

1.	<p>Treatment & Condition</p> <p>Pembrolizumab for untreated PD-L1-positive locally advanced or metastatic urothelial cancer when cisplatin is unsuitable</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance TA522 (June 2018, last updated July 2018)</p> <p>Pembrolizumab (Keytruda[®]) is recommended for use within the Cancer Drugs Fund as an option for untreated locally advanced or metastatic urothelial carcinoma in adults when cisplatin-containing chemotherapy is unsuitable, only if:</p> <ul style="list-style-type: none"> • their tumours express PD-L1 with a combined positive score of 10 or more • pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if the disease progresses and • the conditions of the managed access agreement for pembrolizumab are followed.
3.	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>According to the NICE Resource Impact Statement that accompanies TA522, the managed access agreement allows for up to 635 people in England with untreated locally advanced or metastatic urothelial cancer for whom cisplatin is unsuitable, to be treated each year with pembrolizumab. Extrapolated to the Northern Ireland population, this equates to 22 people per year in Northern Ireland.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(<u>Yes</u>/No)</p> <p>The company (Merck Sharp & Dohme) has a managed access arrangement. This makes pembrolizumab 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 managed access arrangement.</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 on a cost-per-case (CPC) basis for as long as NICE indicates that funding via the Cancer Drugs Fund is appropriate.</p>
<p>8.</p>	<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 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> <p>Numbers of patients who received or are receiving treatment will be monitored by the HSC Board and reported to the Department of Health.</p>
<p>9.</p>	<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> <p>The <i>Rural Needs Act (NI) 2016</i> has been considered and this guidance, which is purely of a technical nature, is not regarded as falling within the scope of the Act.</p>