

1	<p>Treatment & Condition</p> <p>Secukinumab for active ankylosing spondylitis after treatment with nonsteroidal anti-inflammatory drugs or TNF-alpha inhibitors</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal guidance (TA407) September 2016</p> <p>Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF alpha inhibitors). The drug is recommended only if the company provides it with the discount agreed in the patient access scheme.</p> <p>Assess the response to secukinumab after 16 weeks of treatment and only continue if there is clear evidence of response, defined as: 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>
3	<p>Number of people in Northern Ireland expected to take up service/therapy (including new cases per year)</p> <p>According to the Resource Impact Template that accompanies TA407, the patient numbers are as follows:</p> <ul style="list-style-type: none"> • Incident population = 11 patients • Prevalent population = 246 patients • Total number of people in Northern Ireland eligible to take up treatment with secukinumab for this indication = 257
4	<p>Patient Access Scheme availability</p> <p>The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of secukinumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p>
5	<p>Costs (before PAS if applicable)</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p>Secukinumab (Cosentyx[®]). It is a monoclonal antihuman antibody of the IgG1/kappa isotype that targets interleukin-17A. It has a marketing authorisation in the UK for the treatment of active ankylosing spondylitis 'in adults who have responded inadequately to conventional therapy'. The recommended dose is 150mg once weekly given by subcutaneous injection at weeks 0, 1, 2 and 3; followed by a maintenance dose once a month starting at week 4.</p>

	<p>Secukinumab is available at the list price of £609.39 for a 150mg pre-filled pen or syringe. The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of secukinumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence.</p> <p>Cost per patient in Year 1 = £3,046.95 + £6,703.29 = £9,750.24 Cost per patient in Year 2 and subsequently = £7,312.68</p>
5.2	<p>Infrastructure costs per patient 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>
5.3	<p>Current in year costs</p> <p>This therapy provides an additional treatment option for patients with this condition. The NICE resource impact template that accompanies this TA indicates that the availability of this therapy as an additional option will result in a cost saving. This is before the application of the confidential patient access discount. Therefore it is not anticipated that there will be costs incurred in-year.</p>
5.4	<p>Recurrent overall costs per annum (including additional costs)</p> <p>It is anticipated that implementation of this guidance will be <u>cost saving</u>. The resource impact template that accompanies this TA projects the future number of patients with this condition expected to access each of the therapies available. These projections suggest savings of approximately £530k per year before the application of the confidential patient access scheme discount. Therefore it is not anticipated that there will be costs incurred recurrently. NICE guidance suggests that the savings will accrue over a period of 5 years up to 2021/22.</p>
5.5	<p>Opportunities for cost savings and how these will be secured</p> <p>The HSC Board will monitor spending on biologic therapies across all Trusts. The availability of this therapy as an additional treatment option for patients with this condition should offset the overall cost of growth in the use of biologic therapies in future years.</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	Monitoring arrangements 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. All monitoring returns for biologics are reviewed by the specialist services commissioning team monthly.
9	DoH (NI) Legislative/Policy Caveats 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.