

1.	<p>Treatment & Condition</p> <p>Darolutamide with androgen deprivation therapy for treating hormone-relapsed non-metastatic prostate cancer</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE technology Appraisal guidance TA660 (25 November 2020)</p> <p>Darolutamide with androgen deprivation therapy (ADT) is recommended, within its marketing authorisation, as an option for treating hormone-relapsed prostate cancer in adults at high risk of developing metastatic disease. It is recommended only if the company provides darolutamide according to the commercial arrangement.</p>
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>According to the Resource Impact Statement that accompanies TA 660, it is estimated that in year one, 16 patients will be treated with darolutamide and androgen deprivation therapy (ADT) increasing to 28 patients in Year two and three.</p>
4.	<p>Patient Access Scheme Availability (Yes/No)</p> <p>The company (Bayer Plc) has a commercial arrangement in place. This makes darolutamide available to the NHS with a discount. The size of the discount is commercial in confidence.</p> <p>HSC Trusts will be required to claim all relevant reimbursements or discounts that form part of the commercial agreement.</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>
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>