

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Health Technology Evaluation

## Bimekizumab for treating axial spondyloarthritis

## Final scope

**Remit/evaluation objective**

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

**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.<sup>1</sup>

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.<sup>1</sup> The prevalence of non-radiographic axial spondylitis to ankylosing spondylitis is thought to be in a ratio of 1:1, so it is estimated that around 110,000 people have each subtype in the UK.<sup>1</sup> Non-radiographic axial spondyloarthritis affects approximately equal numbers of men and women, whereas ankylosing spondylitis is about 3 times more common in men.<sup>2</sup> Conventional therapy for non-radiographic axial spondyloarthritis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. [NICE technology appraisals 383](#) and [497](#) recommend tumour necrosis factor-alpha (TNF) 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 TNF-alpha inhibitors are not suitable or do not control the condition well enough.

Conventional therapy for ankylosing spondylitis is the same as for non-radiographic axial spondylitis and [NICE technology appraisal 383](#) also recommends tumour necrosis factor-alpha inhibitors, although infliximab is only recommended if the least expensive infliximab product is used. [NICE technology appraisals 407](#), [718](#) and [829](#) recommend secukinumab, ixekizumab and upadacitinib respectively for active ankylosing spondylitis which has not responded to conventional therapy and where TNF-alpha inhibitors are either not tolerated or where the disease has responded inadequately to them.

### The technology

Bimekizumab (Bimzelx, UCB Pharma) does not currently have a marketing authorisation in the UK for treating non-radiographic axial spondyloarthritis or ankylosing spondylitis. It has been studied in clinical trials compared with placebo in adults with non-radiographic axial spondyloarthritis with objective signs of inflammation. It has also 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 a marketing authorisation for treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.

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| <b>Intervention(s)</b> | Bimekizumab   |
| <b>Population(s)</b>   | Adults with active axial spondyloarthritis  |
| <b>Subgroups</b>       | <p>If the evidence allows, the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• Those who have either active non-radiographic axial spondylitis or active ankylosing spondylitis,</li> <li>• Those who have not had previous biological disease modifying anti-rheumatic drug treatments (biological DMARD naïve) or those who have experience with these treatments (biological DMARD experienced).</li> </ul>   |
| <b>Comparators</b>     | <p>For active non-radiographic axial spondylitis</p> <ul style="list-style-type: none"> <li>• TNF-alpha inhibitors including: <ul style="list-style-type: none"> <li>○ Adalimumab</li> <li>○ Certolizumab pegol</li> <li>○ Etanercept</li> <li>○ Golimumab</li> </ul> </li> <li>• Interleukin-17A inhibitors <ul style="list-style-type: none"> <li>○ Secukinumab</li> <li>○ Ixekizumab</li> </ul> </li> <li>• Upadacitinib</li> <li>• Established clinical management without biological treatments</li> </ul> |

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|                                 | <p>For active ankylosing spondylitis</p> <ul style="list-style-type: none"> <li>• TNF-alpha inhibitors including: <ul style="list-style-type: none"> <li>○ Adalimumab</li> <li>○ Certolizumab pegol</li> <li>○ Etanercept</li> <li>○ Golimumab</li> <li>○ Infliximab</li> </ul> </li> <li>• Interleukin-17A inhibitors <ul style="list-style-type: none"> <li>○ Secukinumab</li> <li>○ Ixekizumab</li> </ul> </li> <li>• JAK inhibitors <ul style="list-style-type: none"> <li>○ Upadacitinib</li> <li>○ Tofacitinib (subject to NICE evaluation)</li> </ul> </li> <li>• Established clinical management without biological treatments</li> </ul>   |
| <p><b>Outcomes</b></p>          | <p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• disease activity</li> <li>• functional capacity</li> <li>• disease progression</li> <li>• pain</li> <li>• peripheral symptoms (including enthesitis, peripheral arthritis and dactylitis)</li> <li>• symptoms of extra-articular manifestations (including uveitis, inflammatory bowel disease and psoriasis)</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>  |
| <p><b>Economic analysis</b></p> | <p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social</p> |

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|  | <p>Services perspective.</p> <p>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.</p>   |
| <p><b>Other considerations</b></p>         | <p>The availability and cost of biosimilar and generic products should be taken into account.</p> <p>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.</p>   |
| <p><b>Related NICE recommendations</b></p> | <p><b>Related Technology Appraisals:</b></p> <p><a href="#">‘Ixekizumab for treating axial spondyloarthritis’</a> (2021) NICE technology appraisal 718</p> <p><a href="#">‘Secukinumab for treating non-radiographic axial spondyloarthritis’</a> (2021) NICE technology appraisal 719</p> <p><a href="#">‘Golimumab for treating non-radiographic axial spondyloarthritis’</a> (2018) NICE technology appraisal 497. Review date December 2020.</p> <p><a href="#">‘TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis’</a> (2016) NICE technology appraisal 383. Review date June 2021.</p> <p><a href="#">‘Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors’</a> (2016) NICE technology appraisal 407. Review date September 2019.</p> <p><a href="#">‘Upadacitinib for treating active ankylosing spondylitis’</a> NICE technology appraisal guidance TA829. Review date 2025</p> <p><b>Related Appraisals in Development:</b></p> <p><a href="#">‘Upadacitinib for treating active non-radiographic axial spondyloarthritis’</a> NICE technology appraisal [ID3958]. Expected publication date January 2023.</p> <p><a href="#">‘Tofacitinib for treating active ankylosing spondylitis’</a> NICE technology appraisal [ID3865] Expected publication date to be confirmed.</p> <p><b>Related Guidelines:</b></p> <p><a href="#">‘Spondyloarthritis in over 16s: diagnosis and management’</a> (2017) NICE guideline 65. Review date to be confirmed.</p> <p><b>Related Quality Standards:</b></p> <p><a href="#">‘Spondyloarthritis’</a>. NICE quality standard 170. Review date August 2019.</p> |

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| <b>Related National Policy</b> | <p>The NHS Long Term Plan, 2019. <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2018/2019) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a>. Chapter 5. Adult highly specialised rheumatology services</p> <p>NHS England (2018) <a href="#">NHS England Funding and Resource 2018/19: Supporting 'Next Steps for the NHS Five Year Forward View'</a></p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 1, 2, 4 and 5<br/> <a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p> |
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## 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 April 2023
2. NHS: Ankylosing Spondylitis Overview Available at <https://www.nhs.uk/conditions/ankylosing-spondylitis/> Accessed April 2023