



24 April 2012

Dear [REDACTED],

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

Breakthrough Breast Cancer is dedicated to improving and saving lives through breast cancer prevention, early diagnosis, more targeted treatments and better services for everyone affected by breast cancer.

This submission reflects the views of Breakthrough, based on our experience of working with people with personal experience of, or who are concerned about, breast cancer. To inform our submission to this consultation, we have consulted with members of our Campaigns & Advocacy Network (Breakthrough CAN) for their views on a range of breast cancer issues. Breakthrough CAN brings together over 1,800 individuals, regional groups and national organisations to take action locally on our national campaigns to secure important improvements to breast cancer research, treatments and services. Through supporting and training members, Breakthrough CAN aims to increase the influence of breast cancer advocates on decisions regarding breast cancer issues.

Breakthrough welcomes the opportunity to comment on the appraisal consultation document regarding the use of denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours.

Denosumab is used to prevent the occurrence of skeletal related events (SREs) in patients whose cancer has spread to their bones. This spread (or metastasis) can come from breast cancer and other solid tumours and therefore denosumab will be an important treatment for some breast cancer patients.

Therefore we are very pleased that NICE have provisionally recommended this drug as an option for preventing SREs in patients with bone metastases from breast cancer. Not only

does denosumab show clinical effectiveness over the traditional standard therapy but it will also serve as a treatment option for those patients for whom zoledronic acid is not suitable.

SREs can occur as a result of bone metastases and are defined as pathological bone fractures, compression of the spinal cord or the need for palliative radiotherapy or major orthopaedic surgery for the treatment of bone metastasis. SREs can significantly impact on the quality of life of a patient causing disability, pain and hospitalisation so any treatments that can reduce their occurrence are welcome. If treatments can provide health benefits they may allow patients to continue with normal daily activities such as caring for their families or simply enjoying spending quality time with their loved ones, things that are very important to metastatic breast cancer patients.

We are satisfied NICE have taken the relevant evidence into account in this appraisal. The current treatment for bone metastases and the prevention of SREs in advanced breast cancer patients is bisphosphonates such as zoledronic acid. Studies looking at the effectiveness of denosumab compared to zoledronic acid have found the former to be superior in delaying the time to first and multiple SREs. Denosumab has also been found to be better than zoledronic acid at delaying the worsening of pain of advanced cancer patients with bone metastases.

We are unaware of any aspect of NICE's recommendation that needs particular consideration regarding any unlawful discrimination.

We note that this recommendation is dependant on the manufacturer providing denosumab at a discounted rate as part of a patient access scheme already agreed with the Department of Health. We hope there are no changes to this agreement as we would be very disappointed if breast cancer patients could not gain access to this drug.

If you require any further information please contact [REDACTED], [REDACTED] or [REDACTED].

Yours sincerely,

[REDACTED]

