Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Bimekizumab for treating active psoriatic arthritis TA916		
Available at	https://www.nice.org.uk/guidance/TA916		
Date of issue	4th October 2023	**Implementation deadline**	30 days – 3rd Nov

Medicine details[1]	
Name and brand name	Bimekizumab (Bimzelx)
Manufacturer	UCB Pharma
Mode of action	Bimekizumab, a biologic treatment, specifically targets IL-17A & IL-17F, and is designed to selectively block both IL-17A and IL-17F. This prevents the activation of the subsequent inflammatory cascade, thereby reducing inflammation associated with PsA and the associated symptoms.
Licenced indication	Bimzelx, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adults who have had an inadequate response or who have been intolerant to one or more disease-modifying antirheumatic drugs (DMARDs).
Formulation	Solution for injection (injection). The solution is clear to slightly opalescent and, colourless to pale brownish-yellow.
Dosage	The recommended dose for adult patients with active psoriatic arthritis is 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the recommended dose is the same as for plaque psoriasis [320 mg (given as 2 subcutaneous injections of 160 mg each) at Week 0, 4, 8, 12, 16 and every 8 weeks thereafter]. After 16 weeks, regular assessment of efficacy is recommended and if a sufficient clinical response in joints cannot be maintained, a switch to 160 mg every 4 weeks can be considered. No dose increase is licenced for overweight patients (body weight ≥120 kg) with PsA, however the licence states overweight patients with PsA with coexistent moderate to severe PSO may increase their dose if there is an insufficient response after 16 weeks

Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2]	NICE TA recommends the same dosage as the SPC (at time of publication of the TA). However, the NICE resource impact template at time of publication only considered cost comparison at a dose of 160mg monthly. This is the dose for patients with psoriatic arthritis only and does not account for those psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis. This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations[2]

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.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.
This NICE TA has been assigned an implementation deadline that is fast tracked to 30 days.
The implementation deadline is 3rd November 2023

Clinical effectiveness

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.

Patient safety

- The product should be used within its product licence.
- Bimekizumab is a Black Triangle drug – please note that the black triangle symbol is applicable to all new drugs, and requires that all suspected reactions be reported to MHRA. The triangle is usually in place for 5 years (but can be longer if needed).

Patient factors

- An additional treatment option would be valued by patients, however, there are 2 other IL17 inhibitors already in the available pathway, so does not constitute a novel mode of action or a new line of treatment
- Bimekizumab is usually used as a single subcutaneous injection self-administered by the patient on a monthly basis.
- This medicine is available under a homecare service so will be delivered directly to the patient. When the patient is confident in self-administering, this may reduce the number of hospital appointments to those required for review and/or monitoring.
- Patients must adhere to the storage requirements; bimekizumab is available in a pre-filled syringe, and needs to be stored in a refrigerator (2°C – 8°C), and not allowed to freeze. The pre-filled syringe must be kept in the outer carton in order to protect from light. The pre-filled syringe may be stored at room temperature (up to 25°C) for a single period of maximum 25 days with protection from light. Once removed from the refrigerator and stored under these conditions, discard after 25 days or by the expiry date printed on the container, whichever occurs first. A field for the date is provided on the carton to record the date removed from the refrigerator.
- Patients would need to be reviewed on a regular basis by the prescribing clinician to ensure concordance, monitor for adverse effects and efficacy.

Environmental impact

- Additional packaging will be generated and will be an environmental impact with regards to waste management.
- Homecare deliveries – patients' home (additional carbon – increase air pollution)
- Discharge into wastewater (post metabolism unknown effect)
- Sharps waste requires safe collection and disposal

Equality & diversity

No equality or social value judgement issues were identified by the NICE TA committee, however ICB implications are as follows:

- Paediatric population - The safety and efficacy of bimekizumab in children and adolescents below the age of 18 years have not been established. No data are available.
- Patient with learning or physical disabilities may not be able to self-inject.
- Religion/Beliefs/Vegan – drug is of biologic origin. It is also worth pointing out that no medicines are 100% vegan friendly as they will have been tested on animals at some point.

