NICE National Institute for Health and Care Excellence

NICE guidance

Bimekizumab for treating moderate to severe plaque psoriasis

Technology appraisal guidance

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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 are 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.

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 for treating plaque psoriasis in adults, only if:

- the disease is severe, as defined by a total Psoriasis Area and Severity Index (PASI) of 10 or more and a Dermatology Life Quality Index (DLQI) of more than 10 and
- the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
- the company provides the drug according to the commercial arrangement.

1.2 Stop bimekizumab treatment at 16 weeks if the psoriasis has not responded adequately. An adequate response is defined as:

- a 75% reduction in the PASI score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in DLQI from when treatment started.

1.3 Choose the least expensive treatment if patients and their clinicians consider bimekizumab to be one of a range of suitable treatments (taking into account availability of biosimilar products, administration costs, dosage, price per dose and commercial arrangements).

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

1.5 Take into account any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI and make any appropriate adjustments.

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 the committee made these recommendations

Bimekizumab is an alternative to other biological treatments already recommended by NICE for treating severe plaque psoriasis in adults. Evidence from clinical trials shows that bimekizumab is more effective than adalimumab, secukinumab and ustekinumab. Indirect comparisons suggest that bimekizumab is similarly or more effective than other biological treatments.

For the cost comparison, it is appropriate to compare bimekizumab with brodalumab, risankizumab and ixekizumab because they work in a similar way and would likely be used as an alternative to those treatments. The total costs associated with bimekizumab are similar to or lower than those associated with brodalumab, risankizumab and ixekizumab. Therefore, bimekizumab is recommended as an option for severe plaque psoriasis that has not responded to systemic non-biological treatments, or if these are contraindicated or not tolerated.

2 Information about bimekizumab

Marketing authorisation indication

2.1 Bimekizumab (Bimzelx, UCB Pharma) has a marketing authorisation 'for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy'.

Dosage in the marketing authorisation

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

Price

2.3 The list price of bimekizumab is £2,443 per 320 mg dose (two 160 mg prefilled syringes or prefilled pens; excluding VAT; price as quoted in company's submission).

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 Committee discussion

The appraisal committee considered evidence submitted by UCB Pharma and a review of this submission by the evidence review group (ERG). See the committee papers for full details of the evidence.

Decision problem

The company's proposed population is consistent with previous NICE recommendations for biological treatments for psoriasis

3.1 The company's proposed population was narrower than bimekizumab's marketing authorisation because it excluded people who had not had systemic non-biological therapy or phototherapy. It considered that bimekizumab would be used in adults as an alternative to other biological therapies for psoriasis, that is in those whose disease has not responded adequately to non-biological systemic treatment or phototherapy, or if these treatments are contraindicated or not tolerated. The committee concluded that the proposed population was consistent with previous NICE recommendations for biological treatments for psoriasis, and in line with its expected use in clinical practice.

Brodalumab, risankizumab and ixekizumab are relevant comparators

3.2 The company presented a comparison with 3 NICE-recommended biological treatments (NICE's technology appraisals on brodalumab, risankizumab and ixekizumab for treating moderate to severe plaque psoriasis). The committee noted in a recent guideline from the British Association of Dermatologists (2020) that all of the currently licensed biological therapies are now equally recommended options after non-biological systemic therapy. The committee was aware that adalimumab biosimilars have been available to the NHS since 2019 and are available at considerable discount (exact prices are confidential and cannot be reported here). But it was told that in clinical practice a TNF inhibitor such as adalimumab was frequently used first, followed by an interleukin (IL) inhibitor. Brodalumab and ixekizumab work in a similar way to bimekizumab because they are all IL-17 inhibitors. Risankizumab, an IL-23 inhibitor, is the most recent biological treatment for psoriasis to be

recommended by NICE. The committee noted that if bimekizumab was recommended it would likely displace other IL inhibitors. It was aware that cost comparison recommendations include a statement to note that if patients and their clinicians consider the intervention to be 1 of a range of suitable treatments, the least expensive should be chosen. The committee agreed that this was consistent with the criteria for a cost-comparison appraisal. It concluded that brodalumab, risankizumab and ixekizumab are relevant comparators, and that they adequately represent the NICE-recommended biological treatments for plaque psoriasis overall.

