BIMZELX®▼
(bimekizumab)

Business case and formulary application template

For local adaption or use

Indications covered in this document:

Psoriatic arthritis: Bimekizumab, 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). **Non-radiographic axial spondyloarthritis (nr-axSpA):** Bimekizumab 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). **Ankylosing spondylitis (AS, radiographic axial spondyloarthritis):** Bimekizumab is indicated for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.

For details of other indications, please consult the summary of product characteristics.

Purpose of this document

The business case and formulary application template is intended for use by clinicians in the NHS. It provides some suggested answers to common questions that appear on local NHS formulary application forms. It also includes information to support business case creation.

Further information is available from the UCB Medical Information department:

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▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. See section 4.8 of the Summary of Product Characteristics for how to report adverse reactions. Email: UCBCares.UK@UCB.com or 0800 2793177

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Ireland: Adverse events should be reported to the HPRA Pharmacovigilance either by phone +353 1 6764971 or via the website at www.hpra.ie Adverse events should also be reported to UCB Pharma Ltd.

Prescribing Information and adverse event reporting can be found at the end of this document.

This document has been produced by UCB Pharma Ltd

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Inspired by patients. Driven by science.

Contents

Abbreviations

ACR	American College of Rheumatology
ACR 20	American College of Rheumatology 20% improvement criteria
ACR 50	American College of Rheumatology 50% improvement criteria
Anti-TNFs	Anti-tumor necrosis factors
ASDAS	Ankylosing Spondylitis Disease Activity Score
AS	Ankylosing spondylitis (also known as radiographic axial spondyloarthritis)
ASAS 40	Assessment in SpondyloArthritis International Society ≥40% improvement
ASDAS LDA	Ankylosing Spondylitis Disease Activity Score low disease activity
ASAS-PR	Assessment in SpondyloArthritis International Society partial remission criteria
b/tsDMARD	biological/targeted synthetic disease-modifying antirheumatic drug
BASDAI	Bath Ankylosing Spondylitis Disease Activity Index
BASFI	Bath Ankylosing Spondylitis Functional Index
BSA	Body surface area
BRITSpA	British Society for Spondyloarthritis
BKZ	Bimekizumab
CAP	Commercial Access and Pricing
CI	Confidence interval
CrI	Credible interval
CRP	C-reactive protein
COVID-19	Coronavirus Disease 2019
CYP	Cytochrome
DAPSA	Disease Activity Index for Psoriatic Arthritis
DMARD	Disease-modifying antirheumatic drug
e.g.	For example
EQ-5D VAS	European Quality of Life-Five Dimensions Visual Analogue Score
FE	fixed effect
GP	General practitioner
GIRFT	Getting It Right First Time
GMMMG	Greater Manchester Medicines Management Group
HS	Hidradenitis suppurativa
IGA	Investigator's global assessment
IgG	Immunoglobulin G
IL	Interleukin
MDA	Minimal Disease Activity
mg	milligrams
mL	millilitres
MDT	Multidisciplinary team

MRI	Magnetic Resonance Imaging
MRI-SIJ	Magnetic Resonance Imaging of the Sacroiliac Joints
mNY	modified New York
MTX	Methotrexate
NHS	National Health Service
NMA	Network Meta-analysis
NICE	National Institute for Health and Care Excellence
nr-axSpA	Non-radiographic axial spondyloarthritis
NSAIDs	Non-steroidal anti-inflammatory drugs
NASS	National Axial Spondyloarthritis Society
OR	Odds ratio
PAS	Patient Access Scheme
PASI	Psoriasis Area and Severity Index
PASI 90	Psoriasis Area and Severity Index 90% improvement
PASI 100	Psoriasis Area and Severity Index 100% improvement
PIFU	Patient Initiated Follow Up
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PsARC	Psoriatic Arthritis Response Criteria
Q4	Quarter 4
QW4	Every 4 weeks
RE	Random effects
RTT	Referral to treatment
RCTs	Randomised controlled clinical trials
SAEs	Serious adverse events
SLR	Systematic literature review
SMC	Scottish Medicines Consortium
TA	Technology Appraisal
TEAEs	Treatment emergent adverse events
TNF	Tumor necrosis factor
TNFi	Tumor necrosis factor inhibitor
TNFi-exp	Tumour necrosis factor inhibitor experienced patients
UK	United Kingdom
US	United States of America
vs.	Versus
PSO	Plaque psoriasis
PsA	Psoriatic arthritis
axSpA	Axial spondyloarthritis
r-axSpA	Radiographic axial spondyloarthritis
nr-axSpA	Non-radiographic axial spondyloarthritis

How to use this document

This document is intended to provide a starting point for healthcare professionals wishing to submit a local formulary application or business case for bimekizumab in the treatment of psoriatic arthritis or axial spondyloarthritis.(UCB Pharma Limited BIMZELX SmPC)

Formulary support

Local formulary applications can vary in their structure and wording, but generally they will require the following medicine information:(NICE, 2015)

- General medicine details (indication, dose, administration, mechanism of action etc.)
- Evidence submission with relevant supporting literature, including efficacy, safety and cost effectiveness
- Comparison with existing treatments
- Likely place in therapy, including recommendations for displacement of current formulary medicines if applicable
- Resource impact, including the likely local patient population

This document provides information and guidance to help support your application. Some sections provide general information which can be used directly in local formulary packs or business cases if applicable, but other sections will require customisation according to the demographics and priorities of your local area.

You must check that all information included in your applications is up to date, relevant, and consistent with the expected format of the local formulary application (e.g., use of generic drug names, abbreviations, referencing style etc.)

It is your responsibility to declare conflicts of interest appropriately where required.

Key:	
Grey text	Suitable for direct inclusion in a local formulary application, provided the information is up to date and relevant. May require formatting for consistency
Mid blue text	Requires customisation prior to inclusion
Dark violet text	Provides guidance on what the application form is asking for and how to approach filling the section in

Executive summary

Reasons for change in rheumatology care	• Many patients do not achieve stringent outcomes across symptom domains despite treatment with current biologic options(Zardin-Moraes et al, 2020) • There is a need for new treatments that allow patients to reach stringent outcomes regardless of prior biologic use • Preventing structural damage remains an important treatment goal and unmet need in patients with PsA and/or axSpA(Van Der Heijde et al, 2020, Coates et al, 2022c, Gossec et al, 2020, Protopopov et al, 2018)
NHS rheumatology services – drivers for change	Across the four nations of the UK, NHS rheumatology services are suffering from a lack of capacity and long waiting lists.(NHS England, 2023a, Department of Health and NISRA, 2022, NHS Inform, 2023, Welsh Government, 2023b) Drivers for change include the NHS Long-Term Plan, integrated care system priorities, the Getting It Right First Time rheumatology report, Patient Initiated Follow-up and the need to transform planned and outpatient care.(NHS England, 2019, NHS England, 2023c, Kay L et al, 2021, National Axial Spondyloarthritis Society, 2023, Welsh Government, 2023a)
Bimekizumab	Bimekizumab's selective dual IL-17A & F inhibition results in normalisation of skin inflammation and as a consequence improvement in clinical symptoms associated with psoriasis, psoriatic arthritis, and axSpA(UCB Pharma Limited BIMZELX SmPC) **NICE recommendations:** **Psoriatic arthritis:(NICE, 2023a)** 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 DMARDs or who cannot tolerate them. It is recommended only if they have had 2 conventional DMARDs and: • at least 1 biological DMARD or • anti-TNFs 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. **axSpA:(NICE, 2023b)** Bimekizumab is recommended as an option in adults for treating active AS when conventional therapy has not worked well enough or is not tolerated, or active nr-axSpA with objective signs of inflammation (shown by elevated CRP or MRI) when NSAIDs, have not worked well enough or are not tolerated. It is recommended only if: • anti-TNFs are not suitable or do not control the condition well enough, and

	• the company provides it according to the commercial arrangement As positive recommendations have been made through the NICE fast track appraisal process, NHS England commissioners must provide funding for within 30 days of guidance publication.[(NICE, 2023c)] In Wales, funding must be available within 60 days from Final Appraisal Determination (FAD).[(Welsh Government, 2022)] **Service implications of bimekizumab include:** • Suitability for Patient Initiated Follow Up • A flexible dosing option for patients with PsA and coexistent moderate to severe plaque psoriasis[(UCB Pharma Limited BIMZELX SmPC)] • Simple dosing in axSpA, without the need for a loading dose or dose escalations[(UCB Pharma Limited BIMZELX SmPC)] • Self-administration • No additional blood monitoring requirements as per the SmPC[(UCB Pharma Limited BIMZELX SmPC)]

Evidence of efficacy	The results from Phase 3 trials support previous findings showing the clinical effectiveness and tolerability of dual inhibition of IL-17A and IL-17F with bimekizumab in patients with active psoriatic arthritis and axSpA. Bimekizumab demonstrated consistent efficacy and tolerability across biologic naïve and biologic experienced patients with active psoriatic arthritis and breadth of efficacy across joint and skin outcomes.[(Merola et al, 2023, McInnes et al, 2023)] Bimekizumab demonstrated efficacy across the full spectrum of axSpA in patients with non-radiographic and radiographic axSpA.[(van der Heijde et al, 2023)]
	
	PsA
	• Bimekizumab demonstrated rapid efficacy across joint and skin outcomes[(McInnes et al, 2023, Merola et al, 2023)]
	• Both trials met their primary endpoints[(Merola et al, 2023, McInnes et al, 2023)]
	  ○ BE OPTIMAL: At Week 16, biologic-naïve patients receiving bimekizumab were significantly more likely to meet the primary endpoint of ACR 50 than those receiving placebo (44%, n=189/431 vs. 10%, n=28/281 *P*<0.0001)[(McInnes et al, 2023)]
	  ○ BE COMPLETE: Patients with previous anti-TNF treatment failure or intolerance receiving bimekizumab had significantly higher ACR 50 response rates compared with placebo at Week 16 (43%, n=116/267 vs. 7%, n=9/133 *P*<0.0001)[(Merola et al, 2023)]
	• Almost half (47%) of all biologic naïve bimekizumab-treated patients with baseline psoriasis affecting 3% or more BSA had complete skin clearance (PASI 100) at Week 16 (47%, n=103/217 vs. 2%, n= 3/140, nominal *P*<0.001)[(McInnes et al, 2023)]
	• 59% of bimekizumab-treated biologic inadequate response patients with baseline psoriasis affecting 3% or more BSA had complete skin clearance (PASI 100) at Week 16 (n=103/176 vs. 5%, n=4/88, nominal *P*<0.001)[(Merola et al, 2023)]

	• Bimekizumab demonstrated efficacy in complete resolution of clinical manifestations of PsA at Week 16 regardless of prior biologic treatment(McInnes et al, 2023, Merola et al, 2023) ○ 50% (n=124/249) of bimekizumab-treated patients with enthesitis at baseline experienced complete resolution, which was significant compared with placebo (35%, n=37/106, OR: 1.9 95% CI: 1.2 to 3.1, *P*=0.0012) ○ 76% (n=68/90) of bimekizumab-treated patients with dactylitis at baseline experienced complete resolution, which was significant compared with placebo (51%, n=24/47, OR: 3.4 95% CI: 1.6 to 7.6, *P*=0.0022) • Treatment responses with bimekizumab were sustained for up to 2 years(Coates et al, 2024) ○ Around half of patients achieved minimal disease activity (36.8%-52.4%) and DAPSA remission or low disease activity (46.4%-52.9%) with bimekizumab in open-label extension for up to 2 years(Coates et al, 2024) **axSpA** • Bimekizumab demonstrated rapid efficacy which was superior to placebo across disease domains in both nr-axSpA and radiographic axSpA(van der Heijde et al, 2023) ○ At Week 16, significantly more nr-axSpA patients achieved ASAS 40 compared with placebo (47.7% [n=61/128]) vs. 21.4% (n=27/126) respectively, difference 27.0, 95% CI 15.6 to 38.4, *P*<0.001, primary endpoint). By Week 24, this had increased to 52.3% (n=67/128) in bimekizumab-treated patients(van der Heijde et al, 2023) ○ At Week 16, significantly more r-axSpA patients achieved ASAS 40 compared with placebo (44.8% [n=99/221]) vs. 22.5% (n=25/111) respectively, difference 21.8, 95% CI 11.4 to 32.1, *P*<0.001, primary endpoint). By Week 24, this had increased to 53.8% (n=67/221) in bimekizumab-treated patients(van der Heijde et al, 2023) • Treatment responses with bimekizumab were sustained for up to 2 years(Baraliakos et al, 2024a) ○ At Week 104 patients (nr-axSpA n=189 and r-axSpA n=267) achieved; ASAS40 (nr-axSpA 49.2%; r-axSpA 53.9%), low disease activity (ASDAS <2.1, nr-axSpA 61.2%; r-axSpA 63.4%), inactive disease (ASDAS <1.3, nr-axSpA 31.3%; r-axSpA 31.6%)(Baraliakos et al, 2024a) ○ 85.3% of r-axSpA patients (n=190) had no spinal radiographic progression (mSASSS ≤0.5) with bimekizumab at Week 104(Baraliakos et al, 2024b) • Bimekizumab demonstrated efficacy in complete resolution of clinical manifestations of axSpA at Week 16(van der Heijde et al, 2023) ○ In nr-axSpA patients with enthesitis at baseline, 51.1% (n=48/94) of bimekizumab-treated patients experienced complete resolution at Week 16(van der Heijde et al, 2023) ○ In r-axSpA patients with enthesitis at baseline, 51.5% (n=68/132) of bimekizumab-treated patients experienced complete resolution at Week 16. In placebo-treated patients the proportion was 32.8% (n=22/67)(van der Heijde et al, 2023)

Indirect evidence[*] from a network meta-analysis	• Bimekizumab was associated with consistent high skin clearance, ranking 1st among 11 treatments in biologic-naïve PsA patients for PASI 100. Bimekizumab ranked 1st among 13 treatments in biologic naïve patients for MDA and it was comparable to other available treatments in joint outcomes(Mease PJ et al, 2023) • Bimekizumab was associated with significantly higher response rates compared with secukinumab 150 mg in AS (ASAS 40 and ASAS-PR) and ranked highly in nr-axSpA. Bimekizumab was associated with similar response rates compared with other biologics across remaining outcomes at Week 12-16(Deodhar A et al, 2023) **Important note:** • Other network meta-analyses exist which differ in their methodology and study inclusion which may show different statistical differences between different biologics • There are limited numbers of head-to-head randomised controlled clinical trials that exist for IL-17, IL-23, and IL-12/23 inhibitor therapies • The network meta-analysis was funded by UCB Pharma
Tolerability	• Bimekizumab was generally well tolerated by patients with PsA and axSpA(UCB Pharma Limited BIMZELX SmPC) • A total of 5,862 patients have been treated with bimekizumab in blinded and open-label clinical studies in plaque psoriasis, psoriatic arthritis and axial spondyloarthritis (nr-axSpA and AS), and hidradenitis suppurativa representing 11,468.6 patient-years of exposure. Of these, over 4,660 patients were exposed to bimekizumab for at least one year. Overall, the safety profile of bimekizumab is consistent across all indications(UCB Pharma Limited BIMZELX SmPC)
Acquisition cost	Each pack of two 160 mg bimekizumab pre-filled pens or syringes costs **£2,443** (NHS list price).(BNF) The annual maintenance cost per patient per year is £15,879.50 for PsA and axSpA, based on a dose of 160 mg Q4W for a total of 13 doses. (NHS list price) The company has a commercial arrangement for bimekizumab in psoriatic arthritis and axial spondylitis, subject to NICE decision. This makes bimekizumab available to the NHS with a discount. The size of the discount is commercial in confidence.

