

1	<p>Treatment & Condition (<i>Title</i>)</p> <p>Mifamurtide for treatment of osteosarcoma.</p>
2	<p>Associated appraisal body (<i>NICE/SMC/Other</i>) & Summary of ruling (<i>to include indication, restrictions, other relevant information</i>)</p> <p>NICE Technology Appraisal 235 (TA235) recommends mifamurtide as a possible treatment for some children, adolescents and young adults with osteosarcoma.</p> <p>Children, adolescents and young adults should be able to have mifamurtide if:</p> <ul style="list-style-type: none"> • their tumour is high-grade and non-metastatic; and • they have had an operation to remove the tumour; and • they are also having chemotherapy with multiple drugs.
3	<p>Number of people in Northern Ireland expected to take up service/therapy (<i>including new cases per year</i>)</p> <p>Estimated annual uptake is for 3 patients per year. Given the very small number of patients there may be year to year variation in demand.</p>
4	<p>Patient Access Scheme availability</p> <p>The manufacturer of mifamurtide has agreed a patient access scheme (PAS) with the Department of Health in which mifamurtide for the treatment of osteosarcoma will be available at a reduced cost to the NHS. The nature of this cost reduction is confidential. The Department of Health considered that this patient access scheme does not constitute an excessive administrative burden on the NHS</p>
5	<p>Costs (<i>before PAS if applicable</i>)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The acquisition cost of mifamurtide is £2375 for a 4mg vial (excluding VAT, 'British national formulary' [BNF] edition 67). The manufacturer's submission to NICE states that the cost of a full treatment course of 48 doses of mifamurtide is £114,000 per patient.</p>
5.2	<p>Infrastructure costs per annum</p> <p>Administration Costs: £6,000 x 3 patients = £18,000 Outpatient Costs: = £7,000 Total for 3 patients per annum = £25,000</p> <p>For planning purposes it is estimated that the annual number of patients commencing treatment will remain at 3 per annum. However fluctuations may occur on a year to year basis due to the very small numbers of patients presenting from the overall population.</p>
5.3	<p>Current in year costs</p> <p>Expected in year costs in 2012-13 may be in the region of £175k (before application of any PAS discount) for 3 patients starting in the course of the year. The first year costs</p>

	<p>will depend on the number and timing of diagnoses and the treatment start date.</p> <p>Given the very small numbers expected to present for treatment in Northern Ireland there may be fluctuation of uptake on a year to year basis.</p>
5.4	<p>Recurrent overall costs per annum (<i>including additional costs</i>)</p> <p>Based on treatment of 3 patients per year (before application of any PAS discount):</p> <p>Drug acquisition cost = 3 x £114,000 = £342,000 Administration and outpatient costs = £25,000 Total recurrent overall costs per annum = £367,000</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>None anticipated</p>
6	<p>Expected implementation period</p> <p>Business case has been approved by SSCT. Assuming Departmental approval on the commissioning plan HSCB will proceed to support this regime recurrently for 2012/13.</p> <p>Given the rarity of the condition and the potential benefits of treatment the HSCB would anticipate that in the interim, cases which meet NICE criteria will be supported.</p>
7	<p>Commissioning arrangements</p> <p>HSCB will provide formal approval of the business case and release funds to the Belfast Trust as this is a cancer centre only regime.</p>
8	<p>Monitoring arrangements</p> <p>Following DHSSPSNI approval, the Board will issue a commissioning statement to the service.</p> <p>Normally monitoring arrangements would involve production of an implementation plan within 3 months by the Trust.</p> <p>Given the small number of patients and level of infrastructure required – together with the existing level of oncology/haematology drug budget monitoring, the Board will request assurances in respect of 5 specific issues rather than seeking a full implementation plan:</p> <ul style="list-style-type: none"> - confirmation from Belfast Trust that it has arrangements in place to provide this treatment to adult patients meeting NICE criteria within the appropriate clinical timescale; - confirmation from Belfast Trust that it has arrangements in place to provide this treatment to children and young people cared for in the RBHSC who meet NICE criteria within the appropriate clinical timescale; - confirmation of inclusion of expenditure on the regime in the quarterly monitoring returns which are reviewed by NICA^N Drugs and Therapeutic Committee (which has HSCB/PHA representation) and the Specialist Services Commissioning Team; - confirmation of inclusion of annual report on this regime as part of the normal annual reporting arrangements which are reviewed by NICA^N Drugs and

	<p>Therapeutic Committee (which has HSCB/PHA representation) and the Specialist Services Commissioning Team;</p> <ul style="list-style-type: none">- confirmation that arrangements are in place to fully secure the financial discounts available via the Patient Access Scheme
9	<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. 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>