Definition of response is consistent with other NICE technology appraisal guidance

3.3 The committee recalled that NICE's technology appraisal guidance on risankizumab for treating moderate to severe plaque psoriasis and other biological treatments recommends that treatment should stop if there is an inadequate disease response after an initial treatment period, usually between 12 and 16 weeks. An adequate response is defined as:

- a 75% reduction in the Psoriasis Area and Severity Index score (PASI 75) from when treatment started or
- a 50% reduction in the PASI score (PASI 50) and a 5-point reduction in Dermatology Life Quality Index (DLQI) from when treatment started.

The committee noted that the definition of response to bimekizumab proposed by the company is in line with these criteria. However, it noted that response to bimekizumab should be assessed after 16 weeks, which is the same as timing for risankizumab, whereas disease response to brodalumab and ixekizumab should be assessed after 12 weeks. The committee concluded that definition of response is consistent with other NICE technology appraisal guidance, although timing of this assessment varies slightly between different biological treatments.

Clinical effectiveness

Bimekizumab is more effective than adalimumab, secukinumab and ustekinumab

3.4 Bimekizumab has been studied in 4 randomised controlled trials including a

total of about 2,200 adults with plaque psoriasis. It was directly compared in clinical trials with placebo (BE READY), with placebo and ustekinumab (BE VIVID), with adalimumab (BE SURE) and with secukinumab (BE RADIANT). In these trials, bimekizumab showed higher response rates compared with placebo, ustekinumab, adalimumab and secukinumab for both PASI 90 (90% reduction in PASI score) and PASI 100 (100% reduction in PASI score) at week 16. The committee accepted that the results of these trials showed that bimekizumab was more effective than adalimumab, secukinumab and ustekinumab.

The company's network meta-analyses are suitable for decision making

3.5 The company did a series of network meta-analyses on PASI response rates (50, 75, 90 and 100) and safety outcomes. These compared bimekizumab with all other NICE-recommended biological agents and systemic non-biological treatments. The ERG noted that studies included in network meta-analyses varied considerably in the proportion of patients who had had previous biological therapies. It noted that disease response to subsequent biological treatments may be lower than the level of response achieved by the initial biological therapy. However, it explained that because the proportion of people who had previous biological therapy in bimekizumab trials was at the higher end of the range for the network as a whole, this is unlikely to bias the results in favour of bimekizumab. The ERG also noted that the company had not included DLQI as an outcome in the network meta-analysis. However, it was satisfied that the company's approach was appropriate. The committee accepted the ERG's view, concluding that the network meta-analyses provided by the company was suitable for decision making.

Bimekizumab provides similar or better PASI response rates than other biologicals

3.6 The committee acknowledged that in previous psoriasis appraisals, PASI 75 is the key outcome when deciding whether to continue treatment. It noted that the results of the network meta-analysis suggested that bimekizumab was similarly effective compared with brodalumab, risankizumab and ixekizumab in terms of PASI 75 response. The committee appreciated that PASI 90 and 100 were increasingly becoming important outcomes to patients and were collected

in newer clinical trials. It noted that bimekizumab was more effective compared with brodalumab, risankizumab and ixekizumab in terms of PASI 90 and 100 response. It noted the safety and tolerability outcomes in the company's network meta-analysis and considered that bimekizumab had a similar safety profile to other biologicals for psoriasis. The committee concluded that bimekizumab provides similar or greater benefits than other biological agents including brodalumab, risankizumab and ixekizumab.

More frequent dosing of bimekizumab will be rarely used

3.7 The committee noted that summary of product characteristics states that some patients with body weight 120 kg or more who did not have complete skin clearance at week 16 (PASI100) may improve further if they increase their dosage (320 mg every 4 weeks rather than every 8 weeks). The company explained that only a small proportion of patients in bimekizumab trials had a body weight 120 kg or more, and had not had a PASI 100 response. Also, it explained that this dosing option will not be mandated in label, nor is it anticipated to be standard dosing regimen for patients. The committee recalled that PASI 90 and 100 are important outcomes for patients but PASI 75 was a key outcome when deciding whether to continue treatment. It further noted that between 85% and 90% of people having bimekizumab in the clinical trials had a PASI 90 response and up to 95% of people had a PASI 75 response. It noted people whose disease reached at least a PASI 75 response may not be willing to have their dose increased to achieve PASI 100 because of an increased risk of side effects, or the inconvenience of more frequent dosing. The committee concluded that only a very small number of patients might be eligible for an increased dosage, and only a small proportion of them would be willing to have it.