[*] Only UK licensed treatments for active psoriatic arthritis and nr-axSpA & AS are presented from the full NMA. This does not impact the ranking of bimekizumab within the results.(Mease P et al, 2023, Deodhar A et al, 2023)

Reasons for change in rheumatology care

The unmet needs and challenges facing rheumatology services and patients experiencing PsA and axSpA, including healthcare, social, and patient impact

Many patients do not achieve high outcomes across symptom domains despite treatment with current biologic options[(Zardin-Moraes et al, 2020, Mease P et al, 2021)]

PsA

Many patients do not achieve minimal disease activity (MDA) with current treatment options.

- 68% of patients treated with at least one biologic did not achieve MDA at approximately 6 months of follow-up in a meta-analysis. 91% of patients treated with placebo did not achieve MDA[(Zardin-Moraes et al, 2020)]
- When all biological therapies (anti-TNF, IL-17A inhibitors, and IL-12/23i inhibitors) were grouped, the prevalence of PsA patients with MDA status was 32% (95% CI: 27% to 38%, I^2 = 78%) in the biological therapy arm, compared with only 9% of patients with MDA in the placebo group (95% CI: 5% to 15%, I2 = 78%) at roughly 6 months' follow-up[(Zardin-Moraes et al, 2020)]

Many patients do not achieve American College of Rheumatology (ACR) 50 response with current treatment option.

- Between 57% and 85% of patients treated with a DMARD did not achieve ACR 50 response at up to 24 weeks of follow-up in a meta-analysis[(McInnes et al, 2022)]

Achievement of high treatment targets (including ACR 50 and MDA) is associated with greater improvements in quality of life and physical functioning, as well as reduced risk of irreversible structural damage[(Coates et al, 2018, Smolen J et al, 2018, Kavanaugh et al, 2016)]

Patients who experience both joint and active skin symptoms have more severe overall disease and clinical outcomes than those who experience joint-only symptoms, highlighting the importance of addressing both joint and skin manifestations.[(de Vlam et al, 2018)]

In patients with plaque psoriasis, PASI 75 has traditionally been considered a marker of adequate skin clearance response and is still considered so by NICE.[(Abrouk et al, 2017, NICE, 2017b)] Other groups now suggest that more optimistic treatment goals such as PASI 100 should now be considered.[(Strober et al, 2016)]

PASI 100 represents a clinically meaningful, possible end point and outcome for patients, reflected in experiences of no psoriasis symptoms and no impairment on health-related quality of life.[(Strober et al, 2016, Lacour et al, 2020)]

axSpA

Many patients do not achieve ASAS 40 or ASDAS-Inactive disease (ID) results.

- Between 43% and 68% of patients with nr-axSpA did not achieve ASAS 40 response at up to 16 weeks of follow up in a meta-analysis[(Akkoç et al, 2023)]
- ~76–90% patients do not achieve inactive disease (ASDAS<1.3) with existing biologic therapies at one year[(Ørnbjerg et al, 2019, Michelsen B et al, 2020)]

In a real-world database study, adjusted for drug retention according to LUNDEX:

- 27% of patients treated with anti-TNFs were able to achieve inactive disease at 6 months (n=24,195)[(Ørnbjerg et al, 2019)]
- 7% of patients treated with an IL-17A inhibitor were able to achieve inactive disease through to one year (n=1,860)[(Michelsen B et al, 2020)]

Achievement of high treatment targets is associated with greater improvements in QoL and work productivity, as well as reduced risk of irreversible structural damage.[van der Heijde et al, 2016, Llop et al, 2022]

There is a need for new treatments that allow patients to reach high outcomes regardless of prior biologic use

PsA

In clinical studies including **biologic naïve** patients treated with current advanced therapies:[Mease et al, 2005]

- Approximately 45-50% did not achieve ACR 50 after 24 weeks of treatment
- 70% and 58% did not achieve PASI 90 after 12 and 24 weeks of treatment, respectively

In clinical studies including **anti-TNF experienced** patients treated with current advanced therapies:[Mease et al, 2014, Coates et al, 2022a, Nash et al, 2017, Nash et al, 2018, Mease et al, 2018, Ritchlin et al, 2014, Mease et al, 2021]

- >50% did not achieve ACR 50
- 56% to 88% did not achieve PASI 90 at Week 24

Preventing structural damage remains an important treatment goal and unmet need in patients with PsA and/or axSpA[Van Der Heijde et al, 2020, Coates et al, 2022c, Gossec et al, 2020, Protopopov et al, 2018]

PsA

Achieving high treatment targets such as MDA and ACR 50 reduces the risk of radiographic progression compared with uncontrolled disease.[Coates et al, 2018, Smolen J et al, 2018, Kavanaugh et al, 2016, Snoeck Henkemans et al, 2022]

Patients who achieved and sustained minimal disease activity are more likely to see reductions in radiographic progression compared with those who do not achieve minimal disease activity: [Kavanaugh et al., 2016]

- Patients who achieved MDA on ≥ 4 consecutive visits experienced a significant mean change from baseline of -0.80 in psoriatic arthritis–modified Sharp/van der Heijde score through Week 256 (P<0.01 vs. those who never achieved minimal disease activity, n=not reported/20)
- Patients who achieved MDA on ≥ 3 consecutive visits experienced a significant mean change from baseline of -0.78 in psoriatic arthritis–modified Sharp/van der Heijde score through Week 256 (P<0.005 vs. those who never achieved minimal disease activity, n=not reported/25)
- Patients who never achieved MDA experienced a mean change of +1.29 from baseline through Week 256

Based on data from GO-REVEAL (golimumab 50 mg/100 mg group). Mean change in psoriatic arthritis–modified Sharp/van der Heijde score (SHS) from baseline to Week 256.

UK and international guidelines recommend selecting a treatment which addresses as many disease domains as possible[Coates et al, 2022c, Tucker et al, 2022]

Patients with greater skin disease severity show significantly worse overall disease state and clinical outcomes than those with joint-only involvement, highlighting the importance of addressing both joint and skin disease in PsA.[de Vlam et al, 2018, Kavanaugh et al, 2019]

- In a retrospective cross-sectional survey of 637 patients with PsA, those with skin involvement possessed a more severe global clinical profile, and the PsA clinical symptom severity profile positively correlated with skin severity[de Vlam et al, 2018]

- In an integrated post-hoc analysis of two randomised controlled trials, the greatest improvement in health-related quality of life (EQ-5D VAS) was associated with successful treatment of both joint and skin symptoms (100% improvement in DAPSA and PASI scores)(Kavanaugh et al, 2019)

GRAPPA guidelines state that one of the ultimate goals of therapy for all patients with PsA is to achieve the lowest possible level of disease activity in all domains of disease, and accordingly, it is recommended that wherever possible, treatment for an individual with PsA should be selected to address all active domains of the disease and any related conditions.(Coates et al, 2022c)

BSR guidelines recommend utilising a treat-to-target strategy, whereby an individual's disease activity is proactively measured, and treatment escalated accordingly, should be offered to all people with psoriatic arthritis who require treatment. The aim of treatment should be remission, or alternatively low disease activity, considering patient goals, associated conditions and co-morbidities, and non-inflammatory causes of pain.(Tucker et al, 2022)

axSpA

Uncontrolled inflammation is associated with an increased risk of structural progression and up to 40% of patients with nr-axSpA will progress to AS/r-axSpA.(Michelena et al, 2020, Protopopov et al, 2018, Wang et al, 2016)

The control of inflammation in axSpA is important because a potential causal link between objective signs of inflammation (MRI-SIJ and CRP levels) and structural progression has been identified. High CRP levels and chronic inflammation on MRI are both risk factors for structural damage in the sacroiliac joints and spine.(Michelena et al, 2020, Protopopov et al, 2018)

Key NHS drivers and targets in rheumatology

The NHS Long-Term Plan

The NHS Long Term Plan specifically highlighted outpatient appointments as a priority for reform, with a commitment to reduce appointments by one-third across the NHS, saving patients 30 million visits to hospital and saving the NHS over £1 billion.(NHS England, 2019)

Bringing care closer to patients' homes through outpatient redesign was also cited as a priority. This can include improving support to GPs to avoid the need for a hospital referral, online booking systems, appointments closer to home, alternatives to traditional appointments where appropriate including digital appointments and avoiding patients having to travel to unnecessary appointments supports more productive use of consultant time and enables the capacity of outpatient clinics to be used more efficiently.(NHS England, 2019)

ICS priorities

ICSs aim to improve outcomes in population health and healthcare, tackle inequalities in outcomes, experience and access, enhance productivity and value for money, and help the NHS support broader social and economic development.(NHS England, 2023c)

Delays to referral and disjointed care between primary care centres and secondary care can lead to reduced quality of life.(Berendsen et al, 2009, National Axial Spondyloarthritis Society, 2023)

Getting It Right First Time

The rheumatology report identified variations in service provision, related to an imbalance between capacity and demand in many trusts. Referral to treatment (RTT) times for rheumatology outpatients varied from less than five weeks in the best performing trusts to more than 30 weeks in others. Many trusts were not meeting national quality standards for early assessment and treatment of inflammatory arthritis conditions – for example, fewer than half of units achieve target times for assessment and treatment of early inflammatory arthritis.

Recommendations included:(Kay L et al, 2021)

- RTT times for all conditions that require specialist rheumatology care should not exceed eight weeks
- Improving management of referrals
- Improving management of patients being followed up
- Develop alternatives to outpatient attendance
- Consider extended roles across the skills mix
- Improve the quality of rheumatology-specific training

Aspiring to Excellence – driving improvements in axial SpA care

Aspiring to Excellence is a strategic partnership between NASS, BRITSpA, the NHS Transformation Unit and sponsoring companies AbbVie, Biogen, Lilly, Novartis and UCB. It aims to catalyse improvements in rheumatology departments and the wider NHS. It offers rheumatology teams protected time so that they can work on projects that will improve patient experiences.(National Axial Spondyloarthritis Society, 2023)

Patient Initiated Follow Up (PIFU)

PIFU gives patients the flexibility to initiate an appointment when they need one, rather than to a rigid schedule that may not fit their needs. It forms part of the outpatients transformation requirements for trusts as per the Operational Planning Guidance, intended to help manage

waiting lists and to see the patients most in need more quickly, while reducing inconvenience to those who require less care.(NHS England, 2023b)

Wales: Plan to transform planned care

The Welsh Government plan builds on changes to care delivery made during the COVID-19 pandemic to help manage the backlog of appointments and treatments. Goals of the plan are that 35% of all new appointments and 50% of follow-up appointments should be delivered virtually in future.(Welsh Government, 2023a)

The current state of NHS rheumatology services

England

As of January 2023, 65% of rheumatology patients were waiting less than 18 weeks from referral to treatment, which is 27% lower than the operational standard of 92%. Half of patients were waiting less than 13 weeks, and 92% of patients were waiting less than 39 weeks.(NHS England, 2023a)

The GIRFT rheumatology report found variation in how biologics were used for rheumatology indications across England. Some trusts have lower prescription thresholds than others, which will in turn increase these trusts' expenditure. The GIRFT team also found variation in how patients are started on high-cost drugs. In some units, everyone starting biologic treatment goes through a thorough MDT virtual review, while in other trusts the process is less formal.(Kay L et al, 2021)

Wales

As of February 2023, >10,000 patients were waiting to start treatment in rheumatology. Nearly 3,000 of those were waiting ≥26 weeks.(Welsh Government, 2023c)

In efforts to reduce the need for in-person appointments, there has been significant and accelerated investment in digital technology to offer virtual appointments across primary, community and secondary care. Rheumatology services have introduced video group clinics, which allows the clinical team to assess multiple patients together.(Welsh Government, 2023b)

Scotland

The median waiting time for outpatient rheumatology in Scotland is 10 weeks. In Q1 2023, 5,833 patients were awaiting rheumatology treatment.(NHS Inform, 2023)

Northern Ireland

As of June 2022, >20,000 patients were waiting for outpatient rheumatology care, an increase of about 2,000 in one year. Over 13,000 patients had been waiting more than one year, despite a target than no patients should wait longer than 52 weeks for a first outpatient appointment by March 2023.(Department of Health and NISRA, 2022)

Impact of the COVID-19 pandemic

A survey of consultant rheumatologists, speciality trainees, nurse specialists, and allied health professionals in 4 regions of the UK found that one-fifth of the responders reported that their rheumatology departments were functioning less than 50% capacity during the pandemic. Although access to video consultation was available for up to three-fourths of the clinicians, the majority (90%) used this modality in less than 1 in 4 consultations.(Nune et al, 2021)

Medicine details

Approved name

Bimekizumab(UCB Pharma Limited BIMZELX SmPC)

Brand name

BIMZELX(UCB Pharma Limited BIMZELX SmPC)

Form

- Pre-filled syringe: Solution for injection containing 160 mg bimekizumab in 1 mL(UCB Pharma Limited BIMZELX SmPC)
- Pre-filled pen: Solution for injection containing 160 mg bimekizumab in 1 mL(UCB Pharma Limited BIMZELX SmPC)

Excipients:(UCB Pharma Limited BIMZELX SmPC)

- Glycine
- Sodium acetate trihydrate
- Glacial acetic acid
- Polysorbate 80
- Water for injections

Licensed indications

Plaque psoriasis: Bimekizumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.(UCB Pharma Limited BIMZELX SmPC)

Psoriatic arthritis: Bimekizumab, 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). (UCB Pharma Limited BIMZELX SmPC)

Non-radiographic axial spondyloarthritis: Bimekizumab 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).(UCB Pharma Limited BIMZELX SmPC)

Ankylosing spondylitis (AS, radiographic axial spondyloarthritis): Bimekizumab is indicated for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.(UCB Pharma Limited BIMZELX SmPC)

Hidradenitis suppurativa: Bimekizumab is indicated for the treatment of active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.(UCB Pharma Limited BIMZELX SmPC)

Intended dose and route

Bimekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which bimekizumab is indicated.(UCB Pharma Limited BIMZELX SmPC)

Psoriatic arthritis: 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 Week 16 based on clinical response in joints, 160 mg every 4 weeks can be considered. (UCB Pharma Limited BIMZELX SmPC)

Axial spondyloarthritis (nr-axSpA and AS): The recommended dose for adult patients with axial spondyloarthritis is 160 mg (given as 1 subcutaneous injection) every 4 weeks. (UCB Pharma Limited BIMZELX SmPC)

Bimekizumab is administered by subcutaneous injection.(UCB Pharma Limited BIMZELX SmPC)

- Suitable areas for injection include thigh, abdomen, and upper arm. Injection sites should be rotated, and injections should not be given into psoriasis plaques or areas where the skin is tender, bruised, erythematous, or indurated(UCB Pharma Limited BIMZELX SmPC)
- The pre-filled syringe or pen must not be shaken(UCB Pharma Limited BIMZELX SmPC)
- After proper training in subcutaneous injection technique, patients may self-inject with the pre-filled syringe or pen if their physician determines that it is appropriate, and with medical follow-up as necessary(UCB Pharma Limited BIMZELX SmPC)
- Patients should be instructed to inject the full amount of bimekizumab according to the instructions for use provided in the package leaflet(UCB Pharma Limited BIMZELX SmPC)

Expected duration of treatment

Consideration should be given to discontinuing treatment in patients who have shown no improvement by 16 weeks of treatment.(UCB Pharma Limited BIMZELX SmPC)

Manufacturer

UCB Pharma Limited

License status

Licensed product

Mechanism of action

BIMZELX: The first and only approved dual selective inhibitor of IL-17A and IL-17F for use in axSpA and PsA(UCB Pharma Limited BIMZELX SmPC)

Bimekizumab is a humanised IgG1/κ monoclonal antibody that 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.(UCB Pharma Limited BIMZELX SmPC)

IL-17 plays an important role in plaque psoriasis, psoriatic arthritis, and axial spondyloarthritis – with levels of IL17-A and IL17-F often elevated in patients with psoriatic arthritis and axial spondyloarthritis.(UCB Pharma Limited BIMZELX SmPC)

Contraindications

Hypersensitivity to the active substance or to any of the excipients.(UCB Pharma Limited BIMZELX SmPC)

Clinically important active infections (e.g. active tuberculosis).(UCB Pharma Limited BIMZELX SmPC)

Special populations

Overweight patients

For some patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and 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.(UCB Pharma Limited BIMZELX SmPC)

Elderly

No dose adjustment is required.(UCB Pharma Limited BIMZELX SmPC)

Renal or hepatic impairment

Bimekizumab has not been studied in these patient populations. Dose adjustments are not considered necessary based on pharmacokinetics.(UCB Pharma Limited BIMZELX SmPC)

Drug interactions

No interaction studies have been performed.(UCB Pharma Limited BIMZELX SmPC)

There is no direct evidence for the role of IL-17A or IL-17F in the expression of CYP450 enzymes. The formation of some CYP450 enzymes is suppressed by increased levels of cytokines during chronic inflammation. Thus, anti-inflammatory treatments, such as with the IL-17A and IL-17F inhibitor bimekizumab, may result in normalisation of CYP450 levels with accompanying lower exposure of CYP450-metabolised medicinal products. Therefore, a clinically relevant effect on CYP450 substrates with a narrow therapeutic index, in which the dose is individually adjusted (e.g., warfarin) cannot be excluded. On initiation of bimekizumab therapy in patients being treated with these types of medicinal products, therapeutic monitoring should be considered.(UCB Pharma Limited BIMZELX SmPC)

Population pharmacokinetic data analyses indicated that the clearance of bimekizumab was not impacted by concomitant administration of conventional disease modifying antirheumatic drugs including methotrexate, or by prior exposure to biologics.(UCB Pharma Limited BIMZELX SmPC)

Live vaccines should not be given concurrently with bimekizumab.(UCB Pharma Limited BIMZELX SmPC)

For special warnings and precautions for use, please see Page 38.

