

Quick reference guide

Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis

NOTE: This guidance replaces 'NICE technology appraisal guidance 36' issued in March 2002.

The Institute reviews each piece of guidance it issues.

This review and re-appraisal has additionally included adalimumab for the treatment of rheumatoid arthritis, and has taken into account changes in the marketing authorisations for infliximab and etanercept.

Guidance

- 1 The tumour necrosis factor alpha (TNF- α) inhibitors adalimumab, etanercept and infliximab are recommended as options for the treatment of adults who have both of the following characteristics.
 - Active rheumatoid arthritis as measured by disease activity score (DAS28) greater than 5.1 confirmed on at least two occasions, 1 month apart.
 - Have undergone trials of two disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate (unless contraindicated). A trial of a DMARD is defined as being normally of 6 months, with 2 months at standard dose, unless significant toxicity has limited the dose or duration of treatment.
- 2 TNF- α inhibitors should normally be used in combination with methotrexate. Where a patient is intolerant of methotrexate or where methotrexate treatment is considered to be inappropriate, adalimumab and etanercept may be given as monotherapy.
- 3 Treatment with TNF- α inhibitors should be continued only if there is an adequate response at 6 months following initiation of therapy. An adequate response is defined as an improvement in DAS28 of 1.2 points or more.
- 4 After initial response, treatment should be monitored no less frequently than 6-monthly intervals with assessment of DAS28. Treatment should be withdrawn if an adequate response (as defined in 1.3) is not maintained.
- 5 An alternative TNF- α inhibitor may be considered for patients in whom treatment is withdrawn due to an adverse event before the initial 6-month assessment of efficacy, provided the risks and benefits have been fully discussed with the patient and documented.
- 6 Escalation of dose of the TNF- α inhibitors above their licensed starting dose is not recommended.
- 7 Treatment should normally be initiated with the least expensive drug (taking into account administration costs, required dose and product price per dose). This may need to be varied in individual cases due to differences in the mode of administration and treatment schedules.

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This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

NICE technology appraisal guidance is about the use of new and existing medicines and treatments in the NHS in England and Wales.

- 8 Use of the TNF- α inhibitors for the treatment of severe, active and progressive rheumatoid arthritis in adults not previously treated with methotrexate or other DMARDs is not recommended.
- 9 Initiation of TNF- α inhibitors and follow-up of treatment response and adverse events should be undertaken only by a specialist rheumatological team with experience in the use of these agents.

Implementation tools

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA130).

- A costing statement explaining the resource impact of this guidance.
- Audit criteria to monitor local practice.

Further information

Ordering information

You can download the following documents from www.nice.org.uk/TA130

- A quick reference guide (this document) – a summary of recommendations for healthcare professionals.
- 'Understanding NICE guidance' – information for patients and carers.
- The full guidance.
- Details of all the evidence that was looked at and other background information.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone the NHS Response Line on 0870 1555 455 and quote:

- N1397 (quick reference guide)
- N1398 ('Understanding NICE guidance').

Related NICE guidance

For information about NICE guidance that has been issued or is in development, see the website (www.nice.org.uk).

Published

- Rituximab for the treatment of rheumatoid arthritis. NICE technology appraisal guidance 126 (2007). Available from: www.nice.org.uk/TA126
- Anakinra for rheumatoid arthritis. NICE technology appraisal guidance 72 (2006). Available from: www.nice.org.uk/TA072
- Guidance on the use of etanercept and infliximab for the treatment of rheumatoid arthritis. NICE technology appraisal guidance 36 (2002). Available from: www.nice.org.uk/TA036
- Guidance on the use of etanercept for the treatment of juvenile idiopathic arthritis. NICE technology appraisal guidance 35 (2002). Available from: www.nice.org.uk/TA035

Under development

- Abatacept for the treatment of rheumatoid arthritis. NICE technology appraisal guidance (publication date to be confirmed).
- Rheumatoid arthritis: the management and treatment of rheumatoid arthritis in adults. NICE clinical guideline (publication expected December 2008).

Updating the appraisal

This technology appraisal will be considered for review in September 2010. Information about the progress of a review will be posted on the NICE website (www.nice.org.uk/TA130).