirely in keeping with that predicted from its biological action and do not significantly influence disease management.

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### **Any additional sources of evidence**

Can you provide information about any relevant evidence that might not be found by a technology-focused systematic review of the available trial evidence? This could be information on recent and informal unpublished evidence, or information from registries and other nationally coordinated clinical audits. Any such information must include sufficient detail to allow a judgement to be made as to the quality of the evidence and to allow potential sources of bias to be determined.

### **Implementation issues**

The NHS is required by the Department of Health and the Welsh Assembly Government to provide funding and resources for medicines and treatments that have been recommended by NICE technology appraisal guidance. This provision has to be made within 3 months from the date of publication of the guidance.

If the technology is unlikely to be available in sufficient quantity, or the staff and facilities to fulfil the general nature of the guidance cannot be put in place within 3 months, NICE may advise the Department of Health and the Welsh Assembly Government to vary this direction.

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Please note that NICE cannot suggest such a variation on the basis of budgetary constraints alone.

How would possible NICE guidance on this technology affect the delivery of care for patients with this condition? Would NHS staff need extra education and training? Would any additional resources be required (for example, facilities or equipment)?

Delivery of this technology will not entail any additional facilities or training. Resources and capacity could be increased by comparison with other systemic therapies by community prescription and delivery and there will be less laboratory monitoring required.