NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Bimekizumab for treating ankylosing spondylitis

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of bimekizumab within its marketing authorisation for treating ankylosing spondylitis.

Background

Ankylosing spondylitis (AS) belongs to a clinically heterogeneous group of inflammatory rheumatologic diseases which share common genetic, histological and clinical features (also including psoriatic arthritis, arthritis associated with inflammatory bowel disease, reactive arthritis and undifferentiated spondyloarthritis). Ankylosing spondylitis involves inflammation of the sacroiliac joints and spine which is visible on x-ray as erosions, thickening of the bone, or fusion of joints.

The clinical symptoms of ankylosing spondylitis can vary from person to person, but usually develop slowly over several months or years. The main symptoms can include back pain, usually inflammatory in nature, arthritis (inflammation of the joints in other parts of the body), enthesitis (inflammation where a bone is joined to a tendon), and fatigue. Extra-articular manifestations include uveitis, inflammatory bowel disease and psoriasis. The onset of symptoms typically occurs in the third decade of life, but it can be 7–10 years before a diagnosis is made. Many patients with mild disease may remain undiagnosed.

The prevalence of ankylosing spondylitis in the UK is uncertain, one estimate is that approximately *110,000* people have been diagnosed with AS.[1] Another estimate ranges from 0.05% to 0.23%[2], this would equate to a prevalence between 33,750 and 155,250 based on population estimates in 2022. Ankylosing spondylitis is about 3 times more common in men than in women.[3]

Conventional therapy for ankylosing spondylitis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. When the disease does not respond adequately to conventional therapy, or where NSAIDs are not suitable, tumour necrosis factor-alpha (TNF-alpha) inhibitors (adalimumab, certolizumab pegol, etanercept, golimumab and infliximab) are used, as recommended by , NICE technology appraisal TA383. Biosimilar versions of adalimumab, etanercept and infliximab are available. Infliximab is only recommended if the least expensive infliximab product is used. NICE technology appraisal 407 and NICE technology appraisal 718 recommend the interleukin-17A (IL-17A) inhibitors secukinumab and ixekizumab where TNF-alpha inhibitors are not tolerated or where the disease has responded inadequately to them.

The technology

Bimekizumab (Bimzelx, UCB Pharma) does not have a marketing authorisation in the UK for ankylosing spondylitis. It has been studied in clinical trials compared with placebo and certolizumab pegol in adults with moderate-to-severe active ankylosing spondylitis which has failed to respond to 2 different NSAID treatments.

Bimekizumab has an indication for treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Intervention(s)	Bimekizumab
Population(s)	Adults with moderate-to-severe active ankylosing spondylitis
Subgroups	If the evidence allows, the following subgroups will be considered • Those who have had no previous biological disease modifying anti-rheumatic drug treatments (biological DMARD naïve) • Those who have had a previous biological disease modifying anti-rheumatic drug treatments (biological DMARD experienced)

Comparators	• Interleukin-17A inhibitors:
	  ○ Secukinumab
	  ○ Ixekizumab
	• TNF-alpha inhibitors including:
	  ○ Adalimumab
	  ○ Certolizumab pegol
	  ○ Etanercept
	  ○ Golimumab
	  ○ Infliximab
	• JAK inhibitors
	  ○ Upadacitinib (subject to NICE evaluation)
	  ○ Tofacitinib (subject to NICE evaluation)

Outcomes	The outcome measures to be considered include: • disease activity • functional capacity • disease progression • pain • peripheral symptoms (including enthesitis, peripheral arthritis and dactylitis) • symptoms of extra-articular manifestations (including uveitis, inflammatory bowel disease and psoriasis) • adverse effects of treatment • health-related quality of life
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account The availability of biosimilar and generic products should be taken into account
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations	**Related Technology Appraisals:** 'TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis' NICE Technology appraisal guidance 383 Review date to be confirmed.

	'Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors' NICE technology appraisal guidance 407. Review date to be confirmed 'Ixekizumab for treating axial spondyloarthritis' NICE technology appraisal guidance 718. Review date 2024 'Upadacitinib for treating active ankylosing sponylitis' NICE technology appraisal guidance TA829. Review date 2025 **Related appraisals in development:** Tofacitinib for treating active ankylosing spondylitis' NICE technology appraisal guidance [ID3865]. Publication date to be confirmed **Related Guidelines:** Spondyloarthritis in over 16s: diagnosis and management (2017) NICE guideline 65. Review date to be confirmed. **Related Quality Standards:** Spondyloarthritis (2018) NICE quality standard 170.
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 5 – Adult highly specialist rheumatology services

Questions for consultation

Do you consider the population of adults with moderate-to-severe active ankylosing spondylitis to be appropriate for this appraisal?

Have all relevant comparators for bimekizumab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for active ankylosing spondylitis?

Are all of the outcomes listed appropriate?

Where do you consider bimekizumab will fit into the existing care pathway for ankylosing spondylitis?

Would the technology be a candidate for managed access?

Do you consider that the use of bimekizumab can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit

and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which bimekizumab will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

NICE intends to evaluate this technology through its Single Technology Appraisal process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

NICE's health technology evaluations: the manual states the methods to be used where a cost comparison case is made.

- Would it be appropriate to use the cost-comparison methodology for this topic?

- Is the new technology likely to be similar in its clinical efficacy and resource use to any of the comparators?

- Is the primary outcome that was measured in the trial or used to drive the model for the comparator(s) still clinically relevant?

- Is there any substantial new evidence for the comparator technology/ies that has not been considered? Are there any important ongoing trials reporting in the next year?

References

1. National Ankylosing Spondyloarthritis Society: Facts & Figures. Available at https://nass.co.uk/about-as/as-facts-and-figures/ Accessed September 2022

2. NIHR Innovation Observatory Health Technology Briefing: Tofacitinib for Ankylosing Spondylitis. Available at https://www.io.nihr.ac.uk/techbriefings/tofacitinib-for-ankylosing-spondylitis/ Accessed September 2022

3. NHS: Ankylosing Spondylitis Overview Available at https://www.nhs.uk/conditions/ankylosing-spondylitis/ Accessed September 2022