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 axial spondyloarthritis Technology appraisal guidance TA918		
Available at	https://www.nice.org.uk/guidance/ta918		
Date of issue	11 October 2023	**Implementation deadline**	30 days (11 November 2023) – will be in breach

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.
Licensed indication	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'.
Formulation	[At time of NICE publication] Bimzelx 160 mg solution for injection
Dosage	[At time of NICE publication] The recommended dose for adult patients with axial spondyloarthritis is 160 mg (given as 1 subcutaneous injection) every 4 weeks. For above indications, consideration should be given to discontinuing treatment in patients who have shown no improvement by 16 weeks of treatment.
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). This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the license 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 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.

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.

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 11th November 2023. Please note; that the ICB is technically in breach of this deadline at time of APC.

Clinical effectiveness

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 that 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.

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; bimekizamab 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 axial spondyloarthritis pathway(s) 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.
A cost comparison suggests bimekizumab has lower costs than ixekizumab but higher costs than secukinumab.
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.

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

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

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 Axial Spondyloarthritis pathway(s).

PAD and Joint Formulary

- Remove Axial Spondyloarthritis pathway(s) 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 Accessed 17/10/2023

2 NICE Technology Appraisal Guidance: . Available at: https://www.nice.org.uk/guidance/ta918 Accessed 17/10/2023

3 NICE Resource Impact Report: . Available at: https://www.nice.org.uk/guidance/ta918 Accessed 17/10/2023

4 NICE Resource Impact Template: . Available at: https://www.nice.org.uk/guidance/ta918 Accessed 17/10/2023

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	G. Randall	Senior Pharmacy Technician, MRU	17/10/23	None
Supported by				
Reviewed by	Tejinder Bahra	Lead MRU Pharmacist	31.10.23	None

Explanation of declaration of interest:
None.

Version control sheet:

Version	Date	Author	Status	Comment
1	17/10/23	G. Randall	Draft	Out for consultation
			Final	Out for clinical comment

Blueteq® form: