

1.	<p><b>Treatment &amp; Condition</b></p> <p>Lanadelumab for preventing recurrent attacks of hereditary angioedema</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal guidance TA606, October 2019</p> <p>Lanadelumab (Takhzyro<sup>®</sup>) is recommended as an option for preventing recurrent attacks of hereditary angioedema (HAE) in people aged 12 and older, only if:</p> <ul style="list-style-type: none"> <li>• they are eligible for preventive C1-esterase inhibitor (C1-INH) treatment in line with NHS England's commissioning policy, that is, they are having 2 or more clinically significant attacks (as defined in the policy) per week over 8 weeks despite oral preventive therapy, or oral therapy is contraindicated or not tolerated</li> <li>• the lowest dosing frequency of lanadelumab is used in line with the summary of product characteristics, that is, when the condition is in a stable, attack-free phase and</li> <li>• the company provides lanadelumab according to the commercial arrangement.</li> </ul>
3.	<p><b>Number of people in Northern Ireland expected to take up service/therapy</b></p> <p>Implementation of this guidance offers an additional treatment option for treating hereditary angioedema.</p> <p>The NICE resource impact statement indicates that the guidance is not expected to have a significant impact on resources. This is because the technology is a further treatment option and the eligible population is small.</p>
4.	<p><b>Patient Access Scheme Availability</b></p> <p>(Yes/No)</p> <p>The company (Shire) has a commercial arrangement. This makes lanadelumab available to the NHS with a discount. The size of the discount is commercial in confidence.</p>
5.	<p><b>Infrastructure Requirements</b></p> <p>Any additional infrastructure costs associated will be dealt with as part of the routine commissioning process.</p>
6.	<p><b>Expected implementation period</b></p> <p>There is no impediment to immediate implementation for new patients.</p>
7.	<p><b>Commissioning arrangements</b></p> <p>This regimen will be formally commissioned by the HSCB/PHA via the Specialist</p>

	<p>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>
<b>8.</b>	<p><b>Monitoring arrangements</b></p> <p>The HSCB cost per case process will generate quarterly reports on the number of applications.</p>
<b>9.</b>	<p><b>DoH (NI) Legislative/Policy Caveats</b></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 Rural Needs Act NI 2016 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>