Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey Places & associated partner organisations.

NICE Technology Appraisals: Local implementation

NICE TA Guidance name and number	Bimekizumab for treating moderate to severe plaque psoriasis Technology appraisal guidance 723		
Available at	Overview | Bimekizumab for treating moderate to severe plaque psoriasis | Guidance | NICE		
Date of issue	1st September 2021	**Implementation deadline**	1st October 2021 **Fast track appraisal**

Medicine details	
Name, brand name and manufacturer[2]	Bimekizumab (Bimzelx®). UCB Pharma Limited
Mode of action[2]	Bimekizumab is a humanised IgG1monoclonal antibody produced in a genetically engineered Chinese hamster ovary (CHO) cell line by recombinant DNA technology. It selectively binds with high affinity to IL-17A, IL-17F and IL-17AF cytokines, blocking their interaction with the IL-17RA/IL-17RC receptor complex. Elevated concentrations of IL-17A and IL-17F have been implicated in the pathogenesis of several immune-mediated inflammatory diseases including plaque psoriasis. Bimekizumab inhibits these proinflammatory cytokines, resulting in the normalization of skin inflammation and as a consequence improvement in clinical symptoms associated with psoriasis. From *in vitro* models, bimekizumab was shown to inhibit psoriasis-related gene expression and cytokine production to a greater extent than inhibition of IL-17A alone
Licensed indication[2]	Bimzelx is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.
Formulation[2]	Each pre-filled pen or syringe contains 1b0 mg of bimekizumab in 1 mL solution. Subcutaneous injection. If possible, areas of the skin that show psoriasis should be avoided as injection sites.
Usual dosage[2]	The recommended dose for adult patients with plaque psoriasis is 320 mg (given as 2 subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. Consideration should be given to discontinuing treatment in patients who have shown no improvement by 16 weeks of treatment. For some patients with a body weight ≥ 120 kg who did not achieve complete skin clearance at week 16, 320 mg every 4 weeks after week 16 may further improve treatment response
Comparison with NICE TA use[1],[2]	The NICE TA is narrower than the marketing authorisation because it excluded people who had not had systemic non-biological therapy or phototherapy. 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. The NICE costing template uses the 320mg dose to estimate impact. It does include consideration of increased frequency possibly required for those over 120kg however, the guidance notes: • 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 NICE assumed 10% of patients initiated may want to have increased frequency dosing ***QUESTION for consultation: Can clinicians comment on the likely number of patients? Should routine access to the increased frequency be available or require additional sign off?***

Disease and potential patient group	
Brief description of disease[2,3]	**https://patient.info/skin-conditions/psoriasis-leaflet** Psoriasis is a common condition where there is inflammation of the skin. It typically develops as patches (plaques) of red, scaly skin. Once it develops psoriasis it tends to come and go throughout life. A flare-up can occur at any time. The frequency of flare-ups varies. There may be times when psoriasis clears for long spells. However, in some people the flare-ups occur often. Psoriasis is not due to an infection. It cannot be passed on to other people and it does not turn into cancer. The severity of psoriasis varies greatly. In some people it is mild with a few small patches that develop and are barely noticeable. In others, there are many patches of varying size. In many people the severity is somewhere between these two extremes. However, with an early diagnosis and appropriate treatment, it's possible to slow down the progression of the condition and minimise or prevent permanent damage to the joints.
Potential patient numbers per 100,000[4]	NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or approximately £9,000 per 100,000 population, based on

a population for England of 56.3m people).
This is because the technology is a further treatment option and is available at a similar price

Recommendation of NICE TA 711 for Surrey Heartlands CCG	% of people	Number of people
Total population for area selected (all ages)		1,049,170
Adult population		815,884
Prevalence of psoriasis	1.75%	14,278
Proportion with plaque psoriasis	90%	12,850
Number of people eligible for treatment	2.55%	**323**

Table 1: NICE resource planner – potential number of patients eligible for bimekizumab as per NICE TA723, for NHS Surrey Heartlands CCG.

Potential adult patient numbers: 40/100,000 population for any biologic treatment (this will be 14th available)

SUMMARY

Guidance[1]

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

Cost implications* [2,3,4]

Cost:
The cost of 320mg injection of bimekizumab is £2,443 (excluding VAT[1]). 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. The PAS price only applies to trusts

Annual or monthly cost per patient:
The recommended dose of bimekizumab is 320 mg by subcutaneous injection at weeks 0, 4, 8, 12 and 16, followed by a maintenance dose every 8 weeks.

8 weekly administration:

Annual costs – list price	No of doses	Annual cost
Year 1	10	£23,209
Year 2 onwards	7	£15,880

Has dose escalation been considered as part of the NICE costing template?
No – There may be small use of increased frequency in patients over 120kg that did not show response at 16 weeks. Clinical network has been asked to advise on likelihood.

Costing information per place:
No significant resource impact is anticipated.

NICE do not expect this guidance to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year (or £9,000 per 100,000 population).

This is because the technology is a further treatment option, and the overall cost of treatment will be similar.

Based on current local growth assumptions which indicate continued use of adalimumab in new patients the estimated resource impact for NHS Surrey Heartlands CCG at year 5 is negative £38,000. This does not reach the £100K threshold for an APC decision.

N.B Accuracy of data available to populate NICE costing template should be heavily caveated specifically in terms of activity which cannot be easily obtained. We have used new requests received on Blueteq to estimate the proportion of patients on each drug.

Availability of homecare service (if appropriate):
Yes.

Alternative treatments and cost per patient per year

Other NICE recommended products:

TNF-Alpha inhibitors
- adalimumab, etanercept, infliximab & certolizumab

Fumaric Acid Ester
- dimethyl fumarate

Phosphodiesterase (PDE4) inhibitor
- apremilast

Interleukin 17RA inhibitor
- brodalumab

Interleukin 17 inhibitor
- secukinumab & izekizumab [& now bimekizumab]

Interleukin (IL)23 protein
- guselkumab, tildrakizumab & risankizumab

Interleukin (IL)12/23 inhibitor
- ustekinumab

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

Current high cost drug pathway and guidance for drug choice available on PAD here: FINAL Psoriasis Biologic pathway Dec 20.pdf (res-systems.net)

Impact to patients

- An additional treatment option but of similar class to secukinumab and ixekinumab.
- NICE accepted trial results indicating that bimekizumab was more effective (for PASI 90 and PASI 100) than adalimumab, secukinumab and ustekinumab
- The committee concluded that bimekizumab provides similar or greater benefits than other biological agents including brodalumab, risankizumab and ixekizumab
- Available under a homecare service so will be delivered directly to the patient.

Impact to primary care prescribers

- This is a PbRe drug and is commissioned by CCGs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving bi,ekizumab and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

Impact to secondary care

- The initiation, administration and on-going treatment is managed by secondary care.
- Homecare arrangements will be managed by the trust.
- An additional treatment option but of similar class to secukinumab and ixekinumab
- Blueteq forms for initiation and continuation will need to be completed by dermatology specialists.

Impact to CCGs

- The technology is commissioned by clinical commissioning groups (CCGs) and they are required to comply with the recommendations in a NICE TA within 30 days of its date of publication – for this NICE TA this is **1st October.**
- Providers are NHS hospital trusts.
- No potential savings as bimekizumab is another treatment option within a large group of existing choices.

• Revision of the psoriasis pathway will be required – due for discussion at dermatology network on 30th September
Implementation

• NICE TA implementation must be within 30 days of publication – APC is outside of this deadline
• Blueteq forms to be developed.
• Trusts to follow internal governance procedures to add to their formulary and initiate. Homecare.
• Pathway to be discussed at Dermatology Network. Other points for consideration:
  ○ Choice of drug within the IL-17 class
  ○ Number of patients over 120kg and need to increase dosing frequency

Recommendation to APC
PbRe: Yes **Recommended traffic light status (see attached guidelines):** Red – This is a drug excluded from tariff AND is only available at discounted price through acute providers

References:

1 Bimekizumab for treating moderate to severe plaque psoriasis. Technology appraisal guidance 723. Available at: Overview | Bimekizumab for treating moderate to severe plaque psoriasis | Guidance | NICE Accessed <08.09.21>

2 eMC. Bimzelz 160mg solution for injection in pre-filled pen. Specification of Product Characteristics. Available at: Bimzelx 160 mg solution for injection in pre-filled pen - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) Accessed <08.09.21>

3 What is psoriasis? Patient Platform Ltd. Available at: https://patient.info/health/psoriasis-leaflet

	Name	Role	Date	Declaration of interests (please give details below table)
Prepared by	Sarah Watkin	Associate Director Pharmaceutical Commissioning	08/09/2021	None
Reviewed by:				

Explanation of declaration of interest:
N/A