

1.	<p><b>Treatment &amp; Condition</b></p> <p>Golimumab for severe non radiographic axial spondyloarthritis.</p>
2.	<p><b>Associated appraisal body &amp; Summary of ruling</b></p> <p>NICE Technology Appraisal Guidance 497 (January 2018)</p> <p>Golimumab is recommended, as an option for treating severe non-radiographic axial spondyloarthritis in adults whose disease has responded inadequately to, or who cannot tolerate, nonsteroidal anti-inflammatory drugs.</p> <p>If patients and their clinicians consider golimumab to be one of a range of suitable treatments, including adalimumab, etanercept and certolizumab pegol, the least expensive (taking into account administration costs and patient access schemes) should be chosen.</p> <p>Assess the response to golimumab 12 weeks after the start of treatment. Continue treatment only if there is clear evidence of response, defined as:</p> <ul style="list-style-type: none"> <li>• 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</li> <li>• a reduction in the spinal pain visual analogue scale (VAS) score by 2 cm or more.</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 severe non-radiographic axial spondyloarthritis adults.</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 an option alongside current standard treatment options and the drugs are similarly priced.</p>
4.	<p><b>Patient Access Scheme availability</b></p> <p>The Department of Health and Merck, Sharp &amp; Dohme have agreed that golimumab will be available to the NHS with a patient access scheme which makes it available with a discount. This will make the 100-mg dose of golimumab available to the NHS at the same cost as the 50-mg dose.</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>Golimumab is administered by subcutaneous injection. The recommended dosage is 50 mg once a month, on the same date each month.</p> <p>For patients with a body weight greater than 100 kg whose disease does not</p>

	<p>respond adequately after 3 or 4 doses (50 mg each), the summary of product characteristics states that increasing the dosage of golimumab to 100 mg once a month may be considered.</p> <p>The list price of golimumab is £762.97 for a 50-mg pre-filled disposable injection and £1,525.94 for a 100-mg pre-filled disposable injection (British national formulary [BNF] online [accessed September 2017]).</p> <p>Assuming a patient has 50 mg every month, the annual cost of treatment with golimumab is estimated at £9,156. Due to the patient access scheme, this cost would remain the same for patients with a body weight greater than 100 kg whose disease does not respond adequately to 50 mg per month and who subsequently have monthly doses of 100 mg.</p>
<p><b>5.2</b></p>	<p><b>Infrastructure costs Per annum</b></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>
<p><b>6.</b></p>	<p><b>Expected implementation period</b></p> <p>There is no impediment to implementation of this guidance.</p>
<p><b>7.</b></p>	<p><b>Commissioning arrangements</b></p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team initially on a cost per case basis.</p>
<p><b>8.</b></p>	<p><b>Monitoring arrangements</b></p> <p>The HSC Board has robust arrangements in place for the monthly monitoring of all biologic therapies (patient numbers 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 monthly.</p>
<p><b>9.</b></p>	<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>