Proposed place in therapy

Including proposed changes in service provision and proposed patient pathway

Patients:

Psoriatic arthritis:

- **Bimekizumab alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis**† in adults who have not responded to/cannot tolerate DMARDs(UCB Pharma S.A. BIMZELX SmPC, NICE, 2023a)
- Bimekizumab is recommended after **two conventional DMARDs** and at least **one biological DMARD** or if **TNFis are contraindicated**(NICE, 2023a)
- The response to bimekizumab should be assessed **after 16 weeks** of treatment(UCB Pharma S.A. BIMZELX SmPC, NICE, 2023a)
- Treatment should only be continued if **there is clear evidence of a response** (defined as an improvement in **at least 2 of the 4 Psoriatic Arthritis Response Criteria [PsARC])**, one of which must be **joint tenderness or swelling score**, with **no worsening** in any of the four criteria(NICE, 2023a)
- If the **PsARC response is not adequate** but there is **a PASI 75 response**, a dermatologist should decide whether continuing treatment is appropriate based on **skin response**(NICE, 2023a)
- If bimekizumab is considered **one of a range of suitable treatments (including ixekizumab and secukinumab)**, after discussing the advantages and disadvantages of the options, the **least expensive drug** should be used
- Treatment decisions should take account of **administration costs, dosage, price per dose and commercial arrangements**(NICE, 2023a)

axSpA:

- **Bimekizumab is recommended as an option in adults for treating active AS** when conventional therapy has not worked well enough or is not tolerated, or **active nr-axSpA** with objective signs of inflammation (shown by elevated C-reactive protein or MRI) when NSAIDs have not worked well enough or are not tolerated(UCB Pharma S.A. BIMZELX SmPC, NICE, 2023b)
- Bimekizumab is recommended only if anti-**TNFs are not suitable** or do not control the condition well enough(NICE, 2023b)
- The response to bimekizumab should be assessed **after 16 weeks** of treatment(UCB Pharma S.A. BIMZELX SmPC)
- Treatment should only be continued if there is **clear evidence of a response** (defined as a reduction in **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)(NICE, 2023b)
- If bimekizumab is considered **one of a range of suitable treatments,** after discussing the advantages and disadvantages of the options, the **least expensive drug** should be used(NICE, 2023b)
- Treatment decisions should take account of **administration costs, dosage, price per dose and commercial arrangements**(NICE, 2023b)

† Active PsA is defined as peripheral arthritis with three or more tender joints and three or more swollen joints.

Prescribers and clinical responsibility:

Bimekizumab is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of conditions for which bimekizumab is indicated.(UCB Pharma Limited BIMZELX SmPC)

Suggested Red-Amber-Green rating: Red (Hospital only)

Check what ratings are used in your local area, and ensure you use similar wording. Check what rating your local area has applied to similar treatments.

Example wording (GMMMG): Drugs considered to be specialist medicines and prescribing responsibility for these medicines should normally remain with the consultant or specialist clinician. These drugs should not be initiated or prescribed in primary care. It is recommended that the supply of these specialist medicines should be organised via the hospital pharmacy, this may include arranging for supply via a home care company.(GMMMG, 2021)

Shared care/transfer of care is not anticipated.

Place in treatment pathway:

Bimekizumab provides an additional treatment option for patients with PsA or axSpA who are candidates for systemic therapy.

Evidence summary

PsA

For more information on trial designs, please see the appendix.

The clinical trial programme for bimekizumab in psoriatic arthritis consists of two double-blind phase III randomised controlled trials that enrolled over 1,200 patients spanning biologic naïve and previous treatment failure.(Merola et al, 2023, McInnes et al, 2023)

- BE OPTIMAL – a pivotal, phase 3, randomised 52-week trial in which bimekizumab was compared with placebo in biologic-naïve patients. An active reference arm in which patients were assigned adalimumab was included, but the study was not powered for statistical comparisons vs. adalimumab(McInnes et al, 2023)
- BE COMPLETE – a pivotal, phase 3, randomised 16-week trial in which bimekizumab was compared with placebo in patients with inadequate response or intolerance to anti-TNFs(Merola et al, 2023)
- BE VITAL – ongoing open-label extension study including patients who completed BE OPTIMAL (52 weeks) and BE COMPLETE (16 weeks)(ClinicalTrials.gov, 2019)

Both pivotal trials met their primary endpoints(Merola et al, 2023, McInnes et al, 2023)

- BE OPTIMAL: At Week 16, biologic-naïve patients receiving bimekizumab were significantly more likely to meet the primary endpoint of ACR 50 than those receiving placebo (44%, n=189/431 vs. 10%, n=28/281 respectively, OR: 7.1, 95% CI 4.6 to 10.9, *P*<0.0001)(McInnes et al, 2023)
- BE COMPLETE: Patients with previous anti-TNF treatment failure or intolerance receiving bimekizumab had significantly higher ACR 50 response rates compared with placebo at Week 16 (43% [116/267] vs. 7% [9/133] respectively, OR 11.1, 95% CI 5.4 to 23.0, *P*<0.0001)(Merola et al, 2023)

axSpA

For more information on trial designs, please see the appendix.

The clinical trial programme for bimekizumab in axial spondyloarthritis consists of two double-blind phase III randomised controlled trials that enrolled 586 patients spanning non-radiographic spondyloarthritis and radiographic spondyloarthritis(van der Heijde et al, 2023)

- BE MOBILE 1 – a pivotal, phase 3, randomised 52-week trial in which bimekizumab was compared with placebo in patients with nr-axSpA(van der Heijde et al, 2023)
- BE MOBILE 2 – a pivotal, phase 3, randomised 52-week trial in which bimekizumab was compared with placebo in patients with r-axSpA(van der Heijde et al, 2023)
- BE MOVING – ongoing open-label extension study including patients who completed BE MOBILE 1 and 2 (52 weeks)(ClinicalTrials.gov, 2020)

Both pivotal trials met their primary endpoints(van der Heijde et al, 2023)

- BE MOBILE 1: At Week 16, nr-axSpA patients receiving bimekizumab were significantly more likely to meet the primary endpoint of ASAS 40 than those receiving placebo (47.7% [n=61/128] vs. 21.4% [n=27/126] respectively, difference 27.0, 95% CI 15.6 to 38.4, *P*<0.001)(van der Heijde et al, 2023)
- BE MOBILE 2: Patients with axSpA receiving bimekizumab had significantly higher ASAS 40 response rates compared with placebo at Week 16 ((44.8% [n=99/221) vs. 22.5% (n=25/111) respectively, difference 21.8, 95% CI 11.4 to 32.1, *P*<0.001)(van der Heijde et al, 2023)

Relevance to practice:

The results from these trials support previous findings showing the clinical effectiveness and tolerability of dual inhibition of IL-17A and IL-17F with bimekizumab in patients with active psoriatic arthritis and axSpA. Bimekizumab demonstrated consistent efficacy and tolerability across biologic naïve and biologic experienced patients with active psoriatic arthritis and

breadth of efficacy across joint and skin outcomes.[Merola et al, 2023, McInnes et al, 2023] Bimekizumab demonstrated efficacy across the full spectrum of axSpA in patients with non-radiographic and radiographic axSpA.[van der Heijde et al, 2023]

Evidence of effectiveness

For more information on trial designs, please see the appendix.

PsA - Efficacy in biologic naïve patients

Bimekizumab demonstrated rapid efficacy which was superior to placebo across joint and skin outcomes[McInnes et al, 2023]

Joint outcomes

Differences in responder rates for bimekizumab (n=431) versus placebo (n=281) emerged rapidly, with differences in ACR 20 emerging at Week 2 and ACR 50 differences emerging at Week 4[McInnes et al, 2023]

- ACR 20 at Week 2: following a single dose of bimekizumab, 27% (n=117/431) achieved ACR 20, compared with 8% (n=22/281) with placebo[McInnes et al, 2023]
- ACR 50 at Week 4: 18% (n=76/431) of patients achieved ACR 50 with bimekizumab compared with 3% (n=9/281) with placebo[McInnes et al, 2023]

At Week 16, significantly more patients achieved ACR 50 compared with placebo (44%, n=189/431) vs. 10% (n=28/281) respectively, OR: 7.1, 95% CI 4.6 to 10.9, *P*<0.0001, primary endpoint). By Week 24, this had increased to 45% (n=196/431) in bimekizumab-treated patients.[McInnes et al, 2023]

At Week 16, placebo-treated patients (n=281) were switched to bimekizumab treatment. At Week 24 (following 8 weeks of treatment with bimekizumab), 36% (n=101/281) had achieved ACR 50. [McInnes et al, 2023]

Significantly more patients experienced minimal disease activity with bimekizumab compared with placebo at Week 16 (45% [n=194/431] vs. 13% [n=37/281], OR 5.4, 95% CI: 3.7 to 8.1, *P*<0.0001).[McInnes et al, 2023]

At Week 52, 55% (n=not reported/431) of bimekizumab-treated patients achieved ACR 50. The same proportion (55%, n=not reported/431) achieved minimal disease activity at Week 52.[Ritchlin et al, 2022]

Skin outcomes

Almost half (47%, n=103/207) of all bimekizumab-treated patients with baseline psoriasis affecting 3% or more body surface area (BSA) had complete skin clearance (PASI 100) at Week 16[McInnes et al, 2023]

By Week 52, the proportion of patients treated with bimekizumab throughout achieving PASI 100 had increased to 61% (n=not reported/217).[Ritchlin et al, 2022]

Significantly more patients achieved PASI 90 at Week 16 compared with placebo (61% [n=133/217] *vs.*3% [n=4/140], OR 63.0 95% CI: 22.2 to 178.9, *P*<0.0001) at Week 16.[McInnes et al, 2023]

Efficacy in clinical manifestations

Bimekizumab demonstrated efficacy in complete resolution of clinical manifestations of PsA at Week 16[(McInnes et al, 2023)]

In patients with **enthesitis** at baseline in the BE OPTIMAL trial, ~50% (n=124/249) of bimekizumab-treated patients experienced complete resolution at Week 16. This was significant compared with 35% (n=37/106) of placebo-treated patients (OR 1.9, 95% CI: 1.2 to 3.1 *P*=0.0083).[(McInnes et al, 2023)]

In patients with **dactylitis** at baseline, 76% (n=68/90) of bimekizumab-treated patients experienced complete resolution at Week 16. This was significant compared with 51% (n=24/47) of placebo-treated patients (OR 3.4, 95% CI: 1.6 to 7.6 *P*=0.0022).[(McInnes et al, 2023)]

Sustained efficacy and remission

Treatment responses with bimekizumab were sustained up to 2 years[(Coates et al, 2024)]

In open-label extension at Week 104, minimal disease activity was achieved by 52.4% of patients randomised to bimekizumab (n=349) and 49.8% of patients initially randomised to placebo (n=231).[(Coates et al, 2024)]

In open-label extension at Week 104, DAPSA remission or low disease activity was achieved by 52.9% of patients randomised to bimekizumab (n=349) and 50.2% of patients initially randomised to placebo (n=231).[(Coates et al, 2024)]

PsA - Efficacy in patients with a history or inadequate response or intolerance to one or two anti-TNFs[(Merola et al, 2023)]

Bimekizumab demonstrated rapid efficacy across joint and skin outcomes[(Merola et al, 2023)]

Joint outcomes

Numerical differences in responder rates for bimekizumab versus placebo emerged rapidly, with differences in ACR 20 and ACR 50 emerging at Week 4:[(Merola et al, 2023)]

- ACR 20: 43% (n=114/267) achieved ACR 20, compared with 7% (n=9/133) with placebo[(Merola et al, 2023)]
- ACR 50: 16% (n=43/267) of patients achieved ACR 50 with bimekizumab compared with 2% (n=2/133) with placebo[(Merola et al, 2023)]

At Week 16, significantly more patients achieved ACR 50 compared with placebo (43% [116/267] vs. 7% [9/133] respectively, OR 11.1, 95% CI 5.4 to 23.0, *P*<0.0001, primary endpoint).[(Merola et al, 2023)]

Significantly more patients experienced minimal disease activity with bimekizumab compared with placebo at Week 16 (44% [n=118/267] vs.6% [n=8/133], OR 13.1 95% CI:6.1 to 28.0, *P*<0.0001).[(Merola et al, 2023)]

At Week 52, 52% (n=not reported/231) of bimekizumab-treated patients achieved ACR 50 and 47% (n=not reported/232) achieved minimal disease activity.[(Coates LC et al, 2023)]

Data from an open-label extension of a Phase 2b trial suggests that the efficacy of bimekizumab could be sustained beyond one year. At Week 152, 53% achieved ACR 50 (N=206) and 52% achieved minimal disease activity (N=206).[(Coates et al, 2022b)]

Patients treated with bimekizumab demonstrated a greater improvement in musculoskeletal symptoms versus placebo at Week 16 and patients with PsARC response had numerically greater improvements in HRQoL and improvements in fatigue measures:[(Sharma et al, 2023)]

- PsARC: 85.4% (n=228/267) achieved a response (non-responder imputation), with bimekizumab, and 35 patients were classed as non-responders. 30.8% of placebo-treated patients achieved PsARC response (n=41/133)

In bimekizumab-treated patients:(Sharma et al, 2023)

- Mean HAQ-DI in PsARC responders was -0.40 (95% CI: -0.47 to -0.34, n=228) compared with -0.20 in non-responders (95% CI: -0.31 to -0.08, n=35)
- Mean SF-36 PCS in PsARC responders was 8.20 (95% CI: 7.10 to 9.30), compared with 1.44 in non-responders (95% CI: -1.34 to 4.21, n=35)
- Mean FACIT-Fatigue in PsARC responders was 6.33 (95% CI: 5.06 to 7.59), compared with 0.23 in non-responders (95% CI: -3.10 to 3.56)

Reduction in HAQ-DI values indicates improvement and an increase in SF-36 PCS and FACIT-Fatigue values indicate improvement.