Cost comparison

The total costs associated with bimekizumab are similar to or lower than those associated with brodalumab, risankizumab and ixekizumab

3.8 The company presented a cost-comparison analysis that modelled the total costs of bimekizumab and the comparators brodalumab, risankizumab and ixekizumab over 10 years. It took into account stopping treatment based on

PASI 75 response rates, which was consistent with the stopping rules specified in previous NICE's technology appraisal guidance. The base-case analysis used the same PASI 75 response rates and applied the same rate of long-term stopping of treatment during maintenance therapy for all treatments. The base-case analysis assumed similar monitoring, safety profile, treatment administration and subsequent therapies for bimekizumab and the comparators, and therefore excluded these costs. That is, the base-case analysis considered only the acquisition costs of bimekizumab and the comparators. The committee accepted the company's base-case model. The committee was aware that there was the possibility for some patients to have more frequent dosing but recalled that this would only happen in very rare circumstances (see section 3.7). Assuming that 10% of patients who are eligible would want to have more frequent dosing had a minimal effect on the cost-comparison results (the results are confidential and cannot be reported here). Considering the confidential patient access schemes for bimekizumab and the comparators, the committee concluded that the total costs associated with bimekizumab were similar to or lower than those associated with brodalumab, risankizumab and ixekizumab (the exact results cannot be reported here because the discounts are confidential).

Bimekizumab is recommended as an option for treating severe plaque psoriasis in adults

3.9 The committee concluded that the criteria for a positive cost comparison were met because:

- bimekizumab provided similar or greater overall health benefits than brodalumab, risankizumab and ixekizumab, and
- the total costs associated with bimekizumab were similar to or lower than the total costs associated with brodalumab, risankizumab and ixekizumab.

The committee therefore recommended bimekizumab as an option for treating plaque psoriasis in adults. It concluded that the recommendations for bimekizumab should be consistent with the company's proposal and NICE's recommendations for other biological therapies, that is:

- if the disease is severe (that is, a PASI of 10 or more and a DLQI of more than 10) and

- when the disease has not responded to other systemic treatments, including ciclosporin, methotrexate and phototherapy, or these options are contraindicated or not tolerated and
- when treatment is stopped at 16 weeks if the psoriasis has not responded adequately.

If patients and their clinicians consider bimekizumab to be one of a range of suitable treatments, for example brodalumab, risankizumab and ixekizumab, the least expensive should be chosen (taking into account administration costs, dosage, price per dose and commercial arrangements).

The PASI and DLQI may not be appropriate for all people with psoriasis

3.10 The committee noted, as in previous NICE technology appraisals on psoriasis, potential equality issues:

- the PASI might underestimate disease severity in people with darker skin
- the DLQI has limited validity in some people and may miss anxiety and depression.

The committee concluded that, when using the PASI, healthcare professionals should take into account skin colour and how this could affect the PASI score and make the clinical adjustments they consider appropriate. Also, it concluded that, when using the DLQI, healthcare professionals should consider any physical, psychological, sensory or learning disabilities, or communication difficulties that could affect the responses to the DLQI, and make any adjustments they consider appropriate.

4 Implementation

4.1 Section 7(6) 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 fast track appraisal process, NHS England and commissioning groups have agreed to provide funding to implement this guidance 30 days after publication. 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.

4.2 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 moderate of sever plaque psoriasis 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.

5 Appraisal committee members and NICE project team

Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee B.

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.

The minutes of each appraisal committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each technology appraisal is assigned to a team consisting of a health technology assessment analyst (who acts as technical lead for the appraisal), a health technology assessment adviser and a project manager.

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Accreditation