



National Institute for Health and Clinical Excellence

Tel: 0845 003 7782
www.nice.org.uk

Ref: 2011/101

ISSUED: Thursday 23 June 2011

PRESS RELEASE

NICE appraisal on abatacept for rheumatoid arthritis

The National Institute for Health and Clinical Excellence (NICE) has today (23 June) issued final draft guidance on the use of abatacept (Orencia) as a second-line treatment for people with rheumatoid arthritis. The draft guidance does not recommend abatacept in combination with methotrexate, for treating rheumatoid arthritis in adults whose disease has responded inadequately to one or more conventional non-biological disease modifying anti-rheumatic drugs (DMARDs) including methotrexate. The draft recommendations say that people currently receiving abatacept for treating rheumatoid arthritis in this circumstance should have the option to continue therapy until they and their clinicians consider it appropriate to stop. **NICE has not yet issued final guidance to the NHS.**

NICE has already recommended a range of biological treatments for rheumatoid arthritis. Adalimumab, etanercept, infliximab, certolizumab pegol – and from 22 June also golimumab – are options for second-line use. This is the same point in the treatment pathway at which abatacept is currently being considered. NICE also recommends rituximab for adults with severe active rheumatoid arthritis who have had an inadequate response to at least one tumor necrosis factor (TNF) inhibitor. In addition, for people who cannot take rituximab following an inadequate response to at least one TNF inhibitor, NICE recommends adalimumab, etanercept, infliximab, tocilizumab, abatacept and now also golimumab.

Dr Carole Longson, Health Technology Evaluation Centre Director at NICE

said: “NICE has previously issued a positive recommendation for the use of abatacept in certain circumstances, to help people with rheumatoid arthritis.

However the Appraisal Committee concluded that using abatacept as a second-line treatment option was not supported by the evidence provided. Indeed, the

manufacturer of abatacept had noted that their product would not be cost-effective for second-line use when compared to a range of alternatives including adalimumab, etanercept and certolizumab pegol.

“NICE has already recommended a range of biological treatments for rheumatoid arthritis, providing potential treatment options for people with this condition.”

Until final guidance is issued NHS bodies should make decisions locally on the funding of specific treatments.

Ends

For more information, please call Dr Tonya Gillis at the NICE press office on 0845 003 7782 or (out of hours) 07775 583 813.

Notes to Editors

About the guidance ‘Abatacept for the treatment of rheumatoid arthritis after the failure of conventional disease-modifying anti-rheumatic drugs’

1. More information on this appraisal can be found here:
<http://guidance.nice.org.uk/TA/Wave24/16> .
2. NICE currently recommends a range of treatments for rheumatoid arthritis: adalimumab, etanercept, infliximab, rituximab, abatacept, tocilizumab, certolizumab pegol and golimumab. More information is at:
 - TA130 - Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis: <http://guidance.nice.org.uk/TA130>
 - TA186 - Certolizumab pegol for the treatment of rheumatoid arthritis: <http://guidance.nice.org.uk/TA186>
 - TA195 - Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor: <http://guidance.nice.org.uk/TA195>
 - TA198 – Tocilizumab for the treatment of rheumatoid arthritis: <http://guidance.nice.org.uk/TA198>
 - TA225 - Golimumab for the treatment of rheumatoid arthritis after failure of previous disease-modifying anti-rheumatic drugs: <http://guidance.nice.org.uk/TA225>
3. The manufacturer of abatacept had noted that their product would not be cost-effective for second-line use when compared to adalimumab, etanercept and certolizumab pegol, which are administered by subcutaneous injection. They therefore suggested that abatacept should be compared with infliximab, the only other intravenous treatment option at this stage in the pathway of care. However, the Committee did not consider this to be a relevant comparison since route of administration rarely determines which drug to prescribe. This is because devices used to self-administer subcutaneous injections have improved considerably and few people experience problems handling the injection devices. Subcutaneous injections can also be administered at home by a nurse or a family member.
4. The independent Appraisal Committee also considered whether abatacept could be a cost-effective treatment option for people for whom treatment with a TNF inhibitor was contraindicated because of congestive heart failure. However, the Committee did not consider it appropriate to provide a separate recommendation given that there was no evidence of how much clinical benefit abatacept may provide in this group of people, and

that their health status is not comparable to the overall trial population. In addition, any decision on using biological treatments for this group would need a careful balance of the potential benefits and harms for the individual patient because of their complex medical needs.

5. The manufacturer of abatacept (Orencia) is Bristol-Myers Squibb.
6. Abatacept is a selective T-cell modulator that blocks a co-stimulatory signal required to activate T-cells. Abatacept has a marketing authorisation for use in combination with methotrexate for the treatment of moderate to severe active rheumatoid arthritis in adults whose disease has responded inadequately to previous therapy with one or more DMARDs including methotrexate or a TNF inhibitor. Abatacept is administered as a 30-minute intravenous infusion. After an initial infusion (week 0), a person receives an infusion at week 2, at week 4 and every 4 weeks thereafter. Abatacept is available in 250-mg vials at a cost of £242.17 per vial (excluding VAT; 'British national formulary' [BNF] edition 61). Patients require fourteen infusions in the first year, and 13 infusions in subsequent years. The dose of abatacept depends on body weight: people weighing less than 60 kg, 60–100 kg and over 100 kg require 500 mg, 750 mg and 1000 mg respectively. The annual drug costs associated with abatacept vary according to body weight and the number of infusions required. For a person weighing 60–100 kg, the cost is £10,171.14 in the first year, and £9444.63 in subsequent years. Costs may vary in different settings because of negotiated discounts.

About NICE

7. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance and standards on the promotion of good health and the prevention and treatment of ill health
8. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
9. NICE produces standards for patient care:
 - **quality standards** – these reflect the very best in high quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services
 - **Quality and Outcomes Framework** – NICE develops the clinical and health improvement indicators in the QOF, the Department of Health scheme which rewards GPs for how well they care for patients
10. NICE provides advice and support on putting NICE guidance and standards into practice through its **implementation programme**, and it collates and accredits high quality health guidance, research and information to help health professionals deliver the best patient care through **NHS Evidence**.