

NICE TA 265 – Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours

<p>1</p>	<p>Summary of NICE TA 265</p> <p>NICE recommends denosumab as an option for preventing skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from breast cancer and from solid tumours other than prostate if:</p> <ul style="list-style-type: none"> • bisphosphonates would otherwise be prescribed and • the manufacturer provides denosumab with the discount agreed in the patient access scheme. <p>Denosumab is not recommended for preventing skeletal-related events in adults with bone metastases from prostate cancer.</p>
<p>2</p>	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>The NICE costing template accompanying TA 265 indicates that 1282 patients per year (1177 patients with breast cancer, 105 patients with solid tumours other than prostate) would be expected to take up treatment with denosumab for this indication.</p> <p>As part of the engagement process with local clinicians when exploring the delivery of the new NICE recommended Technology Appraisals, the HSCB/PHA has considered submissions from the Northern Ireland Cancer Network (NICaN), Drugs and Therapeutic (D&T) Committee.</p> <p>The volume of patients projected to benefit by NICaN from this regime is considerably lower than that projected in the NICE costing template. The NICE costing template indicates that the prevalence of breast cancer in Northern Ireland is 16,012 whereas <i>data from the 'NI Cancer Registry'</i> indicates that in Northern Ireland the 10 year prevalence of breast cancer is 8,350 (2011). Application of the 10 year prevalence suggests that 606 patients with breast cancer would be eligible for treatment with denosumab for this indication. These calculations are based on NICE assumptions, however have been adjusted to take account of actual prevalence rates of Breast cancer in NI.</p> <p>In addition it is the view of the NICaN D&T Committee that an average of 10 patients (between 6 and 14 patients per year) with solid tumours other than prostate would be eligible for treatment with denosumab for this indication.</p> <p>NICE assumptions suggest that 45% of patients currently receiving bisphosphonates may instead be treated with denosumab. The HSCB will, at this juncture, apply the assumptions as described by NICE which will ensure that the necessary resources are identified.</p>

	<p>In summary, the HSCB will opt to support the introduction of TA 265 by applying the NICE assumptions, adjusted to take account of actual 10 year prevalence rates for Northern Ireland.</p> <p>Due to the variance in the NICE costing template and the NICaN D&T committee with relation to actual prevalence rates, trusts will be asked to apply for funding for Denosumab on a cost per case basis for a 12 month period in order to monitor usage and thus inform the true position going forward.</p> <p>The final position will be closely monitored via a formal review of the cost per case applications by the specialist services commissioning team on a quarterly basis.</p> <p>For solid tumour other the prostate NICaN has indicated that an average of 10 patients per year will be eligible for this treatment and that there will be no increase year on year due to the survival rates for this patient group.</p> <p>The HSCB intend to review the recommendations with the NICaN Chemotherapy review and this may have implications for shared care in chemotherapy regimes.</p>
3	<p>Costs</p> <p>In year costs will be met through a cost per case arrangement and monitored pending finalisation of the recurrent business case.</p>
3.1	<p>Cost per patient per annum</p> <p>Denosumab is given by subcutaneous injection in a dose of 120mg every 4 weeks. Each 120mg dose costs £309.86 [BNF65 March 2013].</p> <p>Hence cost per patient per annum (13 doses) = £4028.18</p>
3.2	<p>In year cost per patient per annum (for new and prevalent cases)</p> <p>The estimated cost in year assuming increase to 606 and 10 patients respectively by March 2014 will be approximately £500k.</p> <p>Funding will be provided to Trusts on a cost per case basis initially to establish and monitor actual uptake.</p>
3.3	<p>Cost savings and how these will be secured</p> <p>The costing template estimates a saving in administration costs to administer Denosumab. HSCB will work with Trusts to agree any savings which can realised or offset against other new regimes.</p>
3.4	<p>Recurrent overall cost</p> <p>The estimated additional drug cost (before PAS) for introducing TA 265 Denosumab for bone metastases from breast cancer and other cancers other than prostate is £1,089m</p> <p>The manufacturer has agreed that denosumab will be available to the NHS with a</p>

	<p>patient access scheme in which a discount is applied to all invoices. The level of the discount is commercial in confidence. Trusts in Northern Ireland will be expected to avail of this scheme.</p>
4	<p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients. Patients are already commencing on treatment through a cost per case arrangement.</p>
5	<p>Commissioning arrangements</p> <p>This treatment will be delivered in both the Cancer Centre and Cancer Units.</p> <p>For monitoring purposes, commissioning arrangements for this regime will be via the Cost Per Case arrangement for a 12 month period and will be consolidated thereafter in line with the cost per case audit data.</p>
6	<p>Monitoring arrangements</p> <p>HSCB currently reviews quarterly monitoring information in relation to the usage of all recurrently funded specialist cancer drugs across both the Cancer Centre and other Units.</p> <p>The monitoring pro forma will be adapted to capture information in respect of this regime and this group of patients. This monitoring report is submitted to the Specialist Services Commissioning Team for formal review and comment by the Team.</p> <p>The HSCB IFR process will generate quarterly reports on the number of Cost Per Case applications which will be reviewed formally by the Specialist Services Commissioning Team on a quarterly basis.</p> <p>SSCT has a long established relationship with NICaD D&T and will continue regular interface with the committee to discuss the quarterly review of the cost per case applications and identify any necessary action.</p>
7	<p>DHSSPS Legislative/Policy Caveats</p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual patients, in consultation with the patient and/or guardian or carer.</p> <p>This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>