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| 1 | <p>Treatment & Condition</p> <p>Bortezomib for induction therapy in multiple myeloma before high-dose chemotherapy and autologous stem cell transplantation.</p> |
| 2 | <p>Associated appraisal body & Summary of ruling <i>(to include indication, restrictions, other relevant information)</i></p> <p>NICE Technology Appraisal Guidance 311 (April 2014)</p> <p>Bortezomib is recommended as an option within its marketing authorisation, that is, in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adults with previously untreated multiple myeloma, which are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.</p> |
| 3 | <p>Number of people in Northern Ireland expected to take up service/therapy <i>(including new cases per year)</i></p> <p>NICE have not provided a costing template for this therapy. Advice on the anticipated patient numbers was sought from the service via the NICaN Haematology Clinical Lead. The following key points should be considered when estimating patient numbers.</p> <p>The main objective of first-line therapy in myeloma is to achieve a period of stable disease for as long as possible, thereby prolonging survival and maximising quality of life.</p> <p>In the United Kingdom, the choice of first-line treatment depends on a combination of factors including suitability for intensive treatment, including high-dose chemotherapy with stem cell transplantation, because of their age, other health problems or poor performance status.</p> <p>Currently, patients who are considered stem cell transplant eligible will receive a thalidomide based regimen. This regimen comprises of the oral drugs Cyclophosphamide, Thalidomide and Dexamethasone given every 28 days up to 6 cycles.</p> <p>If the patient obtains a partial response or better they then proceed to high dose chemotherapy and stem cell transplant.</p> <p>Stem cell transplantation is considered the gold standard treatment for multiple myeloma because it is associated with improved progression-free survival, greater depth of response and therefore improved survival. Clinicians use biological age, fitness and co-morbidities rather than numerical age to decide eligibility for stem cell transplantation. Around 20–25% of all people with multiple myeloma would be fit enough for high-dose chemotherapy followed by a stem cell transplant.</p> |

Proposed use in NI

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| Total population Northern Ireland | 1.78 million |
| Number of new cases myeloma per annum | 116 |
| Number for whom high dose therapy appropriate | 35 |

This is based on annual rate of diagnosis, current transplant activity in Northern Ireland and the discussion within the NICE technology appraisal guidance 311 (guidance.nice.org.uk/ta311).

It should be noted that at time of diagnosis a patient may be considered eligible for a stem cell transplant but may experience complications, demonstrate inadequate response or other issues that preclude them from proceeding to stem cell transplant.

4 Patient Access Scheme availability

Not available

5 Costs (before PAS if applicable)**5.1 Drug cost per patient per annum (for new and prevalent cases)**

The cost of bortezomib is £762 per 3.5-mg vial (excluding VAT; British National Formulary [BNF] edition 66). According to the marketing authorisation bortezomib should be given in combination with dexamethasone (4 cycles of 21 days each) or with dexamethasone and thalidomide (4 cycles of 28 days each; 2 additional cycles of 28 days each for patients with at least partial response after the fourth cycle). Four intravenous infusions or subcutaneous injections of bortezomib are administered per cycle, on days 1, 4, 8 and 11 of each cycle.

- The average cost of a course of treatment with bortezomib given with dexamethasone is estimated to be £12,261
- The average cost of a course of treatment with bortezomib given with dexamethasone and thalidomide is estimated to be £24,840.

As the costs for dexamethasone and thalidomide will be within Trust baseline, the following cost is based on the cost of Bortezomib alone.

The total average cost of bortezomib alone for an induction course is between £12,198 and £18,297 per patient.

Therefore based on 35 eligible patients a year in Northern Ireland, the total costs will be as follows:

£12,198 x 35 patients = £426,930 (lowest estimate)

£18,297 x 35 patients = £640,395 (highest estimate)

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| 5.2 | <p>Infrastructure costs per patient per annum</p> <p>Additional nursing and pharmacy infrastructure is likely to be required. This will be quantified via the regional service impact group.</p> |
| 5.3 | <p>Current in year costs</p> <p>Assuming a start date of 1st September 2014 in year patient numbers will be about 17 and costs will range from £107k to £160k.</p> |
| 5.4 | <p>Recurrent overall costs per annum (<i>including additional costs</i>)</p> <p>The recurrent cost will be for 35 patients and be in the range £427k to £640k.</p> |
| 5.5 | <p>Opportunities for cost savings and how these will be secured</p> <p>Implementation of NICE TA311 is unlikely to result in any cost savings.</p> |
| 6 | <p>Expected implementation period</p> <p>There is no impediment to immediate implementation for new patients.</p> |
| 7 | <p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team on a CPC basis for use in the cancer centre and cancer units.</p> <p>Currently patients who are transplant eligible receive cyclophosphamide, thalidomide and dexamethasone in their local cancer units before proceeding to high dose chemotherapy and stem cell transplant in Belfast.</p> <p>There will be no significant change in the delivery of induction therapy in the individual haematology cancer units with stem cell transplantation delivered in Belfast</p> |
| 8 | <p>Monitoring arrangements</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>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 regimen 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> |

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DHSSPS Legislative/Policy Caveats (*NICE guidance only*)

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.