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NHS
National Institute for Health and Clinical Excellence

Quick reference guide

Adalimumab, etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis after the failure of a TNF inhibitor

NOTE: This guidance replaces NICE technology appraisal guidance 126 and 141 issued in August 2007 and April 2008 respectively. It also replaces the remaining recommendations in NICE technology appraisal guidance 36 issued in March 2002.

The appraisal of adalimumab and the review of the appraisals of etanercept, infliximab, rituximab and abatacept for the treatment of rheumatoid arthritis have resulted in changes in the guidance. Rituximab in combination with methotrexate is still recommended as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor. Additional treatment options are now recommended for these adults if rituximab therapy is contraindicated or withdrawn because of an adverse event, specifically:

- If rituximab is contraindicated or withdrawn, adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are now recommended as treatment options.
- If rituximab therapy cannot be given because methotrexate is contraindicated or withdrawn because of an adverse event, adalimumab and etanercept, each as monotherapy, are now recommended as treatment options.

Guidance

1 Rituximab in combination with methotrexate is recommended as an option for the treatment of adults with severe active rheumatoid arthritis who have had an inadequate response to, or are intolerant of, other disease-modifying anti-rheumatic drugs (DMARDs), including at least one tumour necrosis factor (TNF) inhibitor. Treatment with rituximab should be given no more frequently than every 6 months.

2 Treatment with rituximab in combination with methotrexate should be continued only if there is an adequate response following initiation of therapy and if an adequate response is maintained following retreatment with a dosing interval of at least 6 months. An adequate response is defined as an improvement in disease activity score (DAS28) of 1.2 points or more.

3 Adalimumab, etanercept, infliximab and abatacept, each in combination with methotrexate, are recommended as treatment options only for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to rituximab, or when rituximab is withdrawn because of an adverse event.

4 Adalimumab monotherapy and etanercept monotherapy are recommended as treatment options for adults with severe active rheumatoid arthritis who have had an inadequate response to, or have an intolerance of, other DMARDs, including at least one TNF inhibitor, and who cannot receive rituximab therapy because they have a contraindication to methotrexate, or when methotrexate is withdrawn because of an adverse event.

NICE technology appraisal guidance 195
The guidance was developed using the NICE multiple technology appraisal process.
NICE technology appraisal guidance is about the use of new and existing medicines and treatments in the NHS in England and Wales.

5 Treatment with adalimumab, etanercept, infliximab and abatacept should be continued only if there is an adequate response (as defined in 2) 6 months after initiation of therapy. Treatment should be monitored, with assessment of DAS28, at least every 6 months and continued only if an adequate response is maintained.

6 When using DAS28, healthcare professionals should take into account any physical, sensory or learning disabilities, communication difficulties, or disease characteristics that could adversely affect patient assessment and make any adjustments they consider appropriate.

7 A team experienced in the diagnosis and treatment of rheumatoid arthritis and working under the supervision of a rheumatologist should initiate, supervise and assess response to treatment with rituximab, adalimumab, etanercept, infliximab or abatacept.

Implementation tools

NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on our website (**www.nice.org.uk/guidance/TA195**).

- Costing template and report to estimate the national and local savings and costs associated with implementation.
- Audit support for monitoring local practice.

Further information

Ordering information

You can download the following documents from **www.nice.org.uk/guidance/TA195**

- A quick reference guide (this document) – the recommendations.
- 'Understanding NICE guidance' – a summary for patients and carers.
- The NICE 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 NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N2245 (quick reference guide)
- N2246 ('Understanding NICE guidance').

Related NICE guidance

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

Published

- Tocilizumab for the treatment of rheumatoid arthritis. NICE technology appraisal guidance 198 (2010). Available from **www.nice.org.uk/guidance/TA198**
- Certolizumab pegol for the treatment of rheumatoid arthritis. NICE technology appraisal guidance 186 (2010). Available from **www.nice.org.uk/guidance/TA186**
- Rheumatoid arthritis: the management of rheumatoid arthritis in adults. NICE clinical guideline 79 (2009). Available from **www.nice.org.uk/guidance/CG79**
- Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis. NICE technology appraisal guidance 130 (2007). Available from **www.nice.org.uk/guidance/TA130**

Under development

- Golimumab for the treatment of rheumatoid arthritis after the failure of previous disease-modifying antirheumatic drugs. NICE technology appraisal guidance (publication expected March 2011)

Updating the appraisal

This technology appraisal will be considered for review in June 2013. Information about the progress of a review will be available at **www.nice.org.uk/guidance/TA195**

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