

1	<p>Treatment & Condition</p> <p>Certolizumab pegol for treating rheumatoid arthritis after inadequate response to a TNF-alpha inhibitor</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance (TA415) October 2016</p> <p>Certolizumab pegol, in combination with methotrexate, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other disease-modifying antirheumatic drugs (DMARDs) including at least 1 tumour necrosis factor-alpha (TNF-alpha) inhibitor, only if:</p> <ul style="list-style-type: none"> • disease activity is severe and • rituximab is contraindicated or not tolerated and • the company provides certolizumab pegol with the agreed patient access scheme <p>Certolizumab pegol, as monotherapy, is recommended as an option for treating active rheumatoid arthritis in adults whose disease has responded inadequately to, or who cannot tolerate, other DMARDs including at least 1 TNF-alpha inhibitor, only if:</p> <ul style="list-style-type: none"> • disease activity is severe and • rituximab therapy cannot be given because methotrexate is contraindicated or not tolerated and • the company provides certolizumab pegol with the agreed patient access scheme <p>Continue treatment only if there is at least a moderate response measured using European League Against Rheumatism (EULAR) criteria at 6 months. After an initial response within 6 months, withdraw treatment if at least a moderate EULAR response is not maintained.</p>
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>The resource impact statement that accompanies TA415 indicates that the implementation of this guidance is not expected to have an impact on resources or projected patient numbers. This therapy is an additional treatment option for patients with this condition.</p>
4.	<p>Patient Access Scheme Availability</p> <p>The company has agreed a patient access scheme with the Department of Health. In the scheme, the first 12 weeks of therapy (currently 10 pre-loaded syringes of 200 mg each) with certolizumab pegol are free of charge. The acquisition cost is £6,793 in the first year of treatment and then £9,295 per year.</p>

5.	Costs (<i>before PAS if applicable</i>)
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>The company has agreed a patient access scheme with the Department of Health. In the scheme, the first 12 weeks of therapy (currently 10 pre-loaded syringes of 200 mg each) with certolizumab pegol are free of charge. The acquisition cost is £6,793 in the first year of treatment and then £9,295 per year.</p>
5.2	<p>Total Drug Costs Per annum</p> <p>The Resource Impact Statement from NICE that accompanies TA415 indicates that no resource impact is anticipated from this technology appraisal. Certolizumab pegol is a further option for patients with rheumatoid arthritis.</p>
5.3	<p>Infrastructure costs Per annum</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 implementation of this guidance.</p>
7.	<p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the 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 monthly 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 monthly.</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>