

NICE TA 238: Arthritis (juvenile idiopathic, systemic) – Tocilizumab

1	<p>Name of Commissioning Team</p> <p>Specialist Services Commissioning Team</p>
2	<p>Summary of NICE TA 238</p> <p>Tocilizumab is recommended for the treatment of systemic juvenile idiopathic arthritis in children and young people aged 2 years and older whose disease has responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs), systemic corticosteroids and methotrexate if the manufacturer makes tocilizumab available with the confidential discount agreed as part of the patient access scheme.</p> <p>Tocilizumab is not recommended for the treatment of systemic juvenile idiopathic arthritis in children and young people aged 2 years and older whose disease continues to respond to methotrexate or who have not been treated with methotrexate.</p> <p>Children and young people currently receiving tocilizumab for the treatment of systemic juvenile idiopathic arthritis who do not meet the criteria above should have the option to continue treatment until it is considered appropriate to stop. This decision should be made jointly by the clinicians, and the child or young person and/or their parents or carers.</p> <p>The regime has NICE approval and the estimated annual incidence of new patients per annum can be accommodated within the projected resources required to achieve and maintain the waiting time target for these regimes in 2012/2013.</p> <p>The Specialist Services Commissioning recommends that this treatment be introduced as part of suite of NICE approved therapies for RA.</p>
3	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>The proportion of children and young people with systemic juvenile idiopathic arthritis is uncertain. The NICE costing statement is based on expert opinion and uses an estimate of 6% for the number of children and young people presenting with the condition in the UK. Using the NICE costing statement assumptions, the target population for this drug in Northern Ireland is estimated at 17 patients.</p> <p>The number of new cases eligible for this treatment per year is not known but is likely to be small, estimated at up to 3 incident cases per year.</p>

4	Outcomes
4.1	Additional life expectancy gain / progress improvement Prevents long-term damage and improves quality of life and function
4.2	Reduction in morbidity Prevents long-term damage and improves quality of life and function.
4.3	Cost per patient per annum The cost per patient is weight dependent. The estimate of annual drug cost quoted by NICE is £7,987 based on an average weight of a child of 20kg. However, older children could have an annual cost per patient of up to £15,000. The manufacturer of tocilizumab has agreed a patient access scheme with the Department of Health (England) which makes tocilizumab available with a discount applied to all invoices. It is assumed that this scheme will also apply in NI. The size of the discount is commercial-in-confidence. Trusts will be expected to procure the medicine at the discounted level which will reduce prescribing costs. The level of discount which the PAS will provide is not known by the Board at this time. The manufacturer has confirmed that the patient access scheme will apply in NI and will share the details of the costs with the Board as commercial-in-confidence for planning purposes.
4.4	In year cost per patient per annum (for new and prevalent cases) In 2002 NICE recommended etanercept for children aged 2 to 17 for patients with active JIA in at least 4 joints whose condition has not adequately responded to methotrexate or who have not been able to tolerate methotrexate. NICE have made a reasonable assumption that patients with JIA are receiving a range of biological treatments. It is not expected that there would be a substantial number of patients who would be eligible for tocilizumab that are not already receiving other biologic drugs. Tocilizumab is recommended at the same stage of the clinical pathway as other biologic drugs and it is not expected that patients will be switched to Tocilizumab after failure of another biologic therapy. In year costs will be for new cases presenting at this stage of the clinical pathway during 2012/13. Treatment is given every 2 weeks The annual additional in year and recurrent cost is likely to be small due to the fact that most eligible cases are already receiving treatment with an alternative drug of a similar cost. This is estimated at approximately new 2-3 patients per year at a total full year cost of £24,000 to £45,000 depending on the weight of the patient. (The in-year cost is estimated in the range £12,000 to £22,500 assuming a mid-year start)

4.5	<p>Any cost savings and how these will be secured</p> <p>Adequate treatment of juvenile arthritis may prevent the need for supportive therapies and surgical interventions such as multiple joint replacements.</p> <p>In addition improved early care of juvenile arthritis should improve the ability to access education with less interruption allowing the individual an improved opportunity to optimise potential and contribution to society.</p>
4.6	<p>Recurrent overall cost</p> <p>The annual additional recurrent cost is likely to be small due to the fact that most eligible cases are already receiving treatment with an alternative drug of a similar cost. This is estimated at approximately new 2-3 patients per year at a total cost of £24,000 to £45,000 depending on the weight of the patient.</p>
4.7	<p>QALY</p> <p>The NICE economic model included the PAS, and included the natural history of systemic JIA. Using cost of treatment as a composite of cost of medication and administration costs that were thought to be a reasonable reflection of clinical practice in the UK, NICE concluded that tocilizumab represents a cost-effective use of NHS resources and should be offered as an option for the treatment of systemic JIA in children and young people aged 2 years and older whose condition has inadequately responded to NSAIDs, corticosteroids and methotrexate.</p> <p>Depending on whether tocilizumab is used prior to infliximab or anakinra, the ICER was calculated to be between £18,194 and £16,923 per QALY respectively.</p>
4.8	<p>Other treatments available for this condition</p> <p>Clinical Specialists in the UK advised NICE that patients with systemic JIA are treated first with NSAIDs and systemic corticosteroids. Methotrexate is then used if disease activity persists. If the child is intolerant of methotrexate or their condition does not adequately respond to an adequate trial of methotrexate, TNF alpha inhibitors or anakinra are the next treatment options to be used.</p> <p>Adalimumab, etanercept and tocilizumab are licensed in JIA. Of these, only etanercept and tocilizumab have NICE approval for this indication. Etanercept is approved for use in ages 4-17 years and Tocilizumab from the age of 2 years.</p> <p>Abatacept is also licensed but has not been approved by NICE.</p> <p>Anakinra is not licensed in JIA</p>
4.9	<p>Readiness to implement</p> <p>Patients with systemic JIA are already receiving treatment with biologic drugs and</p>

	<p>there is no requirement for additional infrastructure for tocilizumab to be made available as a treatment choice for suitable patients who meet the NICE criteria.</p> <p>The patient access scheme which has been agreed with Department of Health is a condition of the NICE recommendation for use. It is not currently available in Northern Ireland because the Manufacturer has required a confidentiality agreement to be in place. The Board has met with the manufacturer's representatives to clarify the requirement for a separate confidentiality agreement in the context of the status of NICE guidance in NI as outlined in the DHSSPS circulars. Following this meeting, the manufacturer has now provided clarification that an additional confidentiality agreement for the Patient Access Scheme is not required in Northern Ireland. As the Patient Access Scheme is not currently available to trusts in Northern Ireland, the Technology Appraisal can only be implemented whenever the agreed discount is made available to Trusts. However, following the clarification obtained from the manufacturer, the Board expects that the PAS will be available to Trusts in NI in the near future.</p>
<p>5</p>	<p>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>6</p>	<p>What will Commissioning Team do to secure funding for the implementation of this TA including any proposals for disinvestment</p> <p>The TA will be funded from the 2012/2013 resources identified to meet the commissioning direction targets as referenced in section 5.</p>
<p>7</p>	<p>Commissioning arrangements</p> <p>The treatment will be commissioned through the existing Investment Proposal Templates and subsequent negotiation process as part of the overall commissioning arrangements for the full suite of NICE approved biologic therapies for rheumatoid conditions to achieve waiting time standards.</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 monitoring pro forma will be adapted to capture information in respect of this regime and this group of patients.</p>

	<p>The Specialist Service Commissioning Team has a long established RA biologics sub group which meets on a bi monthly basis. Service monitoring including the review of the monthly data returns is a key function of this group.</p>
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