

1.	<p><b>Treatment &amp; Condition</b></p> <p>Eluxadoline for treating irritable bowel syndrome with diarrhoea</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA455 (August 2017)</p> <p>Eluxadoline is recommended as an option for treating irritable bowel syndrome with diarrhoea in adults, only if:</p> <ul style="list-style-type: none"> <li>• the condition has not responded to other pharmacological treatments (for example, ant motility agents, antispasmodics, tricyclic antidepressants) or</li> <li>• pharmacological treatments are contraindicated or not tolerated, and</li> <li>• it is started in secondary care.</li> </ul> <p>Treatment with eluxadoline should be stopped at 4 weeks if there is inadequate relief of the symptoms of irritable bowel syndrome with diarrhoea.</p> <p>These recommendations are not intended to affect treatment with eluxadoline that was started before this guidance was published. Adults having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.</p>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>Using the NICE resource impact template that accompanies NICE TA 471 it is estimated that of the 1,417,588 adults in Northern Ireland:</p> <ul style="list-style-type: none"> <li>• 240,990 have irritable bowel syndrome (IBS)</li> <li>• 79,527 have IBS with diarrhoea (IBS-D)</li> <li>• 7,555 will be receiving treatment</li> <li>• 2,909 will not have responded to other pharmacological treatment or pharmacological treatments are contraindicated or not tolerated.</li> <li>• Of these             <ul style="list-style-type: none"> <li>➢ 2473 will be on best supportive care</li> <li>➢ 273 will commence and respond adequately to eluxadoline and will not stop treatment</li> <li>➢ 163 will commence eluxadoline but stop at 4 weeks because of inadequate relief of symptoms and switch back to best supportive care.</li> </ul> </li> </ul> <p><b>In summary, 163 people are expected to take up eluxadoline for 4 weeks and a further 273 people will be expected to take up eluxadoline and not stop.</b></p> <p>The NICE estimates for proportions have been used in absence of any available evidence of variance from these figures for Northern Ireland.</p>

4.	<p><b>Patient Access Scheme Availability</b></p> <p>(Yes/<u>No</u>)</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>Eluxadoline is given orally as follows: The recommended dose is 200 mg daily (one 100 mg tablet, twice daily). For patients who are unable to tolerate the 200 mg daily dose (one 100 mg tablet, twice daily), the dose can be lowered to 150 mg daily (one 75 mg tablet twice daily).</p> <p>The list price is £88.20 for 75mg or 100mg per 56-tablet pack (28 days treatment). The cost per patient per year = £88.20 x 13 = £1,146.60 The cost per patient per 4 week treatment = £88.20</p>
5.2	<p><b>Total Drug Costs Per Annum</b></p> <p>273 patients continue to take eluxadoline 163 patients only take eluxadoline for 4 weeks</p> <p>273 x £1,146.60 = £313,021.80 163 x £88.20 = £14,376.60 Total costs = £327,398.40</p> <p>The NICE Resource Impact Template estimates that use of this drug will increase gradually over a five year period, with costs increasing from £66k in year 1 to the total of £327k in year 5.</p>
5.3	<p><b>Infrastructure costs Per annum</b></p> <p>It is expected that patients who have IBS-D which has not responded to other pharmacological treatments are already likely to be referred for further secondary care investigation and/or advice. Although the drug must be commenced by a secondary care clinician, it is given orally and it does not require ongoing secondary care review or monitoring.</p> <p>The introduction of NICE TA471 is therefore not expected to place a significant additional demand on current infrastructure. The HSC Board will however work with Trusts to identify any changes to demand resulting from this new treatment.</p>
6.	<p><b>Expected implementation period</b></p> <p>There is no impediment to implementation of this guidance.</p>
7.	<p><b>Commissioning arrangements</b></p> <p>The HSCB will commission this treatment to complement the current and future Gastroenterology service provision across the HSC</p>

<b>8.</b>	<b>Monitoring arrangements</b>  The HSCB will incorporate information on this regimen into the existing monthly monitoring arrangements.
<b>9.</b>	<b>DoH (NI) Legislative/Policy Caveats</b>  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.