

## 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 Amit Bahl**

**Name of your organisation : British Uro-oncology Group**

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

- a specialist in the treatment of people with the condition for which NICE is considering this technology? YES
- a specialist in the clinical evidence base that is to support the technology (e.g. involved in clinical trials for the technology)? YES
- 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.)? Executive Committee Member of British Uro-oncology Group
- other? (please specify)

## Appendix D – Clinical specialist statement template

### 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.

#### BREAST CANCER:

The use of bisphosphonates is recommended in NICE guidelines in metastatic breast cancer. However, there is no uniformity in the type of bisphosphonate used. Different cancer networks in the country are implementing this with variation in choice of bisphosphonates.

#### PROSTATE CANCER

The use of bisphosphonate is not routinely recommended in the NICE guidance. There is significant variation in the practice across the UK. This variation is on whether bisphosphonates are used or not and also on the choice of bisphosphonates.

### **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?

#### **EVIDENCE BASE:**

Denosumab has shown superiority to Zoledronic Acid in both metastatic breast cancer and prostate cancer in time to first SRE.

This is important for UK practice and is a significant management option for this group of patients.

#### **DENOSUMAB:**

RANK ligand inhibitor, which can be administered subcutaneously (as opposed to intravenous infusion of pamidronate and Zoledronic acid). Denosumab does not require renal function monitoring and has relatively fewer acute phase reactions as compared to Zoledronic acid.

## Appendix D – Clinical specialist statement template

### **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.

## Appendix D – Clinical specialist statement template

Results from STARS study which prospectively evaluated Health Resource Utilisation for managing skeletal related events. His data was collected from several European countries including UK.

### **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.

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)?

## Appendix D – Clinical specialist statement template

Implementation of Denosumab should not require any additional training or facilities. It is likely to free-up day unit time as the injection can be given subcutaneously.