

1.	<p>Treatment & Condition</p> <p>Ixekizumab for treating axial spondyloarthritis</p>
2.	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology appraisal guidance TA718 (July 2021)</p> <p>2.1 Ixekizumab is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy, or active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs), in adults. It is recommended only if:</p> <ul style="list-style-type: none"> • tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough, and • the company provides ixekizumab according to the <u>commercial arrangement</u>. <p>2.2 Assess response to ixekizumab after 16 to 20 weeks of treatment. Continue treatment only if there is clear evidence of response, defined as:</p> <ul style="list-style-type: none"> • a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and • a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more. <p>2.3 Take into account any communication difficulties, or physical, psychological, sensory or learning disabilities that could affect responses to the BASDAI and spinal pain VAS questionnaires, and make any appropriate adjustments.</p> <p>2.4 These recommendations are not intended to affect treatment with ixekizumab that was started in the NHS before this guidance was published. People 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>Number of people in Northern Ireland expected to take up service/therapy</p> <p>Implementation of this guidance offers an additional treatment option for treating axial spondyloarthritis.</p> <p>The NICE resource impact statement indicates that the guidance is not expected to have an impact on resources. This is because the technology is a further treatment option and is available at a similar price to the current treatment options.</p>
4.	<p>Patient Access Scheme Availability</p> <p>(Yes/No)</p> <p>The company (Eli Lilly) has a commercial arrangement. This makes ixekizumab</p>

	available to the NHS with a discount. The size of the discount is commercial in confidence.
5.	<p>Infrastructure Requirements</p> <p>It is anticipated that infrastructure requirements will be minimal.</p> <p>Infrastructure requirements for the delivery of all biologics are reviewed annually as part of the routine commissioning arrangements for supporting growth in the provision of these therapies.</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 drug will be formally commissioned by HSCB/PHA via the Specialist Services Commissioning Team.</p>
8.	<p>Monitoring arrangements</p> <p>The HSC Board has robust arrangements in place for the quarterly monitoring of all biologic therapies (activity/cost and waiting times) and this regime will be included within the routinely provided return.</p> <p>All monitoring returns for biologics are reviewed by the specialist services commissioning team quarterly.</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> <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>