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| 1. | <p>Treatment & Condition</p> <p>Ibrutinib for treating relapsed or refractory mantle cell lymphoma.</p> |
| 2. | <p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA502 (31 January 2018)</p> <p>Ibrutinib is recommended as an option for treating relapsed or refractory mantle cell lymphoma in adults, only if:</p> <ul style="list-style-type: none"> • they have had only 1 previous line of therapy and • the company provides ibrutinib with the discount agreed in the commercial access agreement with NHS England. |
| 3. | <p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>According to the Resource Impact Template that accompanies TA502, it is expected that 8 people in Northern Ireland will be eligible for treatment annually with ibrutinib in line with this NICE appraisal.</p> |
| 4. | <p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The pricing arrangement considered during guidance development was a patient access scheme agreed with the Department of Health that applied to all indications for ibrutinib. The company (Janssen) subsequently agreed a commercial access agreement with NHS England that replaced the patient access scheme on equivalent terms. The financial terms of the agreement are commercial in confidence.</p> |
| 5. | <p>Infrastructure Requirements</p> <p>Any additional infrastructure costs associated with the introduction of new cancer therapies will be dealt with as part of the routine commissioning process.</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 regimen will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis. Thereafter, numbers of patients who received or are receiving treatment will be reviewed and consideration will be given to moving to recurrent funding to support this regimen.</p> |

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| 8. | <p>Monitoring arrangements</p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p> <p>HSCB currently routinely 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> |
| 9. | <p>DoH (NI) 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> |