NICE National Institute for Health and Care Excellence

NICE guidance

Bimekizumab for treating axial spondyloarthritis

Technology appraisal guidance
Published: 11 October 2023

www.nice.org.uk/guidance/ta918

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Bimekizumab is recommended as an option in adults for treating active ankylosing spondylitis (AS) when conventional therapy has not worked well enough or is not tolerated, or active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation (shown by elevated C-reactive protein or MRI) when non-steroidal anti-inflammatory drugs (NSAIDs), have not worked well enough or are not tolerated. It is recommended only if:

- tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough, and
- the company provides it according to the commercial arrangement.

1.2 Assess response to bimekizumab after 16 weeks of treatment. Continue treatment only 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.

1.3 Take into account any communication difficulties, or physical, psychological, sensory or learning disabilities that could affect responses to the BASDAI and spinal pain VAS questionnaires, and make any appropriate adjustments.

1.4 If people with the condition and their clinicians consider bimekizumab to be 1 of a range of suitable treatments (including ixekizumab and secukinumab), after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

1.5 This recommendation is not intended to affect treatment with bimekizumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them

before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

Why these recommendations were made

Usual treatment for AS and nr-axSpA is TNF-alpha inhibitors. People may have 1 or more TNF-alpha inhibitors before being offered secukinumab or ixekizumab. Bimekizumab works in a similar way to these 2 treatments and would be offered to the same population.

Clinical trial evidence shows that bimekizumab is more effective than placebo. Bimekizumab has not been compared directly with secukinumab and ixekizumab. But the results of an indirect comparison suggest that it is as effective as secukinumab and ixekizumab.

A cost comparison suggests bimekizumab has lower costs than ixekizumab but higher costs than secukinumab. Using NICE's cost-comparison methods, bimekizumab only needs to cost less than 1 relevant comparator that is established practice in the NHS, to be recommended as a treatment option. So, bimekizumab is recommended.

For all evidence see the committee papers. To see what NICE did for secukinumab and ixekizumab, see the committee discussion sections in NICE's technology appraisal guidance on secukinumab in nr-axSpA, NICE's technology appraisal guidance on secukinumab in AS and NICE's technology appraisal guidance on ixekizumab.

2 Information about bimekizumab

Marketing authorisation indication

2.1 Bimekizumab (Bimzelx, UCB Pharma) is indicated for the treatment of:

- 'adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) who have responded inadequately or are intolerant to non-steroidal anti-inflammatory drugs (NSAIDs)' and
- 'adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for bimekizumab.

Price

2.3 The list price of bimekizumab is £2,443 per 320-mg (2×160-mg prefilled syringes) dose (excluding VAT; BNF online accessed August 2023).

2.4 The company has a commercial arrangement. This makes bimekizumab available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires clinical commissioning groups, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this appraisal within 3 months of its date of publication. Because bimekizumab has been recommended through the cost comparison process, NHS England and commissioning groups have agreed to provide funding to implement this guidance 30 days after publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 2 months of the first publication of the final appraisal document.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has axial spondyloarthritis and the doctor responsible for their care thinks that bimekizumab is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

The 4 technology appraisal committees and the highly specialised technologies evaluation committee are standing advisory committees of NICE. This topic was considered by the chair and the vice chair of the highly specialised technologies evaluation committee.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

Rachel Ramsden
Technical lead

Claire Hawksworth
Technical adviser

Leena Issa and Vonda Murray
Project managers

ISBN: 978-1-4731-5478-0

Accreditation