NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Bimekizumab for treating active psoriatic arthritis

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of bimekizumab within its marketing authorisation for treating active psoriatic arthritis.

Background

Psoriatic arthritis (also called psoriatic arthropathy) is an inflammatory arthritis closely associated with psoriasis. It is estimated that around 1 in 5 people with psoriasis develop psoriatic arthritis.[1] Around 70% of people have psoriasis before psoriatic arthritis.[2] The prevalence of psoriatic arthritis in England in 2020 was estimated to be around 84,500 adults.[2,3] Men and women are equally likely to develop psoriatic arthritis with peak onset being between the ages of 30 and 50.[2]

Although psoriatic arthritis is a chronic condition that progresses in the joints, its course may be erratic, with flare-ups and remissions. Arthritis symptoms can range from inflammation of the synovial membrane surrounding a joint (synovitis), ligaments and tendons (enthesitis and tendonitis), and inflammation of digits (dactylitis) to severe progressive erosion of the joints. Axial inflammation might also occur in some cases. Skin symptoms include the presence of patchy, raised, red areas of skin inflammation with scaling. This can affect any part of the body but is most commonly found on the elbows, knees, scalp and ears, the navel, and around the genital areas or anus. Nail symptoms include swelling, discolouration and pitting.

The aim of treatment is to suppress joint, tendon and ligament inflammation, and to manage the skin symptoms of the disease. Current practice involves early diagnosis and early use of non-biological disease-modifying anti-rheumatic drugs (DMARDs), including methotrexate, sulfasalazine and leflunomide, in order to minimise damage to joints. Non-steroidal anti-inflammatory drugs (NSAIDs), physiotherapy and intra-articular corticosteroid injections may also be used.

In addition, biological tumour necrosis factor (TNF)-alpha inhibitors and other non-conventional DMARDs (such as Janus kinase inhibitors and IL-17 inhibitors) may be used for treating people with active psoriatic arthritis. NICE recommends adalimumab, etanercept, infliximab, golimumab, certolizumab pegol, secukinumab, apremilast, ixekizumab or tofacitinib when a person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, and the psoriatic arthritis has not responded to at least 2 standard DMARDs, given on their own or together (NICE technology appraisal guidance 199, 220, 445, 433, 537, and 543). Certolizumab pegol is also recommended when the disease has stopped responding to a TNF-alpha inhibitor after the first 12 weeks (NICE technology appraisal guidance 445). Ixekizumab, secukinumab and tofacitinib are also recommended in people whose disease has not responded within 12 weeks or stopped responding after 12 weeks of treatment with a TNF-alpha inhibitor or when TNF-alpha inhibitors are contraindicated but would otherwise be considered (NICE technology appraisal

guidance 537, 445 and 543). Ustekinumab is recommended when treatment with TNF-alpha inhibitors is contraindicated but would otherwise be considered or the person has had treatment with 1 or more TNF-alpha inhibitors (NICE technology appraisal guidance 340). Risankizumab is recommended when a person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, moderate to severe psoriasis and their disease has not responded well enough to, or they cannot tolerate, 2 conventional DMARDs and at least 1 biological DMARD (NICE technology appraisal guidance 803). Guselkumab and upadacitinib are recommended when a person has peripheral arthritis with 3 or more tender joints and 3 or more swollen joints, moderate to severe psoriasis and their disease has not responded well enough to, or they cannot tolerate, 2 conventional DMARDs and at least 1 biological DMARD, and when treatment with TNF-alpha inhibitors is contraindicated but would otherwise be considered (NICE Technology appraisal guidance 815 and 768). Biosimilar products for some of the biological therapies are also available for use in the NHS.

The technology

Bimekizumab (Bimzelx, UCB Pharma) does not currently have a marketing authorisation for treating active psoriatic arthritis. It has been studied in clinical trials compared with adalimumab or placebo in adults with psoriatic arthritis who have not been treated with biological DMARDs or whose disease has not responded adequately to TNFa inhibitors or for whom TNFa inhibitors are not tolerated.

Bimekizumab has a marketing authorisation in the UK for the treatment of moderate to severe plaque psoriasis in adults whose disease has not responded to conventional DMARDs.

Intervention(s)	Bimekizumab
Population(s)	Adults with active psoriatic arthritis
Comparators	For people who have only received 1 previous conventional disease modifying anti-rheumatic drug (DMARD) • Conventional DMARDs For people whose disease has not responded adequately to at least 2 conventional DMARDs: • Biological DMARDs (with or without methotrexate including etanercept, adalimumab, infliximab, golimumab, certolizumab pegol, ixekizumab and secukinumab) • Apremilast • Tofacitinib • Upadacitinib For people whose disease has not responded adequately to conventional DMARDs and 1 or more TNF-alpha inhibitors: • Ustekinumab • Secukinumab

	• Certolizumab pegol • Tofacitinib • Ixekizumab • Best supportive care For people in whom TNF-alpha inhibitors are contraindicated or not tolerated: • Ustekinumab • Secukinumab • Ixekizumab • Tofacitinib • Guselkumab • Upadacitinib • Best supportive care For people whose disease has not responded adequately to conventional DMARDs and 1 or more biological DMARDs, or for whom these are not tolerated: • Guselkumab • Risankizumab • Best supportive care • Upadacitinib
Outcomes	The outcome measures to be considered include: • disease activity • functional capacity • disease progression • periarticular disease (for example enthesitis, tendonitis, dactylitis) • axial outcomes • mortality • 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 appraisals 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 treatments will be taken into account. The availability and cost 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** 'Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs' (2022) NICE Technology Appraisal 815. Review date: 2024. 'Risankizumab for treating active psoriatic arthritis after inadequate response to DMARDs' (2022) NICE Technology Appraisal 803. Review date: 2025. 'Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs' (2022) NICE Technology Appraisal 803. Review date: 2025. 'Ixekizumab for treating active psoriatic arthritis following inadequate response to disease-modifying anti-rheumatic drugs' (2018) NICE Technology Appraisals 537. Review date: 2021. 'Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs' (2018) NICE Technology Appraisals 543. Review date: 2021. 'Certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease

	modifying anti-rheumatic drugs' (2017) NICE Technology Appraisals 445 (moved to the static list). 'Apremilast for treating active psoriatic arthritis' (2017) NICE Technology Appraisal 433 (moved to the static list). 'Ustekinumab for treating active psoriatic arthritis' (2015). NICE Technology Appraisal 340 (moved to the static list). 'Golimumab for the treatment of psoriatic arthritis' (2011). NICE Technology Appraisal 220 (moved to the static list). 'Etanercept, infliximab and adalimumab for the treatment of psoriatic arthritis (review of technology appraisal guidance 104 and 125)' (2010). NICE Technology Appraisal 199 (moved to the static list). **Related Guidelines** Psoriasis: assessment and management (2012). NICE clinical guideline 153. Last updated: September 2017 **Related Quality Standards** Spondyloarthritis (2018) NICE Quality Standard 170. Psoriasis (2013). NICE Quality Standard 40.
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

Where do you consider bimekizumab will fit into the existing care pathway for active psoriatic arthritis?

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 comparators still clinically relevant?

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

References

1. Psoriasis Association (2018) Psoriasis Arthritis. Accessed September 2022
2. Ogdie, A., Langan, S., Love, T., Haynes, K., Shin, S., Seminara, N., Mehta, N., Troxel, A., Choi, H., Gelfand, J. (2013) 'Prevalence and treatment patterns of psoriatic arthritis in the UK'. Rheumatology (Oxford) Mar 52(3): 568-75
3. Office for National Statistics (2021) Population estimates mid-year 2020. Accessed September 2022