

## USE OF BIOLOGICAL AGENTS IN THE MANAGEMENT OF ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

The Pan Mersey Area Prescribing Committee recommends the use of adalimumab, certolizumab pegol, etanercept, golimumab, infliximab, secukinumab and ixekizumab in the management of ankylosing spondylitis (AS), and non-radiographic axial spondyloarthritis (NRASpA) in accordance with NICE TA383, NICE TA407, NICE TA497, NICE TA718 and NICE TA719.

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[NICE TA383](#) (February 2016) and [NICE TA497](#) (January 2018) recommend that adalimumab, certolizumab pegol, etanercept, golimumab and infliximab are used within their marketing authorisations in adults whose disease has responded inadequately to, or who cannot tolerate, non-steroidal anti-inflammatory drugs. Infliximab is recommended for AS only if treatment is started with the least expensive infliximab product. People currently receiving infliximab should be able to continue treatment with the same infliximab product until they and their NHS clinician consider it appropriate to stop. The choice of treatment should be made after discussion between the clinician and the patient about the advantages and disadvantages of the treatments available. This may include considering associated conditions such as extra-articular manifestations. If more than 1 treatment is suitable, the least expensive (taking into account administration costs and patient access schemes) should be chosen.

[NICE TA407](#) (September 2016) recommends secukinumab as an option where conventional therapy is inadequate and [NICE TA718](#) (July 2021) recommends ixekizumab as an option for treating ankylosing spondylitis within its marketing authorisation in adults, only where the disease has responded inadequately to conventional non-steroidal anti-inflammatory drug (NSAID) therapy and TNF-alpha inhibitors are unsuitable or do not control the condition well enough, and the company provides them with the discount agreed in the patient access schemes.

[NICE TA719](#) (July 2021) and [NICE TA718](#) (July 2021) recommends secukinumab and ixekizumab as options for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with NSAIDs and TNF-alpha inhibitors are not suitable or do not control the condition well enough, and the company provides them according to the commercial arrangement.

The response to any treatment should be assessed 12 weeks after the start of treatment (16 weeks for secukinumab and 16 to 20 weeks for ixekizumab). Treatment should only be continued if there is clear evidence of response, defined as:

- a reduction in the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score to 50% of the pre-treatment value or by 2 or more units and
- a reduction in the spinal pain visual analogue scale (VAS) by 2 cm or more.

**Note:** Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

Treatment with another of the above biological agents is recommended for people who cannot tolerate, or whose disease has not responded to, treatment with the first agent, or whose disease has stopped responding after an initial response as outlined in the [Pan Mersey Treatment Pathway for Ankylosing Spondylitis \(AS\) and Axial Spondyloarthritis \(axial SpA\)](#)