Skin outcomes

59% (n=103/179) of bimekizumab-treated patients with baseline psoriasis affecting 3% or more BSA had complete skin clearance (PASI 100) at Week 16(Merola et al, 2023)

By Week 52, the proportion of patients with PASI 100 had increased to 66% (n=not reported/156).(Coates LC et al, 2023)

Significantly more patients achieved PASI 90 at Week 16 compared with placebo (69% [n=121/176] *vs*.7% [n=6/88], OR 30.2 95% CI: 12.4 to 73.9, *P*<0.0001) at Week 16.(Merola et al, 2023)

Data from an open-label extension of a Phase 2b trial suggests that the efficacy of bimekizumab could be sustained beyond one year. At Week 152, 58% achieved PASI 100 (n=79/137).(Coates et al, 2022b)

Sustained efficacy and remission

Treatment responses with bimekizumab were sustained up to 2 years(Coates et al, 2024)

In open-label extension at Week 88, minimal disease activity was achieved by 46.1% of patients randomised to bimekizumab (n=212) and 36.8% of patients initially randomised to placebo (n=103).(Coates et al, 2024)

In open-label extension at Week 88, DAPSA remission or low disease activity was achieved by 46.4% of patients randomised to bimekizumab (n=212) and 49.6% of patients initially randomised to placebo (n=103).(Coates et al, 2024)

axSpA -Efficacy in non-radiographic axial spondyloarthritis

Bimekizumab demonstrated rapid efficacy which was superior to placebo across disease domains(van der Heijde et al, 2023)

Joint and disease control outcomes

Differences in responder rates for bimekizumab versus placebo emerged rapidly, with differences in ASAS 40 emerging within 1 or 2 weeks(van der Heijde et al, 2023)

At Week 16, significantly more patients achieved ASAS 40 compared with placebo (47.7% [n=61/128] vs. 21.4% [n=27/126] respectively, difference 27.0, 95% CI 15.6 to 38.4, *P*<0.001, primary endpoint). By Week 24, this had increased to 52.3% (n=67/128) in bimekizumab-treated patients.(van der Heijde et al, 2023)

At Week 16, placebo-treated patients (n=126) were switched to bimekizumab treatment. At Week 24 (following 8 weeks of treatment with bimekizumab), 46.8% (n=59/126) had achieved ASAS 40. (van der Heijde et al, 2023)

Significantly more patients experienced major improvement in ASDAS score with bimekizumab compared with placebo (27.3% [n=35/128] vs. 7.1% [n=9/126], difference 19.0 95% CI: 10.7 to 27.2, *P*<0.001).(van der Heijde et al, 2023)

At Week 52, 61% (n=not reported/128) of bimekizumab-treated patients achieved ASAS 40. A similar proportion (62%) achieved ASDAS <2.1 (n=not reported/128).(Baraliakos X et al, 2023)

Differences in BASDAI and BASFI response were observed between bimekizumab and placebo by Week 16:(van der Heijde et al, 2023)

- At Week 16, the change from baseline in BASDAI with bimekizumab was significantly different compared with placebo, mean (SE): -3.1 (0.2) vs. -1.5 (0.2), *P*<0.001(van der Heijde et al, 2023) BASDAI response was sustained to Week 52, at Week 52, the change from baseline with bimekizumab was -3.9 (0.2)(Baraliakos X et al, 2023)
- At Week 16, the change from baseline in BASFI with bimekizumab was significantly different compared with placebo, mean (SE): -2.5 (0.2) vs. -1.0 (0.2), p<0.001.(van der Heijde et al, 2023) BASFI response was sustained to Week 52, at Week 52, the change from baseline with bimekizumab was -3.0 (0.2)(Baraliakos X et al, 2023)

Sustained efficacy and remission

Treatment responses with bimekizumab were sustained up to 2 years(Baraliakos et al, 2024a)

In open-label extension, at Week 104, 49.2% of patients achieved ASAS40, 61.2% achieved low disease activity (ASDAS <2.1), and 31.6% achieved inactive disease (ASDAS <1.3) with bimekizumab (n=189).(Baraliakos et al, 2024a)

Efficacy in clinical manifestations

Bimekizumab demonstrated efficacy in complete resolution of clinical manifestations of axSpA at Week 16(van der Heijde et al, 2023)

In nr-axSpA patients with **enthesitis** at baseline, 51.1% (n=48/94) of bimekizumab-treated patients experienced complete resolution at Week 16. In placebo-treated patients the proportion was 23.9% (n=22/92).(van der Heijde et al, 2023) By Week 52, 54% of patients had complete resolution with bimekizumab.(Ramiro S et al, 2023)

In patients with **peripheral arthritis** at baseline, 57.8% (n=26/45) of bimekizumab-treated patients experienced complete resolution of swollen joints at Week 16. In placebo-treated patients the proportion was 41.9% (n=18/43).(van der Heijde et al, 2023) Similar results were demonstrated with tender joints, with 42.3% (n=33/78) achieving resolution with bimekizumab compared with 24.7% (n=21/85) with placebo.(van der Heijde et al, 2023)

axSpA -Efficacy in radiographic axial spondyloarthritis

Bimekizumab demonstrated rapid efficacy which was superior to placebo across disease domains(van der Heijde et al, 2023)

Joint and disease control outcomes

Differences in responder rates for bimekizumab versus placebo emerged rapidly, with differences in ASAS 40 emerging within 1 or 2 weeks(van der Heijde et al, 2023)

At Week 16, significantly more patients achieved ASAS 40 compared with placebo (44.8% [n=99/221) vs. 22.5% (n=25/111) respectively, difference 21.8, 95% CI 11.4 to 32.1,

P<0.001, primary endpoint). By Week 24, this had increased to 53.8% (n=67/221) in bimekizumab-treated patients.(van der Heijde et al, 2023)

At Week 16, placebo-treated patients (n=111) were switched to bimekizumab treatment. At Week 24 (following 8 weeks of treatment with bimekizumab), 56.8% (n=63/111) had achieved ASAS 40. (van der Heijde et al, 2023)

Significantly more patients experienced major improvement in ASDAS score with bimekizumab compared with placebo at Week 16 (25.8% [n=57/221] vs. 5.4% [n=6/111], difference 18.6 95% CI: 10.9 to 26.3, *P*<0.001).(van der Heijde et al, 2023)

At Week 52, 58% (n=not reported/ 221) of bimekizumab-treated patients achieved ASAS 40. 57% (n=not reported/ 221) achieved ASDAS-LDA (ASDAS <2.1).(Baraliakos X et al, 2023)

Data from an open-label extension of a Phase 2 trial suggests that the efficacy of bimekizumab could be sustained beyond one year. At Week 156, 57% (n=84/147) achieved ASAS 40, and 54% (n=79/147) achieved ASDAS-LDA.(Baraliakos et al, 2022)

Differences in BASDAI and BASFI response were observed between bimekizumab and placebo by Week 16:(van der Heijde et al, 2023)

- At Week 16, the change from baseline in BASDAI with bimekizumab was significantly different compared with placebo, mean (SE): -2.9 (0.1) vs. -1.9 (0.2), p<0.001.(van der Heijde et al, 2023) BASDAI response was sustained to Week 52, at Week 52, the change from baseline with bimekizumab was -3.6 (0.1)(Baraliakos X et al, 2023)
- At Week 16, the change from baseline in BASFI with bimekizumab was significantly different compared with placebo, mean (SE): -2.2 (0.1) vs. -1.1 (0.2), p<0.001.(van der Heijde et al, 2023) BASFI response was sustained to Week 52, at Week 52, the change from baseline with bimekizumab was -2.8 (0.1)(Baraliakos X et al, 2023)

Sustained efficacy and remission

Treatment responses with bimekizumab were sustained up to 2 years(Baraliakos et al, 2024a)

In open-label extension at Week 104, 53.9% of patients achieved ASAS40, 63.4% achieved low disease activity (ASDAS <2.1) and 31.3% achieved inactive disease (ASDAS <1.3), with bimekizumab (n=267).(Baraliakos et al, 2024a)

Of patients with modified Stoke Ankylosing Spondylitis Spinal Score scores available at baseline and Week 104 (n=190), 85.3% had no spinal radiographic progression (mSASSS ≤0.5).(Baraliakos et al, 2024b)

Efficacy in clinical manifestations

Bimekizumab demonstrated efficacy in complete resolution of clinical manifestations of axSpA at Week 16(van der Heijde et al, 2023)

In patients with **enthesitis** at baseline, 51.5% (n=68/132) of bimekizumab-treated patients experienced complete resolution at Week 16. In placebo-treated patients the proportion was 32.8% (n=22/67).(van der Heijde et al, 2023) At Week 52, 51% (n=not reported/132) of bimekizumab-treated patients had complete resolution.(Ramiro S et al, 2023)

In patients with **peripheral arthritis** at baseline, 63.6% (n=28/44) of bimekizumab-treated patients experienced complete resolution of swollen joints at Week 16. In placebo-treated patients the proportion was 36.4% (n=8/22).(van der Heijde et al, 2023) Similar results were demonstrated with tender joints, with 41.4% (n=21/85) achieving resolution with bimekizumab compared with 32.8% (n=20/61) with placebo.(van der Heijde et al, 2023)

Pooled efficacy regardless of prior anti-TNF use

A pooled analysis of the BE MOBILE 1 and 2 studies included 505 anti-TNF naive patients (nr-axSpA: 227; r-axSpA: 278) and 81 patients with prior anti-TNF inadequate response (nr-axSpA: 27; r-axSpA: 54) patients. 302 (59.8%) and 47 (58.0%) of those patients were randomised to bimekizumab, respectively.(Magrey et al, 2023)

At Week 16, 46.0% (n= not reported/302) of anti-TNF naïve patients had achieved ASAS 40. A similar proportion (44.7% [n=not reported/47]) of anti-TNF inadequate responders also achieved ASAS 40 at Week 16. By Week 52, proportions had increased to 59.9% (n=not reported/302) in anti-TNF naïve patients and 55.3% (n=not reported/4) in anti-TNF inadequate responders.(Magrey et al, 2023)

47.9% (n=not reported/302) of anti-TNF naïve patients and 30.2% (n=not reported/47) of anti-TNF inadequate responders achieved ASDAS<2.1 at Week 16. By Week 52, proportions had increased to 62.0% (n=not reported/302) and 54.0% (n=not reported/47) respectively.(Magrey et al, 2023)

Efficacy in comparison with other treatments - network meta-analysis

Important note:

- Other network meta-analyses exist which differ in their methodology and study inclusion which may show different statistical differences between different biologics
- There are limited numbers of head-to-head randomised controlled clinical trials that exist for IL-17, IL-23, and IL-12/23 inhibitor therapies
- The network meta-analysis was funded by UCB Pharma

PsA

A network meta-analysis aimed to establish the relative clinical efficacy and safety of bimekizumab) vs approved biologic or targeted synthetic disease-modifying antirheumatic drugs for psoriatic arthritis.(Mease PJ et al, 2023)

Methods

A systematic literature review was conducted following Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines to identify randomised controlled trials of approved biologic or targeted synthetic disease-modifying antirheumatic drugs in psoriatic arthritis published from January 1991 through 2 May 2022.(Mease PJ et al, 2023)

Bayesian binomial NMAs were conducted to compare the efficacy outcomes, ACR 20/50/70, PASI 90/100, and minimal disease activity for bimekizumab 160 mg with comparators in patients who were biologic or targeted synthetic disease-modifying antirheumatic drug-naïve and TNFi-experienced.(Mease PJ et al, 2023)

Studies reporting data at Week 16 were included. In the absence of 16-week data, data available at Weeks 12, 14, or 24 were included.(Mease PJ et al, 2023)

In the case where the 95% CrI of the ORs included 1, bimekizumab 160 mg and the comparator were considered comparable. In the case where the 95% CrI of the ORs does not include 1, then bimekizumab 160 mg was considered either superior or inferior depending on the direction of the effect.(Mease PJ et al, 2023)

41 studies were included in the NMA.(Mease PJ et al, 2023)

Results‡

Bimekizumab was associated with consistent high skin clearance, ranking 1st among 11 treatments in biologic-naïve patients for PASI 100. It was comparable to other available treatments in joint outcomes(Mease PJ et al, 2023)

Bimekizumab 160 mg ranked 1st among 11 treatments for PASI 100 in biologic-naive patients.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.95**
Guselkumab 100 mg Q4W	1.04 (0.69 – 1.55)	0.93

‡ Only UK licensed treatments for active psoriatic arthritis are presented from the full NMA. This does not impact the ranking of bimekizumab within the results.(Mease P et al, 2023)

Secukinumab 300 mg	1.73 (1.10 – 2.71)	0.73
Guselkumab 100 mg Q8W	1.79 (0.88 – 3.87)	0.71
Secukinumab 300mg	2.49 (1.14 – 4.71)	0.58
Upadacitinib 15 mg	2.90 (1.74 – 4.83)	0.50
Adalimumab 40 mg	3.78 (2.54 – 5.60)	0.34
Secukinumab 150 mg	3.79 (1.77 – 7.62)	0.35
Certolizumab pegol (pooled)	6.71 (3.42 – 13.44)	0.13

Bimekizumab 160 mg ranked 2nd among 7 treatments for PASI 100 in TNFi-experienced patients.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.79**
Guselkumab 100 mg Q4W	0.43 (0.03, 3.12	0.93
Certolizumab pegol (pooled)	2.35 (0.06, 27.96)	0.57
Guselkumab 100 mg Q8W	2.47 (0.42, 11.54)	0.55
Upadacitinib 15 mg	4.80 (1.19, 23.09)	0.36
Ixekizumab 80 mg Q4W	6.55 (1.23, 35.94)	0.29

Bimekizumab 160 mg ranked 1st among 13 treatments in bio-naive patients in minimal disease activity.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.87**
Ixekizumab 80 mg Q4W	1.09 (0.67 – 1.74)	0.78
Secukinumab 300 mg	1.29 (0.85 – 1.90)	0.61
Upadacitinib 15 mg	1.32 (0.88 – 1.89)	0.58
Adalimumab 40 mg	1.35 (0.95 – 2.85)	0.54
Secukinumab 150 mg	1.36 (0.78 – 2.30)	0.54
Certolizumab pegol (pooled)	1.27 (0.49 – 2.41)	0.63
Tofacitinib 5 mg	1.40 (0.74 – 2.59)	0.52
Guselkumab 100 mg Q8W	1.73 (1.09 – 2.64)	0.30
Risankizumab 150 mg	1.99 (1.39 – 2.76)	0.18
Guselkumab 100 mg Q4W	2.03 (1.26 – 3.12)	0.17

Bimekizumab 160 mg ranked 2nd among 11 treatments in TNFi-experienced patients in minimal disease activity.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.78**
Guselkumab 100 mg Q4W	0.89 (0.15 – 5.42)	0.79
Certolizumab pegol (pooled)	1.26 (0.05 – 12.49)	0.66
Secukinumab 300 mg	1.42 (0.04 – 15.09)	0.64
Ixekizumab 80 mg Q4W	1.72 (0.43 – 6.59)	0.59
Guselkumab 100 mg Q8W	1.69 (0.36 – 7.75)	0.58
Upadacitinib 15 mg	2.27 (0.65 – 7.54)	0.49
Secukinumab 150 mg	3.30 (0.05 – 40.52)	0.40
Risankizumab 150 mg	2.95 (0.74 – 11.09)	0.39
Tofacitinib 5 mg	6.47 (2.07 – 20.46)	0.16

Bimekizumab 160 mg ranked 6th among 21 treatments in bio-naive patients in ACR 20.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.75**
Infliximab 5 mg	0.63 (0.35 – 1.04)	0.92
Etanercept 25 mg	0.73 (0.42 – 1.20)	0.88
Golimumab 50 mg	0.87 (0.44 – 1.49)	0.80
Upadacitinib 15 mg	0.98 (0.70 – 1.36)	0.77
Adalimumab 40 mg	1.09 (0.85 – 1.41)	0.68
Secukinumab 300 mg	1.13 (0.85 – 1.50)	0.64
Ixekizumab 80 mg Q4W	1.24 (0.86 – 1.75)	0.56
Secukinumab 150 mg	1.33 (0.98 – 1.77)	0.48
Certolizumab pegol (pooled)	1.45 (0.95 – 2.20)	0.41
Guselkumab 100 mg Q4W	1.45 (1.03 – 2.03)	0.41
Risankizumab 150 mg	1.55 (1.16 – 2.09)	0.35
Guselkumab 100 mg Q8W	1.65 (1.18 – 2.33)	0.30
Tofacitinib 5 mg	1.76 (1.08 – 2.87)	0.27
Abatacept 125 mg	1.93 (1.11 – 3.30)	0.23
Ustekinumab 90 mg	1.93 (1.27 – 2.82)	0.21
Apremilast 30 mg	2.27 (1.65 – 3.10)	0.12
Ustekinumab 45 mg	2.52 (1.68 – 3.70)	0.09

Bimekizumab 160 mg ranked 1st among 16 treatments in TNFi-experienced patients in ACR 20.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.96**
Certolizumab pegol (pooled)	1.07 (0.24 – 4.19)	0.90
Guselkumab 100 mg Q4W	2.16 (0.73 – 6.84)	0.71
Upadacitinib 15 mg	2.39 (1.09 – 6.01)	0.68
Secukinumab 300 mg	2.57 (1.22 – 6.15)	0.65
Apremilast 30 mg	2.46 (0.91 – 7.16)	0.64
Guselkumab 100 mg Q8W	2.67 (1.18 – 6.52)	0.62
Ixekizumab 80 mg Q4W	2.72 (1.13 – 7.37)	0.60
Tofacitinib 5 mg	3.57 (1.38 – 9.32)	0.44
Secukinumab 150 mg	3.78 (1.83 – 8.80)	0.41
Ustekinumab 45 mg	4.68 (1.24 – 16.48)	0.34
Ustekinumab 90 mg	4.98 (1.40 – 17.81)	0.31
Risankizumab 150 mg	4.77 (1.94 – 12.96)	0.30
Abatacept 125 mg	7.29 (3.11 – 19.63)	0.13

Bimekizumab 160 mg ranked 5th among 21 treatments in bio-naive patients in ACR 50.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.74**
Etanercept 25 mg	0.54 (0.15, 1.29)	0.92
Infliximab 5 mg	0.56 (0.23, 1.03)	0.94
Golimumab 50 mg	0.76 (0.28, 1.45)	0.84
Secukinumab 150 mg	1.05 (0.73, 1.49)	0.71
Upadacitinib 15 mg	1.06 (0.77, 1.47)	0.70
Certolizumab pegol (pooled)	1.15 (0.68, 1.82)	0.63
Secukinumab 300 mg	1.17 (0.85, 1.58)	0.62
Adalimumab 40 mg	1.18 (0.90, 1.54)	0.61
Ixekizumab 80 mg Q4W	1.40 (0.97, 2.01)	0.47
Ustekinumab 90 mg	1.71 (1.10, 2.58)	0.34
Tofacitinib 5 mg	1.72 (0.99, 3.00)	0.34
Guselkumab 100 mg Q8W	1.76 (1.19, 2.57)	0.33
Risankizumab 150 mg	2.10 (1.52, 2.89)	0.21

Ustekinumab 45 mg	2.16 (1.36, 3.33)	0.20
Guselkumab 100 mg Q4W	2.18 (1.48, 3.20)	0.19
Apremilast 30 mg	2.24 (1.00, 4.54)	0.22
Abatacept 125 mg	2.77 (1.50, 5.23)	0.12

Bimekizumab 160 mg ranked 2nd among 15 treatments in TNFi-experienced patients in ACR 50.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.84**
Certolizumab pegol (pooled)	0.34 (0.02 – 3.00)	0.95
Upadacitinib 15 mg	1.20 (0.39 – 3.72)	0.79
Ixekizumab 80 mg Q4W	1.28 (0.36 – 4.53)	0.76
Guselkumab 100 mg Q4W	1.52 (0.34 – 5.80)	0.70
Secukinumab 300 mg	1.95 (0.68 – 5.94)	0.62
Guselkumab 100 mg Q8W	2.53 (0.71 – 8.19)	0.49
Risankizumab 150 mg	2.56 (0.55 – 8.91)	0.51
Secukinumab 150 mg	3.09 (1.10 – 9.37)	0.40
Ustekinumab 90 mg	3.66 (0.86 – 17.15)	0.36
Ustekinumab 45 mg	3.91 (0.88 – 17.72)	0.34
Tofacitinib 5 mg	4.10 (1.45 – 12.96)	0.29
Abatacept 125 mg	6.68 (2.09 – 21.34)	0.15

Bimekizumab 160 mg ranked 3rd among 21 treatments in bio-naive patients in ACR 70.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.75**
Infliximab 5 mg	0.78 (0.32 – 1.45)	0.91
Upadacitinib 15 mg	1.03 (0.69 – 1.47)	0.79
Secukinumab 300 mg	1.04 (0.66 – 1.58)	0.77
Adalimumab 40 mg	1.10 (0.80 – 1.49)	0.73
Secukinumab 150 mg	1.13 (0.72 – 1.72)	0.71
Certolizumab pegol (pooled)	1.19 (0.69 – 1.91)	0.67
Guselkumab 100 mg Q8W	1.40 (0.85 – 2.18)	0.54
Tofacitinib 5 mg	1.49 (0.81 – 2.80)	0.49
Golimumab 50 mg	1.68 (0.74 – 3.32)	0.47

Ixekizumab 80 mg Q4W	1.62 (1.03 – 2.47)	0.42
Ustekinumab 90 mg	1.69 (1.00 – 2.74)	0.39
Guselkumab 100 mg Q4W	1.88 (1.11 – 3.06)	0.32
Risankizumab 150 mg	1.94 (1.31 – 2.80)	0.29
Ustekinumab 45 mg	2.08 (1.21 – 3.51)	0.26
Apremilast 30 mg	2.62 (0.80 – 7.64)	0.22
Etanercept 25 mg	2.83 (0.88 – 7.55)	0.19
Abatacept 125 mg	2.77 (1.36 – 6.46)	0.16

Bimekizumab 160 mg ranked 1st among 16 treatments in TNFi-experienced patients in ACR 70.(Mease PJ et al, 2023)

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab 160mg	**Reference**	**0.83**
Certolizumab pegol (pooled)	2.02 (0.12, 9.66)	0.59
Guselkumab 100 mg Q4W	1.12 (0.15, 4.19)	0.80
Upadacitinib 15 mg	2.11 (0.73, 10.88)	0.55
Secukinumab 300 mg	1.24 (0.08, 4.48)	0.25
Guselkumab 100 mg Q8W	5.00 (1.21, 24.73)	0.69
Ixekizumab 80 mg Q4W	1.61 (0.22, 4.92)	0.75
Tofacitinib 5 mg	1.41 (0.04, 7.48)	0.57
Secukinumab 150 mg	2.10 (0.12, 8.07)	0.16
Ustekinumab 45 mg	7.95 (1.25, 118.50)	0.17
Ustekinumab 90 mg	7.23 (1.27, 90.04)	0.55
Risankizumab 150 mg	5.63 (0.58, 22.47)	0.43
Abatacept 125 mg	3.02 (0.17, 12.75)	0.11

axSpA

A network meta-analysis assessed the efficacy of bimekizumab 160 mg every 4 weeks in nr-axSpA and AS compared with approved biologic or targeted synthetic disease-modifying antirheumatic drugs.(Deodhar A et al, 2023)

Methods

A systematic literature review was conducted to identify randomised placebo-controlled trials in axSpA up to April 2022 (in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines).(Deodhar A et al, 2023)

Separate network meta-analyses were run for the separate biologic or targeted synthetic disease-modifying antirheumatic drug networks. Bayesian fixed-effect (nr-axSpA) and fixed effect placebo-adjusted (AS) NMAs were conducted; models were selected based on best model fit.(Deodhar A et al, 2023)

33 trials were available for the predominantly biologic-naive network, and 10 trials were available for the biologic-experienced network.(Deodhar A et al, 2023)

Results§

Bimekizumab was associated with significantly higher response rates compared with secukinumab 150 mg in AS (ASAS 40 [OR: 1.13] and ASAS-PR [OR: 1.65]) and ranked highly in nr-axSpA. Bimekizumab was associated with similar response rates compared with other biologics across remaining outcomes at Week 12-16(Deodhar A et al, 2023)

nr-axSpA: ASAS 40

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab	**Reference**	**76%**
Upadacitinib	1.18 (0.57 – 2.49)	65%
Ixekizumab	1.45 (0.61 – 3.35)	51%
Secukinumab	1.97 (0.97 – 4.01)	29%
Placebo	3.39 (1.96 – 5.96)	0%

§ Only UK licensed treatments for nr-axSpA & AS are presented from the full NMA. This does not impact the ranking of bimekizumab within the results.(Deodhar A et al, 2023)

AS: ASAS 40

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab	**Reference**	**58%**
Upadacitinib	0.83 (0.50 – 1.37)	80%
Ixekizumab	0.83 (0.48 – 1.41)	79%
Tofacitinib	1.04 (0.68 – 1.54)	53%
Secukinumab	1.13 (0.83 -1.54)	39%
Placebo	3.94 (3.03 – 5.08)	0%

nr-axSpA: ASAS-PR

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab	**Reference**	**77%**
Secukinumab	1.26 (0.45 – 3.68)	61%
Upadacitinib	1.66 (0.56 – 5.09)	40%
Placebo	4.69 (2.22 – 10.83)	0%

AS: ASAS-PR

Treatment	OR (95% CrI) vs. bimekizumab	SUCRA vs. bimekizumab
Bimekizumab	**Reference**	**79%**
Upadacitinib	0.91 (0.27 – 2.32)	80%
Tofacitinib	1.44 (0.83 – 2.49)	44%
Ixekizumab	1.69 (0.84-3.57)	35%
Secukinumab	1.65 (1.08 – 2.51)	32%
Placebo	5.02 (3.62 – 6.84)	0%

Safety profile and tolerability

Bimekizumab was generally well tolerated by patients with PsA and axSpA *(UCB Pharma Limited BIMZELX SmPC)*

Adverse reactions

A total of 5,862 patients have been treated with bimekizumab in blinded and open-label clinical studies in plaque psoriasis, psoriatic arthritis and axial spondyloarthritis (nr-axSpA and AS) and hidradenitis suppurativa representing 11,468.6 patient-years of exposure. Of these, over 4,660 patients were exposed to bimekizumab for at least one year. Overall, the safety profile of bimekizumab is consistent across all indications.(UCB Pharma Limited BIMZELX SmPC)

The most frequently reported adverse reactions were upper respiratory tract infections (14.5%, 14.6%, 16.3%, 8.8% in PSO, PsA, axSpA and HS respectively) and oral candidiasis (7.3%, 2.3%, 3.7%, 5.6% in PSO, PsA , axSpA and HS respectively).(UCB Pharma Limited BIMZELX SmPC)

Table 1: List of adverse reactions in clinical studies(UCB Pharma Limited BIMZELX SmPC)

The adverse reactions for bimekizumab are classified by MedDRA System Organ Class and frequency, using the following convention: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

System organ class	Frequency	Adverse reaction
Infections and infestations	Very common	Upper respiratory tract infections
	Common	Oral candidiasis Tinea infections Ear infections Herpes simplex infections Oropharyngeal candidiasis Gastroenteritis Folliculitis Vulvovaginal mycotic infection (including vulvovaginal candidiasis)
	Uncommon	Mucosal and cutaneous candidiasis (including oesophageal candidiasis), Conjunctivitis
Blood and lymphatic system disorders	Uncommon	Neutropenia
Nervous system disorders	Common	Headache
Gastrointestinal disorders	Uncommon	Inflammatory bowel disease
Skin and subcutaneous tissue disorders	Common	Rash, dermatitis, and eczema Acne
General disorders and administration site conditions	Common	Infection site reactions (includes injection site erythema, reaction, oedema, pain, swelling) Fatigue

Infections

In the placebo-controlled period of Phase III clinical studies in plaque psoriasis, infections were reported in 36.0% of patients treated with bimekizumab for up to 16 weeks compared with 22.5% of patients treated with placebo. Serious infections occurred in 0.3% of patients

treated with bimekizumab and 0% treated with placebo.(UCB Pharma Limited BIMZELX SmPC)

The majority of infections consisted of non-serious mild to moderate upper respiratory tract infections such as nasopharyngitis. There were higher rates of oral and oropharyngeal candidiasis in patients treated with bimekizumab consistent with the mechanism of action (7.3% and 1.2% respectively compared to 0% for placebo-treated patients). More than 98% of cases were non-serious, mild or moderate in severity, and did not require treatment discontinuation. A slightly higher incidence of oral candidiasis was reported in patients <70 kg (8.5% *versus* 7.0% in patients ≥70 kg).(UCB Pharma Limited BIMZELX SmPC)

Over the entire treatment period of Phase III studies in plaque psoriasis, infections were reported in 63.2% of patients treated with bimekizumab (120.4 per 100 patient-years). Serious infections were reported in 1.5% of patients treated with bimekizumab (1.6 per 100 patient-years).(UCB Pharma Limited BIMZELX SmPC)

Infection rates observed in PsA and axSpA (nr-axSpA and AS) Phase III clinical studies were similar to those observed in plaque psoriasis apart from oral and oropharyngeal candidiasis rates in patients treated with bimekizumab which were lower at 2.3% and 0% respectively in PsA and 3.7% and 0.3% respectively in axSpA compared to 0% with placebo.(UCB Pharma Limited BIMZELX SmPC)

Infection rates observed in HS Phase III clinical studies were similar to those observed in other indications. In the placebo-controlled period, oral and oropharyngeal candidiasis rates in patients treated with bimekizumab were 7.1% and 0% respectively compared to 0% with placebo.(UCB Pharma Limited BIMZELX SmPC)

Neutropenia

Neutropenia was observed with bimekizumab in phase III clinical studies in plaque psoriasis. Over the entire treatment period of Phase III studies, neutropenia grade 3/4 were observed in 1% of patients treated with bimekizumab.(UCB Pharma Limited BIMZELX SmPC)

The frequency of neutropenia in PsA, axSpA (nr-axSpA and AS) and HS clinical studies was similar to that observed in plaque psoriasis studies.(UCB Pharma Limited BIMZELX SmPC)

Most cases were transient and did not require treatment discontinuation. No serious infections were associated with neutropenia.(UCB Pharma Limited BIMZELX SmPC)

Hypersensitivity

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors.(UCB Pharma Limited BIMZELX SmPC)

Immunogenicity

Approximately 45% of plaque psoriasis patients treated with bimekizumab up to 56 weeks at the recommended dosing regimen (320 mg every 4 weeks up to week 16 and 320 mg every 8 weeks thereafter) developed anti-drug antibodies. Of the patients who developed anti-drug antibodies, approximately 34% (16% of all patients treated with bimekizumab) had antibodies that were classified as neutralising. (UCB Pharma Limited BIMZELX SmPC)

Approximately 31% of patients with psoriatic arthritis treated with bimekizumab at the recommended dosing regimen (160 mg every 4 weeks) up to 16 weeks had anti-drug antibodies. Of the patients with anti-drug antibodies, about 33% (10% of all patients treated with bimekizumab) had antibodies that were classified as neutralising. By week 52, approximately 47% of patients with psoriatic arthritis in the BE OPTIMAL study treated with bimekizumab at the recommended dosing regimen (160 mg every 4 weeks) had anti-drug antibodies. Of the patients with anti-drug antibodies, about 38% (18% of all patients in the BE OPTIMAL study treated with bimekizumab) had antibodies that were classified as neutralising.(UCB Pharma Limited BIMZELX SmPC)

Approximately 57% of patients with nr-axSpA treated with bimekizumab up to 52 weeks at the recommended dosing regimen (160 mg every 4 weeks) had anti-drug antibodies. Of the patients with anti-drug antibodies, approximately 44% (25% of all patients treated with bimekizumab) had antibodies that were classified as neutralising.(UCB Pharma Limited BIMZELX SmPC)

Approximately 44% of patients with AS treated with bimekizumab up to 52 weeks at the recommended dosing regimen (160 mg every 4 weeks) had anti-drug antibodies. Of the patients with anti-drug antibodies, approximately 44% (20% of all patients treated with bimekizumab) had antibodies that were classified as neutralising.(UCB Pharma Limited BIMZELX SmPC)

Approximately 59% of HS patients treated with bimekizumab up to 48 weeks at the recommended dosing regimen (320 mg every 2 weeks up to Week 16 and 320 mg every 4 weeks thereafter) developed anti-drug antibodies. Of the patients who developed anti-drug antibodies, approximately 63% (37% of all patients treated with bimekizumab) had antibodies that were classified as neutralizing.(UCB Pharma Limited BIMZELX SmPC)

Across indications, no clinically meaningful impact on clinical response was associated with anti-bimekizumab antibodies development and an association between immunogenicity and treatment emergent adverse events has not been clearly established.(UCB Pharma Limited BIMZELX SmPC)

Elderly patients (≥65 years)

Exposure is limited in elderly patients. Elderly patients may be more likely to experience certain adverse reactions such as oral candidiasis, dermatitis and eczema when using bimekizumab.(UCB Pharma Limited BIMZELX SmPC)
In the placebo-controlled period of Phase III clinical studies in psoriatic arthritis, oral candidiasis was observed in 8.1% of patients ≥65 years versus 2.3% in <65 years, dermatitis and eczema in 4.2% of patients ≥65 years versus 0.4% in <65 years.(UCB Pharma Limited BIMZELX SmPC)

Special warnings and precautions for use

Traceability

The name and the batch number of the administered product should be clearly recorded.(UCB Pharma Limited BIMZELX SmPC)

Infections

Bimekizumab may increase the risk of infections such as upper respiratory tract infections and oral candidiasis:(UCB Pharma Limited BIMZELX SmPC)

- Caution should be exercised when considering use in patients with a chronic infection or a history of recurrent infection. Treatment must not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated(UCB Pharma Limited BIMZELX SmPC)
    - Patients treated with bimekizumab should be instructed to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection, the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy, treatment should be discontinued until the infection resolves.(UCB Pharma Limited BIMZELX SmPC)

Pre-treatment evaluation for tuberculosis

Prior to initiating treatment, patients should be evaluated for tuberculosis infection:(UCB Pharma Limited BIMZELX SmPC)

- Bimekizumab should not be given in patients with active tuberculosis(UCB Pharma Limited BIMZELX SmPC)

- Patients should be monitored for signs and symptoms of active tuberculosis(UCB Pharma Limited BIMZELX SmPC)
    - Anti-tuberculosis therapy should be considered prior to initiating bimekizumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. (UCB Pharma Limited BIMZELX SmPC)

Inflammatory bowel disease

Cases of new or exacerbations of inflammatory bowel disease have been reported with bimekizumab. Bimekizumab is not recommended in patients with inflammatory bowel disease.(UCB Pharma Limited BIMZELX SmPC)

If a patient develops signs and symptoms of inflammatory bowel disease or experiences an exacerbation of pre-existing inflammatory bowel disease, bimekizumab should be discontinued and appropriate medical management should be initiated.(UCB Pharma Limited BIMZELX SmPC)

Hypersensitivity

Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors.(UCB Pharma Limited BIMZELX SmPC)

If a serious hypersensitivity reaction occurs, administration should be discontinued immediately, and appropriate therapy initiated.(UCB Pharma Limited BIMZELX SmPC)

Vaccinations

Prior to initiation, consider completion of all age appropriate immunisations according to current immunisation guidelines:(UCB Pharma Limited BIMZELX SmPC)

- Live vaccines should not be given in patients treated with bimekizumab(UCB Pharma Limited BIMZELX SmPC)
- Patients treated with bimekizumab may receive inactivated or non-live vaccinations(UCB Pharma Limited BIMZELX SmPC)
- Healthy individuals who received a single 320 mg dose of bimekizumab two weeks prior to vaccination with an inactivated seasonal influenza vaccine had similar antibody responses compared to individuals who did not receive bimekizumab prior to vaccination(UCB Pharma Limited BIMZELX SmPC)

Fertility, pregnancy, and lactation

- Women of childbearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment(UCB Pharma Limited BIMZELX SmPC)
- There is a limited amount of data on the use of bimekizumab in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonic/foetal development, parturition, or postnatal development. As a precautionary measure, it is preferable to avoid the use of bimekizumab during pregnancy(UCB Pharma Limited BIMZELX SmPC)
- It is unknown whether bimekizumab is excreted in human milk. A risk to the new born/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from bimekizumab therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman(UCB Pharma Limited BIMZELX SmPC)
- The effect of bimekizumab on human fertility has not been evaluated. Animal studies do not indicate direct or indirect harmful effects with respect to fertility(UCB Pharma Limited BIMZELX SmPC)

Local health economy resource impact

Budget impact

This section has been populated using UK data. Customise this section with information on number of potential patients in your local area.

Include costs across the whole health economy, tailored to your local area.

Table 2: Number of PsA patients eligible to be treated with bimekizumab

Per 100,000 general population	Percentage (%)*	No. of people
Total adult population(ONS, 2022)	79.35%	79,354
Prevalence of people with PsA(Ogdie et al, 2013, Schweikert et al, 2020)	0.19%	151
People eligible for biologic and targeted synthetic DMARD(Colombo et al, 2018)	16%	24
People who have inadequate response to existing therapy(Haberhauer et al, 2010)	38%	**9**
Estimated number of people eligible for bimekizumab treatment	***Complete with local data***	***Complete with local data***

*Percentages (%) are applied to the numbers in the row above.

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.(NICE, 2023a)

Table 3: Number of axSpA patients eligible to be treated with bimekizumab

Per 100,000 general population	Percentage (%)*	No. of people
Total adult population(ONS, 2022)	79.35%	79,354
Prevalence of people with axSpA(Morgan et al, 2020)	0.175%	139
People eligible for biologic and targeted synthetic DMARD(Perrone et al, 2020)	17%	24
People who are biologic naïve(Haberhauer et al, 2010)	62%	**15**
People who have inadequate response to existing therapy(Haberhauer et al, 2010)	38%	**6**
Estimated number of people eligible for bimekizumab treatment	***Complete with local data***	***Complete with local data***

*Percentages (%) are applied to the numbers in the row above.

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.(NICE, 2023b)

Each pack of two 160 mg bimekizumab pre-filled pens or syringes costs **£2,443** (NHS list price).[(BNF)]

The annual maintenance cost per patient per year is £15,879.50 for PsA and axSpA, based on a dose of 160 mg Q4W for a total of 13 doses (NHS list price).

The annual maintenance cost per patient per year is £15,879.50 for PsA and axSpA, based on a dose of 160 mg Q4W for a total of 13 doses (NHS list price). Multiply this by the estimated number of people eligible for bimekizumab treatment in your area to complete this section.

Patient Access Scheme

The company has a commercial arrangement for bimekizumab in psoriatic arthritis and axial spondylitis. This makes bimekizumab available to the NHS with a discount. The size of the discount is commercial in confidence.

For bench marking purposes, please use the established plaque psoriasis patient access price of bimekizumab for financial forecasting in the PsA and axSpA indications. The patient access price for bimekizumab Details of the patient access price can be found within the NHS Commercial Access and Pricing (CAP) portal, which can be accessed by the relevant NHS Pharmacists including your Chief Pharmacist at your local Trust.

Funding Stream in England

Excluded from the aligned payment and incentive fixed element in the National Tariff.[(NHS England, 2022)] Funded according to the local pricing rules, on a cost and volume basis.

Cost per responder analysis overview

A cost per responder tool is an analysis that evaluates and compares the costs and effectiveness of various treatments.

A cost per responder analysis of bimekizumab *vs.* other licensed anti-IL therapies in PsA/axSpA from a UK perspective based on publicly available list prices was estimated based on a network meta-analysis that evaluated the comparative efficacy and safety of bimekizumab and other approved biologic therapies in achieving improved skin and joint outcomes within 16 to 24 weeks of treatment.

The network meta-analysis was funded by UCB Pharma and informed by a systematic literature review of randomised controlled trials that were run in 2022. Although the NMA included all available biologics licensed for the treatment of PSA/axSpA, the tool only analysed bimekizumab and other IL-inhibitor therapies.

The drugs used in the model may be subject to patient access schemes available on the NHS which may include discounted prices. Due to confidentiality, the tool used the 2023 NHS list price for cost comparison of available treatments as published in the British National Formulary (BNF) based on dose recommendations.

Note: Although data explored in the NMA covers weeks 16-24 , the estimated cost per patient only includes the number of vials required until Week 16. This number is then multiplied by the unit cost per treatment

Patient Access Schemes

Many of the medicines listed below have an NHS negotiated commercial arrangement in psoriatic arthritis and axial spondylitis. This makes these products available to the NHS with a discount or through some other commercial

arrangement which may affect the net price available to the NHS. The size of any discount or the net price are commercial in confidence and are not publicly available for use in the comparison below. As such, NHS list prices are used below for all products.

Details of the patient access scheme and net price for any medicine listed below can be found within the NHS Commercial Access and Pricing (CAP) portal, which can be accessed by the relevant NHS Pharmacists including your Chief Pharmacist at your local Trust.

Notes and disclaimers:

NMA limitations

- Although the number of comparators included in the PsA NMA was large, there were relatively few trials included comparing the same treatments (mostly one trial per treatment) which may have reduced the confidence of the estimates and limited the ability to assess consistency within networks
- Not all trials reported outcomes at the same timepoint, which could lead to lack of comparability of trial results
- Due to the lack of randomised controlled data data in AS and nr-axSpA NMAs, mixed bDMARD naïve and experienced populations are used to compare the short-term efficacy of bimekizumab versus other biologic systemic therapies
- Combined regimens are based on dual dose ratios
- The NMA analysis included unpublished UCB trial data sources to enable patient groups who were purely naïve and for a comprehensive set of outcomes
- For some of the binomial outcomes, there were low/zero events in the placebo arm and too few studies reporting the outcome of interest which had an impact on the estimation for some of the contrasts

Cost per responder tool limitations:

- NHS List prices for included comparators are used
- All calculations that are based on treatment units are for estimating costs and not for clinical comparisons of safety and/or efficacy
- Costs relating to drug administration and monitoring are not taken into account
- The NHS may have access to other discounts or agreements that may affect the overall cost or price of the product
- Assessment is based on Week 16 - 24 as NICE requests that treatment outcomes are often assessed at Week 16
- All modelled scenarios are hypothetical and inputs used in the model are informed by published UK sources including the British National Formulary (BNF)

There are limited numbers of head-to-head randomised control clinical trials that exist for IL-17, IL-23, and IL-12/23 inhibitor therapies.

Combination doses

- For secukinumab, according to real-world Swedish data, 54% of PsA-only-patients were initiated on a dose of 150 mg(Song et al, 2023)
    - This retrospective observational cohort study utilised data from Swedish national administrative health care registers. Adult patients with an existing PsA diagnosis and a new biologic pharmacy dispensation between 2017–2021 were identified. Index date was that of the first observed dispensation qualifying as a new biologic, i.e.,

without prior exposure to the index biologic. Prior biologic exposure and patient characteristics (including comorbidities) were screened for from 2005 and 2001, respectively. For patients initiating secukinumab, prescribed dosing was reported separately for patients with and without psoriasis manifestations given the variability in prescribing recommendations(Song et al, 2023)
    - The split in the UK population may differ. This data is used as an approximation only
- For ustekinumab, the ratio is based on manufacturers base case analysis in NICE TA180. It assumes a weighted average of weight-based dosing whereby 80% of people received 45mg dose and 20% received 90mg dose(NICE, 2009)
- For bimekizumab, the base case assumption is a 100% split of PsA patients are assumed to be treated with 160mg Q4W. BE COMPLETE and BE OPTIMAL efficacy data demonstrated similar treatment responses regardless of baseline psoriasis severity in a subgroup population with BSA >10% that were treated with 160mg Q4W(Gottlieb et al, 2023)
- For ixekizumab, it adopts the same approach as bimekizumab with a dose of 160 mg Q4W(Taltz SmPC)

Table 4: NHS List price of available biologics for PsA and axSpA

NOTE: Not all biologics listed in the table below are licensed in PsA and axSpA indications. Please refer to the relevant product SmPCs

	Pharmaceutical form	NHS List price
Bimekizumab(BNF)	2x pre-filled disposable injection	£2,443.00
Guselkumab(BNF)	1x pre-filled disposable injection	£2,250.00
Ixekizumab(BNF)	1x pre-filled disposable injection	£1,125.00
Risankizumab(BNF)	1x pre-filled disposable injection	£3,326.09
Secukinumab(BNF)	1x pre-filled disposable injection (300mg) or 2x pre-filled disposable injection (150mg)	£1,218.78
Ustekinumab(BNF)	1x pre-filled disposable injection or vial (45mg) or 1x pre-filled disposable injection or vial (90mg) or	£2,147.00

Table 5: PsA (biologic naïve) treatment cost per responder based on NHS List price

	PsARC response probability at 16-24 weeks (%) (UCB Data on File, 2023)	Cost per patient for 16 weeks' treatment based on NHS list price (BNF, BNF, BNF, BNF, BNF)	NNT (vs BSC) to achieve PsARC response	Cost per responder (calculated)
Bimekizumab	**78%**	**£6,108**	**1.28**	**£7,830**
Guselkumab 100mg week and 4 then 100mg Q8W	63%	£6,750	1.59	£10,714
Ixekizumab	62%	£6,750	1.61	£10,887
Secukinumab combined dose	66.46%	£7,118	1.50	£10,710
Ustekinumab combined dose	59%	£6,441	1.69	£10,917

Table 6: PsA (TNFi experienced) treatment cost per responder based on NHS List price

	PsARC response probability at 16-24 weeks (%) (UCB Data on File, 2023)	Cost per patient for 16 weeks' treatment based on NHS list price (BNF, BNF, BNF)	NNT (vs BSC) to achieve PsARC response	Cost per responder (calculated)
Bimekizumab	**85%**	**£6,108**	**1.18**	**£7,185**
Ixekizumab combined dose	67%	£6,750	1.49	£10,075
Ustekinumab combined dose	58.2%	£6,441	1.72	£11,067

Table 7: r-axSpA treatment cost per responder based on NHS List price

	ASAS 40 response probability at 16-24 weeks (%) (UCB Data on File, 2023)	Cost per patient for 16 weeks' treatment based on NHS list price (BNF, BNF, BNF)	NNT (*vs.* BSC) to achieve ASAS 40 response	Cost per responder (calculated)
Bimekizumab	**44.6%**	**£6,108**	**2.24**	**£13,694**
Secukinumab 150 mg weekly for 5 doses then Q4W	41.6%	£4,875	2.4	£11,719
Ixekizumab 160mg for 1 dose then 80mg Q4W	48.3%	£6,750	2.07	£13,975

Table 8: nr-axSpA treatment cost per responder based on NHS List price

	ASAS 40 response probability at 16-24 weeks (%) (UCB Data on File, 2023)	Cost per patient for 16 weeks' treatment based on NHS list price (BNF, BNF, BNF)	NNT (vs BSC) to achieve ASAS 40 response	Cost per responder (calculated)
Bimekizumab	**44.2%**	**£ 6,108**	**2.26**	**£ 13,818**
Secukinumab 150 mg weekly for 5 doses then Q4W	28.6%	£4,875	3.50	£17,046
Ixekizumab 160mg for 1 dose then 80mg Q4W	35.4%	£6,750	2.82	£19,068

Service implications

Suitability for Patient Initiated Follow Up

Once stable on medication, patients may have long periods when their condition is well controlled or in remission. During that time, individuals express a wish to get on with their lives rather than fit in with regular checks that they see as unnecessary.(NHS, 2022)

Total annual healthcare cost for patients with PsA can be high, and dependent on disease severity. When the cost of medications is excluded, secondary care consultations appear to be the main driver of the association between disease severity and cost. Each secondary care consultation for PsA costs around £678.(McHugh et al, 2020)

Rapid, and sustained efficacy in consistent high skin and joint outcomes in PsA and axSpA may contribute to patients requiring fewer outpatient appointments compared with uncontrolled disease.

Patient Initiated Follow Up guidance recommends that suitable patients have established optimal disease control. (NHS, 2022)

Bimekizumab provides patients with rapid and sustained efficacy in consistent high skin and joint outcomes in PsA and axSpA:(McInnes et al, 2023, Merola et al, 2023, van der Heijde et al, 2023, Coates et al, 2022b, Baraliakos et al, 2022)

- PsA, biologic-naïve patients:
  - At Week 16, biologic-naïve patients receiving bimekizumab were significantly more likely to meet the primary endpoint of ACR 50 than those receiving placebo (44%, n=189/431 vs. 10%, n=28/281 *P*<0.0001)(McInnes et al, 2023)
  - Almost half (47%) of all biologic naïve bimekizumab-treated patients with baseline psoriasis affecting 3% or more BSA had complete skin clearance (PASI 100) at Week 16 (47%, n=103/217 vs. 2%, n= 3/140, nominal *P*<0.001)(McInnes et al, 2023), anti-TNF
- PsA, previous anti-TNF failure
  - Patients with previous anti-TNF treatment failure or intolerance receiving bimekizumab had significantly higher ACR 50 response rates compared with placebo at Week 16 (43%, n=116/267 vs. 7%, n=9/133 *P*<0.0001)(Merola et al, 2023)
  - 59% of bimekizumab-treated biologic inadequate response patients with baseline psoriasis affecting 3% or more BSA had complete skin clearance (PASI 100) at Week 16 (n=103/176 vs. 5%, n=4/88, nominal *P*<0.001)(Merola et al, 2023)

- nr-axSpA
  - At Week 16, significantly more nr-axSpA patients achieved ASAS 40 compared with placebo (44.8% [n=99/221) vs. 22.5% (n=25/111) respectively, difference 21.8, 95% CI 11.4 to 32.1, *P*<0.001, primary endpoint). By Week 24, this had increased to 53.8% (n=67/221) in bimekizumab-treated patients(van der Heijde et al, 2023)
- r-axSpA
  - At Week 16, significantly more r-axSpA patients achieved ASAS 40 compared with placebo (44.8% [n=99/221]) vs. 22.5% (n=25/111) respectively, difference 21.8, 95% CI 11.4 to 32.1, *P*<0.001, primary endpoint). By Week 24, this had increased to 53.8% (n=67/221) in bimekizumab-treated patients(van der Heijde et al, 2023)

This could contribute to bimekizumab-treated patients:

- Having a high probability of becoming candidates for PIFU
- Becoming a candidate for PIFU early in treatment
- Potentially requiring fewer outpatient appointments compared with patients with uncontrolled disease
- Being suitable candidates for virtual review in those who achieve successful results

Simple, convenient dosing

Treatment with bimekizumab in PsA and axSpA alone requires one injection per dose. It does not require a loading dose, or any dose escalation.(UCB Pharma Limited BIMZELX SmPC)

Bimekizumab is administered every four weeks in PsA and axSpA alone,(UCB Pharma Limited BIMZELX SmPC) meaning patients do not require daily injections.

A flexible dosing option is available for patients with PsA and coexistent moderate to severe plaque psoriasis.(UCB Pharma Limited BIMZELX SmPC)

Bimekizumab is suitable for self-administration(UCB Pharma Limited BIMZELX SmPC)

After proper training in subcutaneous injection technique, patients may self-inject bimekizumab with the pre-filled syringe or pre-filled pen if their physician determines that it is appropriate and with medical follow-up as necessary.(UCB Pharma Limited BIMZELX SmPC)

Bimekizumab does not require additional therapeutic drug monitoring(UCB Pharma Limited BIMZELX SmPC)

Patients should be reviewed in line with local guidelines, but additional routine monitoring is not usually required.(UCB Pharma Limited BIMZELX SmPC)

- If a patient develops a clinically important infection, they should be carefully monitored(UCB Pharma Limited BIMZELX SmPC)
- Patients receiving bimekizumab should be monitored for signs and symptoms of active tuberculosis(UCB Pharma Limited BIMZELX SmPC)

BIMZELX Select home care service

A home care service is offered by UCB, which includes:

- Practical support for patients, including injection training and an online portal for managing medication deliveries
- Nurse support for the first year of bimekizumab treatment
- Motivational coaching to help set personal lifestyle goals according to patient needs
- Providing the first dose to patients within one week of treatment initiation
- Optional disease assessments and phlebotomy service for routine monitoring according to local requirements
- A secure online portal for healthcare professionals to allow communication of treatment progress

Appendix 1: Trial designs

BE OPTIMAL (NCT03895203)

Citation:

McInnes IB. *et al.* Bimekizumab in patients with psoriatic arthritis, naive to biologic treatment: a randomised, double-blind, placebo-controlled, phase 3 trial (BE OPTIMAL). *The Lancet*. 2023;**401**(10370):25-37

Aims and objectives:

To assess the efficacy and safety of subcutaneous bimekizumab (160 mg every 4 weeks) in patients with active psoriatic arthritis who are naive to biologic disease-modifying antirheumatic drugs.(McInnes et al, 2023)

Design:

A 52-week, phase 3, multicentre, randomised, double-blind, placebo-controlled, active reference (adalimumab) study.(McInnes et al, 2023)

The study was not powered for statistical comparisons between adalimumab and bimekizumab.(McInnes et al, 2023)

Population:

Eligible patients were 18 years or older and had a documented diagnosis of adult-onset psoriatic arthritis for at least 6 months before screening. Patients had active psoriatic arthritis with: (McInnes et al, 2023)

- a tender joint count of three or more (of 68),
- Swollen joint count of three or more (of 66), and
- one or more active psoriatic lesions or a documented history of psoriasis (or both)

Concomitant non-steroidal anti-inflammatory drugs, analgesics, oral corticosteroids, or conventional synthetic DMARDs at stable doses were allowed. Patients with current or previous exposure to any biologics for the treatment of psoriatic arthritis or psoriasis were excluded.(McInnes et al, 2023)

Intervention and comparator:

- Subcutaneous bimekizumab 160 mg every 4 weeks (n=431)
- Subcutaneous placebo every 2 weeks (n=281)
- Reference: (subcutaneous adalimumab 40 mg) every 2 weeks (n=140)

Outcomes:

The primary endpoint was the proportion of patients achieving ACR 50 at week 16 (bimekizumab vs placebo)(McInnes et al, 2023)

Ranked secondary endpoints at Week 16 included:(McInnes et al, 2023)

- PASI 90 (in patients with baseline psoriasis affecting 3% or more body surface area)
- Proportion of patients achieving minimal disease activity response

Safety outcomes included incidence of treatment-emergent adverse events, incidence of treatment-emergent serious adverse events , and TEAEs leading to study withdrawal.(McInnes et al, 2023)

BE COMPLETE (NCT03896581)

Citation:

Merola JF. *et al.* Bimekizumab in patients with active psoriatic arthritis and previous inadequate response or intolerance to tumour necrosis factor- inhibitors: a randomised, double-blind, placebo-controlled, phase 3 trial (BE COMPLETE). *The Lancet.* 2023;**401**(10370):38-48

Aims and objectives:

To assess the efficacy and safety of subcutaneous bimekizumab treatment in patients with active psoriatic arthritis, who have inadequate response or intolerance to one or two TNFis(Merola et al, 2023)

Design:

A 16-week, phase 3, multicentre, randomised, double-blind, placebo-controlled study.(Merola et al, 2023)

Population:

Eligible patients were 18 years or older and had a documented diagnosis of adult-onset psoriatic arthritis for at least 6 months before screening. Patients had active psoriatic arthritis with:(Merola et al, 2023)

- a tender joint count of three or more (of 68),
- Swollen joint count of three or more (of 66), and
- one or more active psoriatic lesions or a documented history of psoriasis (or both)
- a history of inadequate response or intolerance to treatment with one or two TNFis for either psoriatic arthritis or psoriasis, as assessed by the investigator

Concomitant non-steroidal anti-inflammatory drugs, analgesics, oral corticosteroids, or conventional synthetic DMARDs at stable doses were allowed.(Merola et al, 2023)

Intervention and comparator:

- Subcutaneous bimekizumab 160 mg every 4 weeks
- Placebo every 4 weeks

Outcomes:

The primary endpoint was the proportion of patients achieving ACR 50 at week 16 (bimekizumab vs placebo)(Merola et al, 2023)

Ranked secondary endpoints at Week 16 included:(Merola et al, 2023)

- PASI 90 (in patients with baseline psoriasis affecting 3% or more body surface area)
- Proportion of patients achieving minimal disease activity response

Safety outcomes included incidence of treatment-emergent adverse events, incidence of treatment-emergent serious adverse events, and TEAEs leading to study withdrawal.(Merola et al, 2023)

BE MOBILE 1 (NCT03928704)

Citation:

van der Heijde D. *et al.* Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomised controlled trials. *Annals of the Rheumatic Diseases.* 2023:ard-2022-223595

Aims and objectives:

To evaluate efficacy and safety of bimekizumab across the axSpA spectrum(van der Heijde et al, 2023)

Design:

A phase 3, multicentre, randomised, double-blind, placebo-controlled trial(van der Heijde et al, 2023)

Population:

Patients had nr-axSpA as determined by clinical diagnosis and by fulfilling ASAS classification criteria. Patients with nr-axSpA were also required to have objective inflammation at screening, specifically active sacroiliitis on MRI fulfilling the ASAS criteria MRI+ and/or elevated C-reactive protein ≥6.0 mg/L.(van der Heijde et al, 2023)

Prior failure of ≥2 NSAIDs, or history of intolerance or contraindication to NSAIDs was required.(van der Heijde et al, 2023)

Intervention and comparator:

- Bimekizumab 160 mg every 4 weeks
- Placebo every 4 weeks

Outcomes:

The primary efficacy endpoint was ASAS 40 response at Week 16.(van der Heijde et al, 2023)

Secondary efficacy endpoints included ASDAS states and ASAS 40 responses by prior biologic experience.(van der Heijde et al, 2023)

Incidence of treatment-emergent adverse events, treatment-emergent serious adverse events and TEAEs leading to withdrawal from the trial drug were all prespecified secondary endpoints.(van der Heijde et al, 2023)

BE MOBILE 2 (NCT03928743)

Citation:

van der Heijde D. *et al.* Efficacy and safety of bimekizumab in axial spondyloarthritis: results of two parallel phase 3 randomised controlled trials. *Annals of the Rheumatic Diseases.* 2023:ard-2022-223595

Aims and objectives:

To evaluate efficacy and safety of bimekizumab across the axSpA spectrum(van der Heijde et al, 2023)

Design:

A phase 3, multicentre, randomised, double-blind, placebo-controlled trial(van der Heijde et al, 2023)

Population:

Patients had r-axSpA and fulfilled modified New York criteria, including documented radiographic evidence of sacroiliitis (grade ≥2 bilateral or grade ≥3 unilateral); prior to enrollment, at the randomisation stage, fulfilment of the ASAS classification criteria was also checked and all patients in BE MOBILE 2 met both mNY and ASAS classification criteria. In both trials, prior failure of ≥2 NSAIDs, or history of intolerance or contraindication to NSAIDs was required.(van der Heijde et al, 2023)

Intervention and comparator:

- Bimekizumab 160 mg every 4 weeks
- Placebo every 4 weeks.

Outcomes:

The primary efficacy endpoint was ASAS 40 response at Week 16.(van der Heijde et al, 2023)

Secondary efficacy endpoints included ASDAS states and ASAS 40 responses by prior biologic experience.(van der Heijde et al, 2023)

Incidence of treatment-emergent adverse events, treatment-emergent serious adverse events and TEAEs leading to withdrawal from the trial drug were all prespecified secondary endpoints.(van der Heijde et al, 2023)

Appendix 2: Licensed therapies

	Licensed indication (PsA and axSpA) NOTE: Products may have other indications which are not listed here, please refer to the relevant SmPCs
Bimekizumab(UCB Pharma Limited BIMZELX SmPC)	PsA 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). axSpA *Non-radiographic axial spondyloarthritis (nr-axSpA)* Bimekizumab 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). *Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)* Bimekizumab is indicated for the treatment of adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy.
Guselkumab(Tremfya SmPC)	PsA Alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy.
Ixekizumab(Taltz SmPC)	PsA Alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. axSpA *Ankylosing spondylitis (radiographic axial spondyloarthritis)* For the treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis* For the treatment of adult patients 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 to nonsteroidal anti-inflammatory drugs (NSAIDs).
Risankizumab(Skyrizi SmPC)	PsA Alone or in combination with methotrexate (MTX), 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).
Secukinumab(Cosentyx SmPC)	PsA Alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate. axSpA *Ankylosing spondylitis (AS, radiographic axial spondyloarthritis)* For the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy. *Non-radiographic axial spondyloarthritis (nr-axSpA)* For the treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence in adults who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs).
Ustekinumab(Stelara SmPC)	PsA Alone or in combination with MTX, is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Appendix 3: National guidelines

PsA

	National guidelines
Bimekizumab	**NICE TA 916**[NICE, 2023a] 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 DMARDs or who cannot tolerate them. It is recommended only if they have had 2 conventional DMARDs and: • at least 1 biological DMARD or • anti-TNFs 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.
Guselkumab	**NICE TA815**[NICE, 2022a] Guselkumab, alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults whose disease 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: • have had 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). Guselkumab is recommended only if the company provides it according to the commercial arrangement. Active psoriatic arthritis is defined as peripheral arthritis with 3 or more tender joints and 3 or more swollen joints. **SMC2360**[SMC, 2021] guselkumab (Tremfya®) is accepted for restricted use within NHS Scotland. Indication under review: alone or in combination with methotrexate (MTX) for the treatment of active psoriatic arthritis in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug (DMARD) therapy. SMC restriction: (i) patients whose disease has not responded adequately or who have been intolerant to two previous conventional disease-modifying antirheumatic drug (DMARD) therapies but have not received biologic DMARD therapy (biologic-naïve population); (ii) patients whose disease has not responded adequately to conventional DMARDs and one or more tumour necrosis factor (TNF) inhibitors (biologic-experienced population); and (iii) patients in whom TNF inhibitors are contraindicated or not tolerated. Three phase III studies demonstrated superiority of guselkumab when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a tumour necrosis factor (TNF) inhibitor medication and in those with an inadequate response or intolerance to TNF inhibitors. This advice applies only in the context of an approved NHS Scotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.
Ixekizumab	**NICE TA537**[NICE, 2018] Ixekizumab alone, or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults, only if: • it is used as described in NICE's technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or • the person has had a tumour necrosis factor (TNF)-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after the first 12 weeks or

	• 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). Ixekizumab is only recommended if the company provides it according to the commercial arrangement. **SMC2097**[SMC, 2018] Ixekizumab (Taltz®) is accepted for restricted use within NHS Scotland. Indication under review: ixekizumab, alone or in combination with methotrexate, is indicated for the treatment of active psoriatic arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drug (DMARD) therapies. SMC restriction: patients whose disease has not responded adequately to at least two conventional DMARDs given either alone or in combination, and who have had an inadequate response to a tumour necrosis factor (TNF)-inhibitor. Two phase III studies demonstrated superiority of ixekizumab when compared with placebo in reducing signs and symptoms of psoriatic arthritis in patients who had not previously received a biologic medication and those with an inadequate response or intolerance to TNF-inhibitors. This SMC advice takes account of the benefits of a Patient Access Scheme (PAS) that improves the cost-effectiveness of ixekizumab. This advice is contingent upon the continuing availability of the PAS in NHS Scotland or a list price that is equivalent or lower.
Risankizumab	**NICE TA803**[NICE, 2022b] Risankizumab, alone or with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults whose disease has not responded well enough to disease-modifying antirheumatic drugs (DMARDs) or who cannot tolerate them. It is recommended only if they have: • peripheral arthritis with 3 or more tender joints and 3 or more swollen joints • moderate to severe psoriasis (a body surface area of at least 3% affected by plaque psoriasis and a Psoriasis Area and Severity Index [PASI] score greater than 10) • had 2 conventional DMARDs and at least 1 biological DMARD. Risankizumab is recommended only if the company provides it according to the commercial arrangement.
Secukinumab	**NICE TA445**[NICE, 2017a] Secukinumab alone, or in combination with methotrexate, is recommended as an option for treating active psoriatic arthritis in adults only if: • it is used as described in the NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (recommendations 1.1 and 1.2) or • the person has had a TNF-alpha inhibitor but their disease has not responded within the first 12 weeks or has stopped responding after 12 weeks or • TNF-alpha inhibitors are contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis). Secukinumab is only recommended if the company provides it as agreed in the patient access scheme.
Ustekinumab	**NICE TA340**[NICE, 2017c] Ustekinumab is recommended as an option, alone or in combination with methotrexate, for treating active psoriatic arthritis in adults only when: • treatment with tumour necrosis factor (TNF) alpha inhibitors is contraindicated but would otherwise be considered (as described in NICE technology appraisal guidance on etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis and golimumab for the treatment of psoriatic arthritis) or • the person has had treatment with 1 or more TNF–alpha inhibitors.

	National guidelines
Bimekizumab	**NICE TA918**[NICE, 2023b] Bimekizumab is recommended as an option in adults for treating active AS when conventional therapy has not worked well enough or is not tolerated, or active nr-axSpA with objective signs of inflammation (shown by elevated CRP or MRI) when NSAIDs, have not worked well enough or are not tolerated. It is recommended only if: • anti-TNFs are not suitable or do not control the condition well enough, and • the company provides it according to the commercial arrangement
Ixekizumab	**NICE TA718**[NICE, 2021a] Ixekizumab is recommended as an option for treating active ankylosing spondylitis that is not controlled well enough with conventional therapy, or active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs), in adults. 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 ixekizumab according to the commercial arrangement. **SMC2440**[SMC, 2022] ixekizumab (Taltz®) is not recommended for use within NHSScotland. Indication under review: Ankylosing spondyloarthritis (radiographic axial spondyloarthritis) Treatment of adult patients with active ankylosing spondylitis who have responded inadequately to conventional therapy. Non-radiographic axial spondyloarthritis Treatment of adult patients 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 to nonsteroidal anti-inflammatory drugs (NSAIDs). In three phase III studies, ixekizumab, compared with placebo, significantly improved symptoms of active radiographic and non-radiographic axial spondyloarthritis (axSpA) in patients who had not previously received biologic medicines, and in patients with active radiographic axSpA who had an inadequate response or intolerance to TNF-alpha inhibitors. The submitting company did not present a sufficiently robust economic analysis to gain acceptance by SMC.
Secukinumab	**NICE TA407**[NICE, 2016] Secukinumab is recommended, within its marketing authorisation, as an option for treating active ankylosing spondylitis in adults whose disease has responded inadequately to conventional therapy (non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors). The drug is recommended only if the company provides it with the discount agreed in the patient access scheme. **NICE TA719**[NICE, 2021b] Secukinumab is recommended as an option for treating active non-radiographic axial spondyloarthritis with objective signs of inflammation (shown by elevated C-reactive protein or MRI) that is not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs) in adults. 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 secukinumab according to the commercial arrangement

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UCB Pharma S.A. BIMZELX SmPC. BIMZELX Summary of Product Characteristics
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PRESCRIBING INFORMATION FOR HCP's in GREAT BRITAIN

(Please consult the Summary of Product Characteristics (SmPC) before prescribing)

Bimzelx® ▼ (bimekizumab)

Active Ingredient: bimekizumab – *solution for injection in pre-filled syringe or pre-filled pen: 160 mg of bimekizumab in 1 mL of solution (160 mg/mL)*.

Indications: Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Alone or in combination with methotrexate, for active psoriatic arthritis in adults who have had an inadequate response or intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). 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). Adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy. Active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy.

Dosage and Administration: Should be initiated and supervised by a physician experienced in the diagnosis and treatment of conditions for which Bimzelx is indicated. **Recommended dose:** *Plaque Psoriasis:* 320 mg (given as two subcutaneous injections of 160 mg each) at week 0, 4, 8, 12, 16 and every 8 weeks thereafter. *Psoriatic arthritis:* 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. 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. *Axial spondyloarthritis (nr-axSpA and AS):* 160 mg (given as 1 subcutaneous injection) every 4 weeks. For patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and 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. Consider discontinuing if no improvement by 16 weeks of treatment. *Hidradenitis suppurativa:* 320 mg (given as 2 subcutaneous injections of 160mg each) every 2 weeks up to Week 16 and every 4 weeks thereafter.*Renal or hepatic impairment:* No dose adjustment needed. *Elderly:* No dose adjustment needed. Administer by subcutaneous injection to thigh, abdomen or upper arm. Rotate injection sites and do not inject into psoriatic plaques or skin that is tender, bruised, erythematous or indurated. Do not shake pre-filled syringe or pre-filled pen. Patients may be trained to self-inject.

Contraindications: Hypersensitivity to bimekizumab or any excipient; Clinically important active infections (e.g. active tuberculosis).

Warnings and Precautions*:* Record name and batch number of administered product.

Infection: Bimekizumab may increase the risk of infections e.g. upper respiratory tract infections, oral candidiasis. Caution when considering use in patients with a chronic infection or a history of recurrent infection. Must not be initiated if any clinically important active infection until infection resolves or is adequately treated. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection, the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy do not administer bimekizumab until infection resolves. *TB:* Evaluate for TB infection prior to initiating bimekizumab – do not give if active TB. While on bimekizumab, monitor for signs and symptoms of active TB. Consider anti-TB therapy prior to bimekizumab initiation if past history of latent or active TB in whom adequate treatment course cannot be confirmed. *Inflammatory bowel disease:* Bimekizumab is not recommended in patients with inflammatory bowel disease. Cases of new or exacerbations of inflammatory bowel disease have been reported. If inflammatory bowel disease signs/symptoms develop or patient experiences exacerbation of pre-existing inflammatory bowel disease, discontinue bimekizumab and initiate medical management. *Hypersensitivity*: Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, discontinue immediately and treat. *Vaccinations*: Complete all age appropriate immunisations prior to bimekizumab initiation. Do not give live vaccines to bimekizumab patients. Patients may receive inactivated or non-live vaccinations.

Interactions: A clinically relevant effect on CYP450 substrates with a narrow therapeutic index in which the dose is individually adjusted e.g. warfarin, cannot be excluded. Therapeutic monitoring should be considered.

Fertility, pregnancy and lactation: Women of child-bearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy. No data available on human fertility.

Driving and use of machines: No or negligible influence on ability to drive and use machines.

Adverse Effects: Refer to SmPC for full information. *Very Common (≥ 1/10):* upper respiratory tract infection*; Common (≥ 1/100 to < 1/10):* oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue*;* vulvovaginal mycotic infection (including vulvovaginal candidiasis); *Uncommon (≥ 1/1,000 to < 1/100):* mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease.

Storage precautions: Store in a refrigerator (2ºC – 8ºC), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25ºC for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.

Legal Category: POM

Marketing Authorisation Numbers: PLGB 00039/0802 (Pre-filled Syringe), PLGB 00039/0803 (Pre-filled Pen).

UK NHS Costs: £2,443 per pack of 2 pre-filled syringes or pens of 160 mg each.

Marketing Authorisation Holder: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE, United Kingdom.

Further information is available from: UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE. *Tel:* 0800 2793177 *Email*: ucbcares.uk@ucb.com

Date of Revision: June 2024 (GB-BK-2400297)

Bimzelx is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at http://www.mhra.gov.uk/yellowcard. Adverse events should also be reported to UCB Pharma Ltd at ucbcares.uk@ucb.com or 0800 2793177

PRESCRIBING INFORMATION FOR HCP'S IN REPUBLIC OF IRELAND AND NORTHERN IRELAND

(Please consult the Summary of Product Characteristics (SmPC) before prescribing)

Bimzelx® ▼ (bimekizumab)

Active Ingredient: bimekizumab – *solution for injection in pre-filled syringe or pre-filled pen: 160 mg of bimekizumab in 1 mL of solution (160 mg/mL)*. **Indications:** Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy. Alone or in combination with methotrexate, for active psoriatic arthritis in adults who have had an inadequate response or intolerant to one or more disease-modifying antirheumatic drugs (DMARDs). 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). Adults with active ankylosing spondylitis who have responded inadequately or are intolerant to conventional therapy. Active moderate to severe hidradenitis suppurativa (acne inversa) in adults with an inadequate response to conventional systemic HS therapy. **Dosage and Administration:** Should be initiated and supervised by a physician experienced in the diagnosis and treatment of conditions for which Bimzelx is indicated. **Recommended dose:** *Plaque Psoriasis:* 320 mg (given as two subcutaneous injections of 160 mg each) at week 0, 4, 8, 12,16 and every 8 weeks thereafter. *Psoriatic arthritis:* 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. 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. *Axial spondyloarthritis (nr-axSpA and AS):* 160 mg (given as 1 subcutaneous injection) every 4 weeks. For patients with plaque psoriasis (including psoriatic arthritis with coexistent moderate to severe psoriasis) and 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. Consider discontinuing if no improvement by 16 weeks of treatment. *Hidradenitis suppurativa*: 320 mg (given as 2 subcutaneous injections of 160mg each) every 2 weeks up to Week 16 and every 4 weeks thereafter. *Renal or hepatic impairment:* No dose adjustment needed. *Elderly:* No dose adjustment needed. Administer by subcutaneous injection to thigh, abdomen or upper arm. Rotate injection sites and do not inject into psoriatic plaques or skin that is tender, bruised, erythematous or indurated. Do not shake pre-filled syringe or pre-filled pen. Patients may be trained to self-inject. **Contraindications:** Hypersensitivity to bimekizumab or any excipient; Clinically important active infections (e.g. active tuberculosis). **Warnings and Precautions***:* Record name and batch number of administered product. *Infection:* Bimekizumab may increase the risk of infections e.g. upper respiratory tract infections, oral candidiasis. Caution when considering use in patients with a chronic infection or a history of recurrent infection. Must not be initiated if any clinically important active infection until infection resolves or is adequately treated. Advise patients to seek medical advice if signs or symptoms suggestive of an infection occur. If a patient develops an infection, the patient should be carefully monitored. If the infection becomes serious or is not responding to standard therapy do not administer bimekizumab until infection resolves. *TB:* Evaluate for TB infection prior to initiating bimekizumab – do not give if active TB. While on bimekizumab, monitor for signs and symptoms of active TB. Consider anti-TB therapy prior to bimekizumab initiation if past history of latent or active TB in whom adequate treatment course cannot be confirmed. *Inflammatory bowel disease:* Bimekizumab is not recommended in patients with inflammatory bowel disease. Cases of new or exacerbations of inflammatory bowel disease have been reported. If inflammatory bowel disease signs/symptoms develop or patient experiences exacerbation of pre-existing inflammatory bowel disease, discontinue bimekizumab and initiate medical management. *Hypersensitivity*: Serious hypersensitivity reactions including anaphylactic reactions have been observed with IL-17 inhibitors. If a serious hypersensitivity reaction occurs, discontinue immediately and treat. *Vaccinations*: Complete all age appropriate immunisations prior to bimekizumab initiation. Do not give live vaccines to bimekizumab patients. Patients may receive inactivated or non-live vaccinations. **Interactions:** A clinically relevant effect on CYP450 substrates with a narrow therapeutic index in which the dose is individually adjusted e.g. warfarin, cannot be excluded. Therapeutic monitoring should be considered. **Fertility, pregnancy and lactation**: Women of child-bearing potential should use an effective method of contraception during treatment and for at least 17 weeks after treatment. Avoid use of bimekizumab during pregnancy. It is unknown whether bimekizumab is excreted in human milk, hence a risk to the newborn/infant cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Bimzelx therapy. No data available on human fertility. **Driving and use of machines**: No or negligible influence on ability to drive and use machines. **Adverse Effects: Refer to SmPC for full information.** *Very Common (≥ 1/10):* upper respiratory tract infection*; Common (≥ 1/100 to < 1/10):* oral candidiasis, tinea infections, ear infections, herpes simplex infections, oropharyngeal candidiasis, gastroenteritis, folliculitis; headache, rash, dermatitis and eczema, acne, injection site reactions, fatigue, Vulvovaginal mycotic infection (including vulvovaginal candidiasis) *; Uncommon (≥ 1/1,000 to < 1/100):* mucosal and cutaneous candidiasis (including oesophageal candidiasis), conjunctivitis, neutropenia, inflammatory bowel disease. **Storage precautions:** Store in a refrigerator (2ºC – 8ºC), do not freeze. Keep in outer carton to protect from light. Bimzelx can be kept at up to 25ºC for a single period of maximum 25 days with protection from light. Product should be discarded after this period or by the expiry date, whichever occurs first.

Legal Category: POM

Marketing Authorisation Numbers: EU/1/21/1575/002 (2 x 1 Pre-filled Syringes), EU/1/21/1575/006 (2 x 1 Pre-filled Pens)

UK NHS Costs: £2,443 per pack of 2 pre-filled syringes or pens of 160 mg each.

Marketing Authorisation Holder: UCB Pharma S.A., Allée de la Recherche 60, B-1070 Brussels, Belgium.

Further information is available from: *Republic of Ireland:* UCB (Pharma) Ireland Ltd, United Drug House, Magna Drive, Magna Business Park, City West Road, Dublin 24, Ireland. *Tel:* 1800-930075 *Email:* UCBCares.IE@ucb.com ; *Northern Ireland:* UCB Pharma Ltd, 208 Bath Road, Slough, Berkshire, SL1 3WE.Tel: +44 (0) 1753 777100. Fax: +44 (0)1753 536632. Email: UCBCares.UK@ucb.com

Date of Revision: April 2024 (IE-BK-2400115)

Bimzelx is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk for Northern Ireland and hpra.ie/homepage/about-us/report-an-issue for Ireland Adverse events should also be reported to UCB Pharma Ltd