

<p><b>1</b></p>	<p><b>Treatment &amp; Condition</b></p> <p>Olaparib (Lynparza®) for maintenance treatment of relapsed, platinum-sensitive, BRCA mutation-positive ovarian, fallopian tube and peritoneal cancer after response to second-line or subsequent platinum based chemotherapy.</p>																														
<p><b>2</b></p>	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal Guidance TA381 (January 2016)</p> <p>Olaparib is recommended within its marketing authorisation as an option for treating adults with relapsed, platinum sensitive ovarian, fallopian tube or peritoneal cancer who have BRCA1 or BRCA2 mutations and whose disease has responded to platinum based chemotherapy only if:</p> <ul style="list-style-type: none"> <li>• they have had 3 or more courses of platinum based chemotherapy and</li> <li>• the drug cost of olaparib for people who remain on treatment after 15 months will be met by the company.</li> </ul>																														
<p><b>3</b></p>	<p><b>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</b></p> <p>The table below estimates the number of people with ovarian, fallopian tube and peritoneal cancer in Northern Ireland and those who may be eligible for treatment with this technology.</p> <table border="1" data-bbox="247 1220 1437 1870"> <thead> <tr> <th colspan="3" style="text-align: center;"><b>Number of people who have ovarian, fallopian tube and peritoneal cancer in Northern Ireland and the estimated population eligible for treatment with olaparib</b></th> </tr> <tr> <th style="text-align: center;"><b>Population</b></th> <th style="text-align: center;"><b>Proportion</b></th> <th style="text-align: center;"><b>Number of people</b></th> </tr> </thead> <tbody> <tr> <td>Women aged 18 and over</td> <td></td> <td style="text-align: right;">726,522</td> </tr> <tr> <td>Incidence of ovarian cancer</td> <td style="text-align: center;">0.028%</td> <td style="text-align: right;">203</td> </tr> <tr> <td>Percentage of women with high grade serous carcinoma</td> <td style="text-align: center;">70%</td> <td style="text-align: right;">142</td> </tr> <tr> <td>Women who receive and respond to first-line platinum-based chemotherapy</td> <td style="text-align: center;">76%</td> <td style="text-align: right;">108</td> </tr> <tr> <td>Women who receive and respond to second-line platinum-based chemotherapy</td> <td style="text-align: center;">60%</td> <td style="text-align: right;">65</td> </tr> <tr> <td>Women who receive and respond to third-line platinum based chemotherapy</td> <td style="text-align: center;">50%</td> <td style="text-align: right;">33</td> </tr> <tr> <td>Women who have the BRCA1/2 mutation</td> <td style="text-align: center;">35%</td> <td style="text-align: right;">11</td> </tr> <tr> <td>Total number of women eligible for treatment with olaparib (at steady state)</td> <td></td> <td style="text-align: right;">11</td> </tr> </tbody> </table> <p>Hence, it is estimated that around 11 women will be eligible for treatment with olaparib each year at steady state. It is estimated that 75% of these women will take up treatment with olaparib so the actual number of women treated will be <b>8 per year</b> with full uptake anticipated from year one.</p>	<b>Number of people who have ovarian, fallopian tube and peritoneal cancer in Northern Ireland and the estimated population eligible for treatment with olaparib</b>			<b>Population</b>	<b>Proportion</b>	<b>Number of people</b>	Women aged 18 and over		726,522	Incidence of ovarian cancer	0.028%	203	Percentage of women with high grade serous carcinoma	70%	142	Women who receive and respond to first-line platinum-based chemotherapy	76%	108	Women who receive and respond to second-line platinum-based chemotherapy	60%	65	Women who receive and respond to third-line platinum based chemotherapy	50%	33	Women who have the BRCA1/2 mutation	35%	11	Total number of women eligible for treatment with olaparib (at steady state)		11
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4	<p><b>Patient Access Scheme availability</b></p> <p>The company (AstraZeneca) has agreed a patient access scheme with the Department of Health. This scheme involves the NHS paying for a patient's treatment with olaparib up to a certain time, with the company providing olaparib free-of-charge beyond that point and for as long as each individual patient continues to have olaparib.</p> <p>The average treatment period is 18 months with the NHS paying for the first 15 months of each individual treatment. The drug cost of olaparib after 15 months of each individual treatment will be met by the company.</p> <p>The Department of Health considered that this patient access scheme would not constitute an excessive administrative burden on the NHS.</p>
5	<p><b>Costs</b> <i>(before PAS if applicable)</i></p>
5.1	<p><b>Drug cost per patient per annum (for new and prevalent cases)</b></p> <p>Olaparib is administered orally and the recommended dose is 400 mg twice daily.</p> <p>The list price of olaparib is £3,550 per pack, with each pack containing 448 capsules of 50 mg each (equivalent to 28 days' treatment of 16 capsules per day at continuous full dose of treatment). Thus, the list price per patient per annum is £46,277</p> <p>The average treatment period is 18 months with the NHS paying for the first 15 months of each individual treatment. The drug cost of olaparib after 15 months of each individual treatment will be met by the company.</p>
5.2	<p><b>Infrastructure costs per patient per annum</b></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><b>Current in year costs</b></p> <p>The current in year costs will be covered via the cost per case arrangement.</p>
5.4	<p><b>Recurrent overall costs per annum</b> <i>(including additional costs)</i></p> <p>The Resource Impact Template suggests uptake will be phased in over 5 years starting with 6 patients and reaching 8 patients by year 5.</p> <p>However, it is the view of local clinicians that the expected volume of patients receiving Olaparibin line with this TA is in the region of 8 from year 1.</p> <p>Total costs at steady state with 8 patients are:</p>

			<b>£</b>
	Drug costs (at steady state)		<b>462,768</b>
	Outpatient Visits		9,120
	CT scans		4,656
	First administration of drug		952
	<b>Cost of genetic testing to the NHS</b>		
	*BRCAm testing		5,600
	Counselling cost		720
			<b>21,048</b>
			<b>483,816</b>
			<b>£</b>
	Drug costs (at steady state)		<b>462,768</b>
<b>5.5</b>	<b>Opportunities for cost savings and how these will be secured</b>		
	Cost savings are not anticipated		
<b>6</b>	<b>Expected implementation period</b>		
	There is no impediment to implementation for new patients		
<b>7</b>	<b>Commissioning arrangements</b>		
	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.		
<b>8</b>	<b>Monitoring arrangements</b>		
	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.		
<b>9</b>	<b>DHSSPS Legislative/Policy Caveats</b>		

	<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>
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