NICE National Institute for Health and Care Excellence

NICE guidance

Bimekizumab for treating active psoriatic arthritis

Technology appraisal guidance
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www.nice.org.uk/guidance/ta916

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 alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis (defined as peripheral arthritis with 3 or more tender joints and 3 or more swollen joints) in adults whose condition has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is recommended only if they have had 2 conventional DMARDs and:

- at least 1 biological DMARD or
- tumour necrosis factor (TNF)-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis).

Bimekizumab is recommended only if the company provides it according to the commercial arrangement.

1.2 Assess response to bimekizumab after 16 weeks of treatment. Stop bimekizumab if the psoriatic arthritis has not responded adequately using the Psoriatic Arthritis Response Criteria (PsARC; an adequate response is an improvement in at least 2 of the 4 criteria, 1 of which must be joint tenderness or swelling score, with no worsening in any of the 4 criteria). If the PsARC response is not adequate but there is a Psoriasis Area and Severity Index (PASI) 75 response, a dermatologist should decide whether continuing treatment is appropriate based on skin response.

1.3 Take into account any physical, sensory or learning disabilities, or communication difficulties that could affect the responses to the PsARC and make any adjustments needed.

1.4 Take into account how skin colour could affect the PASI score and make any adjustments needed

1.5 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.

1.6 These recommendations are not intended to affect treatment with bimekizumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations 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 psoriatic arthritis is DMARDS, including biological DMARDs such as ixekizumab and secukinumab. Bimekizumab works in a similar way to these 2 treatments, and would be offered to the same population.

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

A cost comparison suggests bimekizumab has lower costs than ixekizumab. 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 ixekizumab and secukinumab, see the committee discussion section in NICE's technology appraisal guidance on ixekizumab and secukinumab.

2 Information about bimekizumab

Marketing authorisation indication

2.1 Bimekizumab (Bimzelx, UCB Pharma) is indicated for the treatment of 'adults with active psoriatic arthritis who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs)'.

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 (two 160 mg prefilled syringes or two 160 mg prefilled pens) 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 integrated care boards, 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 integrated care boards 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 draft guidance.

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 psoriatic arthritis 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 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.

Luke Cowie
Technical lead

Claire Hawksworth
Technical adviser

Celia Mayers and Kate Moore
Project manager

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