

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Final draft guidance

### Bimekizumab for treating axial spondyloarthritis

#### 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 (see [section 2](#)).
- 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 which 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 (simple discount patient access scheme). 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.

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Project managers

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