

Quick reference guide

Adalimumab, etanercept and infliximab for ankylosing spondylitis

Guidance

- 1 Adalimumab or etanercept are recommended as treatment options for adults with severe active ankylosing spondylitis only if all of the following criteria are fulfilled.
 - The patient's disease satisfies the modified New York criteria for diagnosis of ankylosing spondylitis.
 - There is confirmation of sustained active spinal disease, demonstrated by:
 - a score of at least 4 units on the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) **and**
 - at least 4 cm on the 0 to 10 cm spinal pain Visual Analogue Scale (VAS).These should both be demonstrated on two occasions at least 12 weeks apart without any change of treatment.
 - Conventional treatment with two or more non-steroidal anti-inflammatory drugs taken sequentially at maximum tolerated or recommended dosage for 4 weeks has failed to control symptoms.
- 2 When using BASDAI and spinal pain VAS scores to inform conclusions about whether or not sustained active spinal disease is present, healthcare professionals should be mindful of the need to secure equality of access to treatment for patients with disabilities and patients from different ethnic groups. There are circumstances in which it may not be appropriate for healthcare professionals to use a patient's BASDAI and spinal pain VAS scores to inform their conclusion about the presence of sustained active spinal disease.

These are:

- where the BASDAI or spinal pain VAS score is not a clinically appropriate tool to inform a clinician's conclusion on the presence of sustained active spinal disease because of a patient's learning or other disabilities (for example, sensory impairments) or linguistic or other communication difficulties

or

- where it is not possible to administer the BASDAI or spinal pain VAS questionnaire in a language in which the patient is sufficiently fluent for it to be an appropriate tool to inform a conclusion on the presence of sustained active spinal disease, or there are similarly exceptional reasons why use of a patient's BASDAI or spinal pain VAS score would be an inappropriate tool to inform a conclusion on the presence of sustained active spinal disease in that individual patient's case.

In such cases, healthcare professionals should make use of another appropriate method of assessment, which may include adapting the use of the questionnaire to suit the patient's circumstances.

The same approach should apply in the context of a decision about whether to continue the use of the drug in accordance with sections 3 and 4.

- 3 It is recommended that the response to adalimumab or etanercept treatment should be assessed 12 weeks after treatment is initiated, and that treatment should be only continued in the presence of an adequate response as defined in section 4.

- 4 For the purposes of this guidance, an adequate response to treatment is defined as a:
- reduction of the BASDAI score to 50% of the pre-treatment value or by 2 or more units **and**
 - reduction of the spinal pain VAS by 2 cm or more.
- 5 Patients who have experienced an adequate response to adalimumab or etanercept treatment, as defined in section 4, should have their condition monitored at 12-week intervals. If the response to treatment, as defined in section 4, is not maintained, a repeat assessment should be made after a further 6 weeks. If at this 6-week assessment the response defined in section 4 has not been maintained, treatment should be discontinued.
- 6 For patients who have been shown to be intolerant of adalimumab or etanercept before the end of the 12-week initial assessment period, as in section 3, the other one of this pair of TNF- α inhibitor treatments is recommended as an alternative treatment.
- 7 Prescription of an alternative TNF- α inhibitor is not recommended in patients who have either not achieved an adequate initial response to treatment with adalimumab or etanercept, as defined in section 4, or who experience loss of the initially adequate response during treatment.
- 8 It is recommended that the use of adalimumab or etanercept for severe active ankylosing spondylitis should be initiated and supervised only by specialist physicians experienced in the diagnosis and treatment of this condition.
- 9 Infliximab is not recommended for the treatment of ankylosing spondylitis.
- 10 Patients currently receiving infliximab for the treatment of ankylosing spondylitis should have the option to continue therapy until they and their clinicians consider it appropriate to stop.

Implementation tools

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA143).

- Local costing template incorporating a costing report to estimate the savings and costs associated with implementation.
- Audit criteria to monitor local practice.

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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Further information

Ordering information

You can download the following documents from www.nice.org.uk/TA143

- 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 NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N1570 (quick reference guide)
- N1571 (‘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

- Adalimumab, etanercept and infliximab for the treatment of rheumatoid arthritis. NICE technology appraisal guidance 130 (2007). Available from: www.nice.org.uk/TA130
- Adalimumab for the treatment of psoriatic arthritis. NICE technology appraisal guidance 125 (2007). Available from: www.nice.org.uk/TA125
- Etanercept and infliximab for the treatment of adults with psoriatic arthritis. NICE technology appraisal guidance 104 (2006). Available from: www.nice.org.uk/TA104
- Etanercept and efalizumab for the treatment of adults with psoriasis. NICE technology appraisal guidance 103 (2006). Available from: www.nice.org.uk/TA103

Updating the appraisal

This technology appraisal will be considered for review in October 2010. Information about the progress of a review will be posted on the NICE website (www.nice.org.uk/TA143).