Note: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

Bimekizumab, as an IL17 inhibitor, belongs to the same class of drugs as secukinumab and ixekizumab and therefore will not constitute a new line of treatment, and in the PsA pathway which will be updated accordingly

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet.

Cost-effectiveness

The drug cost per Place according to NICE resources does not exceed £100,000.

Section 1: cost of the technology
Annual cost per patient

Costs in secondary care:
The list price of bimekizumab is £2443 for 2x 160mg/1ml pre-filled syringe (Hospital only) minus VAT if supplied via homecare.
Annual treatment costs (NICE assumed 13 doses per year) – £15,879.50 (using list price above) +/- VAT

Availability of CAP/PAS price:
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.

Price relative to comparable medicines:

The NICE resource impact statement says that the comparators are ixekizumab and secukinumab.
At CAP/PAS cost (and depending on the dose) secukinumab is the most cost effective, followed by bimekizumab and then ixekizumab. At high dose secukinumab is the most expensive.

Section 2: NICE resource impact statement and template
Potential patient numbers per 100,000: 7 per 100,000 (72 in the Surrey Heartlands ICS geography)

a. NICE resource impact statement

We expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 56.6 million people).

This is because the technology is a further treatment option and is available at a similar price to the current treatment options. Bimekizumab works in a similar way to ixekizumab and secukinumab, and would be offered to the same population.

Bimekizumab and the other treatment options have discounts that are commercial in confidence.

A resource impact template is provided for completion at a local level. This is because there are numerous treatment options that are recommended by NICE for treating active psoriatic arthritis.

Bimekizumab is commissioned by integrated care boards. Providers are NHS hospital trusts.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

b. NICE resource impact template

Drug costs for Surrey Heartlands: Does this exceed the £100,000 per Place threshold? No

NICE costing template assumes that only 72 patients in the Surrey Heartlands geography will be eligible for using bimekizamab using the criteria stipulated in the TA over the next 5 years.

To date only 3 Surrey Heartlands patients have applied for a 4th line treatment, which are all proposed and discussed via the APC-agreed SH Rheumatology Network MDT process.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme
Yes

Recommended traffic light status and rationale:
RED – Specialist ONLY drugs - treatment initiated and continued by specialist clinicians.

PAD definitions, available at: Traffic Light Status (res-systems.net)

Implementation

NICE TA implementation must be within 30 days of publication.

Actions to implement:
Primary care

- This is a National Tariff excluded high-cost drug and is commissioned by ICSs. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine 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.

Secondary care

- Providers are NHS hospital trusts.
- Trusts to follow internal governance procedures to add to their formulary and initiate homecare.
- The initiation, administration and on-going treatment is managed by secondary care.
- Specialists will be required to notify the high-cost drugs teams of initiation and response to treatment using the Blueteq® system.
- Homecare arrangements will be managed by the trust.

ICS

- This technology is commissioned by integrated care systems.
- Pathway to be discussed with Rheumatology Network Group to consider its place in Psoriatic arthritis Pathway

PAD and Joint Formulary

• Remove Psoriatic arthritis Pathway from all treatments for this condition from PAD and replace with revised pathway. • New PAD profile for bimekizumab will be required.
Proposed tick box forms
Blueteq® forms have been developed.

References:

1 Summary of Product Characteristics. emc. Available at: https://www.medicines.org.uk/emc/product/12833/smpc#gref Accessed 09/10/2023

2 NICE Technology Appraisal Guidance: https://www.nice.org.uk/guidance/TA916 Available at: Accessed 09/10/2023

3 NICE Resource Impact Report: https://www.nice.org.uk/guidance/TA916 Available at: Accessed 09/10/2023

4 NICE Resource Impact Template: https://www.nice.org.uk/guidance/TA916 Available at: Accessed 09/10/2023

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	G. Randall	Senior Pharmacy Technician	09/10/2023	None
Supported by				
Reviewed by				

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1	09/10/23	G. Randall	Draft	Out for consultation
			Final	Out for clinical comment

Blueteq® form: