NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Bimekizumab for treating active non-radiographic axial spondyloarthritis

Draft scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of bimekizumab within its marketing authorisation for treatment of active non-radiographic axial spondyloarthritis with objective signs of inflammation.

Background

Axial spondyloarthritis 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 spondylarthritis). Axial spondyloarthritis involves inflammation of the sacroiliac joints and spine. If inflammation is visible on x-ray (as erosions, thickening of the bone, or fusion of joints), the disease is classified as radiographic axial spondyloarthritis (also known as ankylosing spondylitis). If x-rays of the sacroiliac joints and spine are normal, but there are other objective signs of inflammation (elevated C-reactive protein or evidence on magnetic resonance imaging) the disease is classified as non-radiographic axial spondyloarthritis.

The clinical symptoms of axial spondyloarthritis can vary from person to person, but usually develop slowly over several months or years. The main symptoms can include back pain, which will be inflammatory in nature, peripheral arthritis (inflammation in 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 average age of onset of symptoms is 24 years, with an average of 8.5 years before a diagnosis is made, by which time damage to the spine which can be irreversible may have occurred.[1]

Around 220,000 adults have been diagnosed as having axial spondyloarthritis and an estimated 1 in 200 of the adult population in the UK is affected.[1] Non-radiographic axial spondyloarthritis affects approximately equal numbers of men and women, but there are limited data on the prevalence of the condition.

Conventional therapy for non-radiographic axial spondyloarthritis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. NICE technology appraisal guidance 383 and 497 recommend tumour necrosis factor-alpha inhibitors adalimumab, certolizumab pegol, etanercept and golimumab as treatment options in people with disease that does not respond adequately to or cannot tolerate NSAIDs. Biosimilar versions of adalimumab, etanercept and golimumab are now available.

NICE technology appraisals 719 and 718 recommend secukinumab and ixekizumab as options 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) only if

tumour necrosis factor (TNF)-alpha inhibitors are not suitable or do not control the condition well enough.

The technology

Bimekizumab (Bimzelx, UCB Pharma does not currently have a marketing authorisation in the UK for treating non-radiographic axial spondyloarthritis. It has been studied in clinical trials compared with placebo in adults with non-radiographic axial spondyloarthritis with objective signs of inflammation.

Bimekizumab has a marketing authorisation for treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

Intervention(s)	Bimekizumab
Population(s)	Adults with active non-radiographic axial spondyloarthritis
Subgroups	If the evidence allows consideration will be given to subgroups who have not received TNF-alpha inhibitors, and those for whom TNF-alpha inhibitors are not suitable or do not control the condition well enough

Comparators	• Upadacitinib (subject to NICE evaluation)
	• Secukinumab
	• Ixekizumab
	• TNF-alpha inhibitors including:
	  ○ Adalimumab
	  ○ Certolizumab pegol
	  ○ Etanercept
	  ○ Golimumab
	• Established clinical management without biological treatments

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 any managed access arrangement for the intervention will be taken into account.
Other considerations	The availability and cost of biosimilar and generic products should be taken into account. 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:** 'Ixekizumab for treating axial spondyloarthritis' (2021) NICE technology appraisal 718 'Secukinumab for treating non-radiographic axial spondyloarthritis' (2021) NICE technology appraisal 719 'Golimumab for treating non-radiographic axial spondyloarthritis' (2018) NICE technology appraisal 497. Review date December 2020. 'TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis' (2016) NICE technology appraisal 383. Review date June 2021. 'Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors' (2016) NICE technology appraisal 407. Review date September 2019. **Related Appraisals in Development:** 'Upadacitinib for treating active non-radiographic axial spondyloarthritis' NICE technology appraisal [ID3958].

	Expected publication date January 2023. 'Upadacitinib for treating active ankylosing spondylitis' NICE technology appraisal [ID3848]. Expected publication date September 2022. **Related Guidelines:** 'Spondyloarthritis in over 16s: diagnosis and management' (2017) NICE guideline 65. Review date to be confirmed. **Related Quality Standards:** 'Spondyloarthritis'. NICE quality standard 170. Review date August 2019.
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 specialised rheumatology services NHS England (2018) NHS England Funding and Resource 2018/19: Supporting 'Next Steps for the NHS Five Year Forward View' Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 1, 2, 4 and 5 https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017

Questions for consultation

Where do you consider bimekizumab will fit into the existing care pathway for non-radiographic axial spondyloarthritis?

Are the comparators and outcomes for bimekizumab considered appropriate?

Would bimekizumab 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 Axial Spondyloarthritis Society. *What are the issues in axial SpA (AS)?* Available from: https:// nass.co.uk/about-as/as-facts-and-figures/. Accessed September 2022