

1	<p>Treatment & Condition</p> <p>Abatacept, adalimumab, etanercept and tocilizumab for treating juvenile idiopathic arthritis</p>
2	<p>Associated appraisal body & Summary of ruling</p> <p>NICE Technology Appraisal Guidance 373 (TA373). December 2015.</p> <p>This guidance replaces NICE technology appraisal guidance on the use of etanercept for the treatment of juvenile idiopathic arthritis (TA35, March 2002).</p> <p>Abatacept, adalimumab, etanercept and tocilizumab are recommended, within their marketing authorisations, as options for treating polyarticular juvenile idiopathic arthritis (JIA), including polyarticular-onset, polyarticular-course and extended oligoarticular JIA. That is:</p> <ul style="list-style-type: none"> • for abatacept, people 6 years and older whose disease has responded inadequately to other disease-modifying anti-rheumatic drugs (DMARDs) including at least 1 tumour necrosis factor (TNF) inhibitor • for adalimumab, people 2 years and older whose disease has responded inadequately to 1 or more DMARD • for etanercept, people 2 years and older whose disease has responded inadequately to, or who are intolerant of, methotrexate • for tocilizumab, people 2 years and older whose disease has responded inadequately to previous therapy with methotrexate. <p>Abatacept and tocilizumab are recommended only if the companies provide them with the discounts agreed in the patient access schemes for these technologies.</p> <p>Adalimumab and etanercept are recommended, within their marketing authorisations, as options for treating enthesitis-related JIA, that is, for people 6 years and older (adalimumab) and 12 years and older (etanercept) whose disease has responded inadequately to, or who are intolerant of, conventional therapy.</p> <p>Etanercept is recommended, within its marketing authorisation, as an option for treating psoriatic JIA, that is, in people aged 12 years and over whose disease has responded inadequately to, or who are intolerant of, methotrexate.</p> <p>When more than 1 technology is suitable (taking into account extra-articular manifestations) treatment should be started with the least expensive technology, taking into account administration costs, the dose needed and the product cost per dose.</p>

3	<p>Number of people in Northern Ireland expected to take up service/therapy</p> <p>Each year in Northern Ireland the number of patients receiving biologic therapies for rheumatoid arthritis increases by around 500 across all five Trusts. At the end of March 2016, there were around 4,300 rheumatoid arthritis patients receiving biologic therapies. The projections for 2016/17 suggest that there will be a similar growth in patient numbers during the year. Information available from NICE indicated that in NI around 20-30 children would be included in the growth figures above.</p>
4	<p>Patient Access Scheme availability</p> <p>The manufacturers of abatacept and tocilizumab have agreed patient access schemes with the Department of Health. These schemes provide a simple discount to the list price of these drugs with the discount applied at the point of purchase or invoice. The levels of the discounts are commercial in confidence.</p>
5	<p>Costs</p>
5.1	<p>Drug cost per patient per annum (for new and prevalent cases)</p> <p><u>Abatacept</u> (Orencia[®]) is administered by intravenous infusion. Abatacept costs £302.40 for a 250 mg vial. The dose of abatacept depends on body weight. For children and young people who weigh less than 75 kg, the dose is 10 mg/kg. For young people weighing over 75 kg, the adult dosing regimen applies, up to a total dose of 1000 mg per administration. Abatacept is given at 2 and 4 weeks after the initial intravenous infusion and then every 4 weeks. These costs exclude the discount available through a patient access scheme which is commercial in confidence.</p> <p><u>Adalimumab</u> (Humira[®]) is administered by subcutaneous injection. Adalimumab costs £352.14 for a 40 mg prefilled pen or prefilled syringe and for a 40 mg/0.8 ml vial. The dose of adalimumab depends on body surface area. For children younger than 13 years, the dose is 24 mg/m², up to a maximum single dose of 20 mg in children aged 2–4 years and 40 mg in children aged 4–12 years. It is given every other week. For young people 13 years and older, the dose is 40 mg every other week regardless of body surface area.</p> <p><u>Etanercept</u> (Enbrel[®]) is administered by subcutaneous injection. Etanercept costs £35.75 for a 10 mg vial and £89.38 for a 25 mg vial. The dose of etanercept is either 0.4 mg/kg given twice weekly up to a maximum of 25 mg per dose or 0.8 mg/kg given once weekly up to a maximum of 50 mg per dose.</p> <p><u>Tocilizumab</u> (RoActemra[®]) is given by intravenous infusion. Tocilizumab costs £102.40 for an 80 mg vial, £256.00 for a 200 mg vial and £512.00 for a 400 mg vial. The dose of tocilizumab is 8 mg/kg once every 4 weeks in patients weighing 30 kg or more or 10 mg/kg once every 4 weeks in patients weighing less than 30 kg. These costs exclude the discount available through a patient access scheme which is commercial in confidence.</p>

<p>5.2</p>	<p>Infrastructure costs per patient per annum</p> <p>The Resource Impact Report that accompanies TA373, estimates that the guidance will not result in a significant change in infrastructure requirements because it is considered that the recommendations are consistent with current clinical practice.</p> <p>The HSC Board will work with Trusts to identify any infrastructure requirements, including the needs of relevant paediatric services.</p>
<p>5.3</p>	<p>Current in year costs</p> <p>The HSC Board financial plan for 2016/17 includes around £2.6m for the in-year costs of the projected growth of around 500 patients with rheumatoid arthritis on biologic treatments. The costs of implementing TA373 are included in these costs.</p> <p>NICE guidance indicates there will be no significant change in the pattern of resource use as the recommendations are considered to reflect current clinical practice and existing NICE guidance.</p>
<p>5.4</p>	<p>Recurrent overall costs per annum</p> <p>The projected recurrent costs of rheumatoid arthritis patients commenced on treatment in 2016/17 are £4.5m. The recurrent costs are included in the HSC Board financial plan for 2016/17.</p> <p>NICE believes that there will be no significant change in the level of resource required as a result of the guidance. This is because the recommendations are considered to reflect current clinical practice and existing NICE guidance.</p>
<p>5.5</p>	<p>Opportunities for cost savings and how these will be secured</p> <p>Cost savings are not expected.</p>
<p>6</p>	<p>Expected implementation period</p> <p>There is no barrier to immediate implementation of this guidance.</p>
<p>7</p>	<p>Commissioning arrangements</p> <p>This regime will be formally commissioned by the HSCB/PHA via the Specialist Services Commissioning Team.</p>
<p>8</p>	<p>Monitoring arrangements</p> <p>HSCB currently reviews monthly monitoring information from all Trusts on all biologics used, number of patients treated (adults and children), and number of patients waiting to commence treatment by banded waiting times.</p> <p>The Specialist Service Commissioning Team has a long established biologics sub group which meets on a quarterly basis. Service monitoring including the review of the monthly data returns is a key function of this group.</p>

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DHSSPS 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.