

1	<p>Treatment & Condition</p> <p>Ruxolitinib for treating disease-related splenomegaly or symptoms in adults with myelofibrosis</p>																																				
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance (TA386) March 2016</p> <p>Ruxolitinib is recommended as an option for treating disease-related splenomegaly or symptoms in adults with primary myelofibrosis (also known as chronic idiopathic myelofibrosis), post polycythaemia vera myelofibrosis or post essential thrombocythaemia myelofibrosis, only: in people with intermediate-2 or high-risk disease, and if the company provides ruxolitinib with the discount agreed in the patient access scheme.</p>																																				
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The number of people in Northern Ireland estimated to have ruxolitinib each year is shown in the table below. These numbers are based on an extrapolation of the data in the Resource Impact Template that accompanies TA386.</p> <table border="1" data-bbox="245 1140 1445 1666"> <thead> <tr> <th colspan="6">Estimated number of people in Northern Ireland requiring ruxolitinib</th> </tr> <tr> <th></th> <th>2016/17</th> <th>2017/18</th> <th>2018/19</th> <th>2019/20</th> <th>2020/21</th> </tr> </thead> <tbody> <tr> <td>Number starting treatment with ruxolitinib each year</td> <td>10</td> <td>8</td> <td>8</td> <td>8</td> <td>8</td> </tr> <tr> <td>Number continuing treatment in year 2</td> <td>0</td> <td>6</td> <td>6</td> <td>6</td> <td>6</td> </tr> <tr> <td>Number continuing treatment in year</td> <td>0</td> <td>0</td> <td>3</td> <td>3</td> <td>3</td> </tr> <tr> <td>Total number treated each year</td> <td>10</td> <td>14</td> <td>17</td> <td>17</td> <td>17</td> </tr> </tbody> </table> <p>This is the cumulative incidence less people who stop treatment, based on average treatment duration of 2.4 years.</p>	Estimated number of people in Northern Ireland requiring ruxolitinib							2016/17	2017/18	2018/19	2019/20	2020/21	Number starting treatment with ruxolitinib each year	10	8	8	8	8	Number continuing treatment in year 2	0	6	6	6	6	Number continuing treatment in year	0	0	3	3	3	Total number treated each year	10	14	17	17	17
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4	<p>Patient Access Scheme availability</p> <p>The Department of Health and the manufacturer of ruxolitinib (Novartis) have agreed that panobinostat will be available to the NHS with a patient access scheme, which makes it available with a discount. The size of the discount is commercial in confidence.</p>																																				

5	Costs <i>(before PAS if applicable)</i>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Ruxolitinib (Jakavi®) is administered orally. The recommended starting dose is 15mg twice daily for patients with a platelet count between 100,000/mm³ and 200,000/mm³, and 20mg twice daily for patients with a platelet count of more than 200,000/mm³. The maximum recommended starting dose for patients with platelet counts between 50,000/mm³ and 100,000/mm³ is 5mg twice daily.</p> <p>The list price of ruxolitinib is £3,360 for a 56 tablet pack of 10mg, 15mg or 20mg tablets, or £1,680 for a 56 tablet pack of 5mg tablets.</p> <p>As the dosage is variable, the drug costs listed in the costing template is based on the weighted average dosage given in the COMFORT-II trial.</p> <p>The cost per patient is estimated at £41,363 (Before PAS)</p>
5.2	<p>Infrastructure costs per patient per annum</p> <p>Any additional infrastructure costs associated with the introduction of new cancer therapies will be taken forward as part of the routine commissioning process.</p>
5.3	<p>Current in year costs</p> <p>Patients are already accessing this treatment in 2016/17 (6 in total for April and May). In line with the estimates set out in section 3, the in year cost for 10 patients will be approximately £200,000 (before PAS).</p>
5.4	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p>According to the Resource Impact Template that accompanies TA386 and local clinical opinion, there will be 17 patients eligible for this treatment by year 3. The estimated recurrent cost will be £700,000 (before PAS).</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>Cost savings are not anticipated.</p>
6	<p>Expected implementation period</p> <p>There is no impediment to implementation for new patients.</p>
7	<p>Commissioning arrangements</p> <p>This drug will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost-per-case (CPC) basis for a period of 12 months. After this time, 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>

8	Monitoring arrangements The HSCB cost per case process will generate quarterly reports on the number of applications. 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. 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.
9	DHSSPS Legislative/Policy Caveats 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.