

1	<p>Treatment & Condition (<i>Title</i>)</p> <p>Abiraterone (Zytiga®) for treating metastatic hormone-relapsed prostate cancer before chemotherapy is indicated.</p>																								
2	<p>Associated appraisal body) & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA387 (April 2016)</p> <p>NICE has recommended abiraterone in combination with prednisone or prednisolone, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer.</p>																								
3	<p>Number of people in Northern Ireland expected to take up service/therapy (<i>including new cases per year</i>)</p> <p>Based on a pro rata calculation from the Resource Impact Report that accompanies TA387, the number of people eligible for treatment in Northern Ireland is given in the table below.</p> <table border="1" data-bbox="247 1030 1437 1467"> <thead> <tr> <th colspan="3">Number of people eligible for treatment in Northern Ireland</th> </tr> <tr> <th>Population</th> <th>Proportion</th> <th>Number of people</th> </tr> </thead> <tbody> <tr> <td>Total NI population</td> <td></td> <td>1,840,498</td> </tr> <tr> <td>People aged 18 years and over</td> <td></td> <td>680,815</td> </tr> <tr> <td>Incidence of prostate cancer</td> <td>0.20%</td> <td>1332</td> </tr> <tr> <td>People with metastatic hormone-relapsed prostate cancer</td> <td>19.50%</td> <td>260</td> </tr> <tr> <td>People with metastatic hormone-relapsed prostate cancer who have no or mild symptoms</td> <td>75%</td> <td>195</td> </tr> <tr> <td>Uptake of treatment with abiraterone 2017/18 onwards</td> <td>31%</td> <td>60</td> </tr> </tbody> </table> <p>At steady state, 195 patients would be eligible for treatment with abiraterone and 60 patients are likely to take up treatment.</p> <p>Local clinical advice suggests that patients are more likely to receive Enzalutamide which has been approved and funded under TA 377.</p>	Number of people eligible for treatment in Northern Ireland			Population	Proportion	Number of people	Total NI population		1,840,498	People aged 18 years and over		680,815	Incidence of prostate cancer	0.20%	1332	People with metastatic hormone-relapsed prostate cancer	19.50%	260	People with metastatic hormone-relapsed prostate cancer who have no or mild symptoms	75%	195	Uptake of treatment with abiraterone 2017/18 onwards	31%	60
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4	<p>Patient Access Scheme availability</p> <p>The manufacturer has agreed a complex patient access scheme (PAS) for abiraterone in which the HSC pays the list price for abiraterone (£2,300 for 120 tablets) for the first 10 months of treatment. After 10 months, the company will rebate the cost of any subsequent tablets prescribed.</p>																								
5	<p>Costs (<i>before PAS if applicable</i>)</p>																								

<p>5.1</p>	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The new list price of abiraterone (Zytiga®) is £2,300 for 120 tablets. The recommended dose of abiraterone is 1,000 mg (four 250 mg tablets) as a single daily dose. Hence the cost of one month's treatment with abiraterone is £2,300.</p> <p>The manufacturer has agreed a complex patient access scheme (PAS) for abiraterone in which the HSC pays the list price for abiraterone for the first 10 months of treatment. After 10 months, the company will rebate the cost of any subsequent tablets prescribed.</p> <p>Hence the annual cost per patient per annum is £23,000. Without discount, and assuming a normal treatment cycle of 15 months the gross cost will be £35,000 approximately.</p>
<p>5.2</p>	<p>Infrastructure costs per patient per annum</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>
<p>5.3</p>	<p>Current in year costs</p> <p>The current in year costs will be covered via the cost per case arrangement.</p>
<p>5.4</p>	<p>Recurrent overall costs per annum (including additional costs)</p> <p>Prior to the application of the PAS discount, the NICE Resource Impact Template estimates the net resource impact will be £653k annually.</p> <p>This assumes 40 patients will be treated with abiraterone (40 switching from enzalutamide at a similar cost) and a further 20 in total will receive abiraterone as a drug treatment rather than supportive therapy.</p> <p>The approximate gross cost of treating another 20 patients with abiraterone is £653k</p> <p>However, local clinical advice suggests that patients are more likely to receive enzalutamide (TA 377) which has already been endorsed and funded. If this assumption is correct, it is anticipated that there will be no additional costs associated with TA 387.</p> <p>Usage of abiraterone will continue to be monitored in the quarterly cancer network drug report and additional funding will be provided if required.</p>
<p>5.5</p>	<p>Opportunities for cost savings and how these will be secured</p> <p>Cost savings are not anticipated.</p>
<p>6</p>	<p>Expected implementation period</p> <p>There is no impediment to immediate 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 regime.</p>
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>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>