NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

HEALTH TECHNOLOGY APPRAISAL PROGRAMME

Equality impact assessment – Guidance development

MTA Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours

The impact on equality has been assessed during this appraisal according to the principles of the NICE equality scheme.

Consultation

1.	Have the potential equality issues identified during the scoping process been addressed by the Committee, and, if so, how?
Yes	The Committee discussed potential equalities issues, noting those raised about gender and transgender in relation to breast and prostate cancer. It gave particular consideration to avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity. The Committee did not consider that the wording of the recommendations affected access to treatment by these groups.

2.	Have any other potential equality issues been raised in the submissions, expert statements or academic report, and, if so, how has the Committee addressed these?
No	

3.	Have any other potential equality issues been identified by the Committee, and, if so, how has the Committee addressed these?
No	

4.	Do the preliminary recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No	

5.	Is there potential for the preliminary recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No	

6.	Are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?
No	

7.	Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?
Yes: 4.3.24 The Committee discussed potential equalities issues, noting those raised about gender and transgender in relation to breast and prostate cancer. It gave particular consideration to avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity. The Committee did not consider that the wording of the recommendations affected access to treatment by these groups.	

Approved by Associate Director (name): Frances Sutcliffe

Date: 21/03/2012

Second consultation

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed these?

The Committee considered the comment received at consultation in which it was suggested that the differences in the recommendations for prostate and breast cancer might be attributed to discrimination. The recommendations therefore mean that people with prostate cancer, that is, men and transgender women, cannot access treatment with denosumab for preventing skeletal-related events, whilst women with breast cancer can. The Committee agreed that the reason denosumab was not recommended for preventing skeletal-related events in prostate cancer was not because prostate cancer occurs in men and transgender women, nor was it related in any way to the different gender profile of the patients. Instead, the Committee considered that the evidence indicates that current clinical management and disease course varies between breast, prostate and other solid tumours. The Committee noted that separate clinical trials have been carried out in these different cancer types, and that the trials showed different efficacy profiles for denosumab between the cancer types. The ICER for using denosumab in prostate cancer compared with best supportive care is high (more than £70,000 per QALY gained) and therefore beyond the threshold at which NICE would normally recommend a treatment. Bearing in mind NICE's duties and functions and the requirement for the Committee's recommendations to be based on the clinical and cost effectiveness of treatments, the Committee considered that the recommendation for prostate cancer was a means of achieving a legitimate aim. Given the high level of the ICER for using denosumab in prostate cancer, the Committee was satisfied that the recommendation is a proportionate means of achieving that aim and that its recommendations do not lead to unlawful discrimination. Therefore it concluded that it did not need to add to or change its recommendations in light of the consultation comments.

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

In the first consultation document denosumab was recommended for a subgroup of patients with painful bone metastasis from castrate resistant prostate cancer. In the second ACD denosumab is no longer recommended for patients with solid tumours from prostate cancer. The recommendation for denosumab changed based on comments received from stakeholders in the first ACD consultation. The comments received indicated that the appropriate comparator for this group of patients was best supportive care rather than bisphosphonates, and that the cost effectiveness of denosumab should be considered compared to best supportive care rather than bisphosphonates.

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
No	

5.	Have the Committee's considerations of equality issues been described in the appraisal consultation document, and, if so, where?
Yes, 4.3.26	

Approved by Associate Director (name): Frances Sutcliffe

Date: 31/05/2012

Final appraisal determination

1.	Have any additional potential equality issues been raised during the consultation, and, if so, how has the Committee addressed these?
No.	

2.	If the recommendations have changed after consultation, are there any recommendations that make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?
No	

3.	If the recommendations have changed after consultation, is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?
No	

4.	If the recommendations have changed after consultation, are there any recommendations or explanations that the Committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 2 and 3, or otherwise fulfil NICE's obligations to promote equality?
No	

5.	Have the Committee's considerations of equality issues been described in the final appraisal determination, and, if so, where?

Yes, 4.3.27

Approved by Centre or Programme Director: Meindert Boysen

Date: 30 October 2012