

1	<p>Treatment & Condition</p> <p>Enzalutamide 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 [TA377] (January 2016)</p> <p>Enzalutamide is recommended, within its marketing authorisation, as an option for treating metastatic hormone-relapsed prostate cancer:</p> <ul style="list-style-type: none"> • in people who have no or mild symptoms after androgen deprivation therapy has failed, and before chemotherapy is indicated • and only when the company provides it with the discount agreed in the patient access scheme 																								
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The table below shows the number of people who are diagnosed with metastatic hormone-relapsed prostate cancer in Northern Ireland, the estimated number of people from this population who are eligible for treatment with enzalutamide, and estimated uptake.</p> <table border="1" data-bbox="247 1187 1444 1713"> <thead> <tr> <th colspan="3">NICE TA377: Estimated number of people eligible for treatment and forecast uptake 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>Males 18 years and over</td> <td></td> <td>680,815</td> </tr> <tr> <td>Incidence of prostate cancer</td> <td>0.2%</td> <td>1,332</td> </tr> <tr> <td>People with metastatic hormone-relapsed prostate cancer</td> <td>19.5%</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 enzalutamide</td> <td>80%</td> <td>156</td> </tr> </tbody> </table> <p>Therefore it is estimated that approximately 195 people in Northern Ireland are eligible for treatment with enzalutamide each year.</p> <p>It is estimated that approximately 156 people will have treatment with enzalutamide each year once full year effect of 80 % uptake.</p>	NICE TA377: Estimated number of people eligible for treatment and forecast uptake in Northern Ireland			Population	Proportion	Number of people	Total NI population		1,840,498	Males 18 years and over		680,815	Incidence of prostate cancer	0.2%	1,332	People with metastatic hormone-relapsed prostate cancer	19.5%	260	People with metastatic hormone-relapsed prostate cancer who have no or mild symptoms	75%	195	Uptake of treatment with enzalutamide	80%	156
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4	<p>Patient Access Scheme availability</p> <p>The Department of Health and the manufacturer of enzalutamide (Astellas) have agreed that enzalutamide will be available to the NHS with a patient access</p>																								

	<p>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>The list price of enzalutamide (Xtandi®) is £2,735 for a 112 capsule pack. The daily dose of enzalutamide is 160 mg and costs £98 per day. The company has agreed a patient access scheme with the Department of Health. This is a simple discount to the list price of enzalutamide. The level of the discount is commercial in confidence.</p> <p>Thus the annual cost per patient per year <u>before</u> application of the PAS discount is £35,650.</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 dealt with as part of the routine commissioning process.</p>
5.3	<p>Current in year costs</p> <p>The current in year costs will be covered via the cost per case arrangement.</p>
5.4	<p>Recurrent overall costs per annum <i>(including additional costs)</i></p> <p><u>Before</u> application of any PAS discount for enzalutamide or abiraterone: According to the Resource Impact Template that accompanies TA377, the net resource impact in year 1 will be £5.097m and in year 2 and onwards will be £5.561m</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 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</p>

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.