

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Filgotinib for treating axial spondyloarthritis ID6594

Final scope

**Remit/evaluation objective**

To appraise the clinical and cost effectiveness of filgotinib 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 (formerly 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. Other health problems that can happen with this condition include uveitis, inflammatory bowel disease and psoriasis. The average age of onset of symptoms is 26 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 radiographic axial spondyloarthritis to non-radiographic axial spondyloarthritis 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>2</sup> Non-radiographic axial spondyloarthritis affects approximately equal numbers of men and women, whereas radiographic axial spondyloarthritis is about 3 times more common in men.<sup>3</sup>

Conventional therapy for axial spondyloarthritis includes anti-inflammatory treatment with non-steroidal anti-inflammatory drugs (NSAIDs) and physiotherapy. If the condition does not respond adequately to this, people will then have tumour necrosis factor (TNF)-alpha inhibitors. Interleukin-17 (IL-17) inhibitors and Janus kinase (JAK) inhibitors are usually used when TNF-alpha inhibitors are not suitable or do not control the condition well enough. TNF-alpha and IL-17 inhibitors are biological disease-modifying antirheumatic drugs (DMARDs) that reduce inflammation and slow disease progression. JAK inhibitors are synthetic DMARDs. The following NICE technology appraisals (TAs) are available for axial spondyloarthritis:

### Radiographic axial spondyloarthritis (formerly known as ankylosing spondylitis)

- TNF-alpha inhibitors
  - [TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis TA383](#)
- IL-17 inhibitors
  - [Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors TA407](#)
  - [Ixekizumab for treating axial spondyloarthritis TA718](#)
  - [Bimekizumab for treating axial spondyloarthritis TA918](#)
- JAK inhibitors
  - [Upadacitinib for treating active ankylosing spondylitis TA829](#)
  - [Tofacitinib for treating active ankylosing spondylitis TA920](#)

### Nonradiographic axial spondylarthritis

- TNF-alpha inhibitors
  - [TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis TA383](#)
  - [Golimumab for treating non-radiographic axial spondyloarthritis TA497](#)
- IL-17 inhibitors
  - [Ixekizumab for treating axial spondyloarthritis TA718](#)
  - [Secukinumab for treating non-radiographic axial spondyloarthritis TA719](#)
  - [Bimekizumab for treating axial spondyloarthritis TA918](#)
- JAK inhibitors
  - [Upadacitinib for treating active non-radiographic axial spondyloarthritis TA861](#)

### The technology

Filgotinib (Jyseleca, Alfasigma UK Ltd) does not currently have a marketing authorisation in the UK for treating radiographic or non-radiographic axial spondyloarthritis. It has been studied in clinical trials compared with placebo in adults with radiographic and non-radiographic axial spondyloarthritis with inadequate response to NSAIDs.

<b>Intervention(s)</b>	Filgotinib
<b>Population(s)</b>	Adults with active axial spondyloarthritis, not controlled well enough with non-steroidal anti-inflammatory drugs (NSAIDs), specifically: <ul style="list-style-type: none"> <li>• <b>radiographic axial spondyloarthritis</b>, and</li> <li>• <b>non-radiographic axial spondyloarthritis</b>.</li> </ul>
<b>Subgroups</b>	If the evidence allows, the following subgroups will be considered with the 2 main populations: <ul style="list-style-type: none"> <li>• <b>TNF-inhibitors naïve</b> - disease that has not been treated with TNF-inhibitors, and</li> <li>• <b>TNF-inhibitors experienced</b> - disease that was treated with TNF-inhibitors, but it was not controlled well enough.</li> </ul>
<b>Comparators</b>	<b>For active radiographic axial spondyloarthritis:</b>

	<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>• IL-17 inhibitors including:<ul style="list-style-type: none"><li>- Secukinumab</li><li>- Ixekizumab</li><li>- Bimekizumab</li></ul></li><li>• JAK inhibitors including:<ul style="list-style-type: none"><li>- Upadacitinib</li><li>- Tofacitinib</li></ul></li></ul> <p><b>For active non-radiographic axial spondyloarthritis:</b></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>• IL-17 inhibitors including:<ul style="list-style-type: none"><li>- Secukinumab</li><li>- Ixekizumab</li><li>- Bimekizumab</li></ul></li><li>• JAK inhibitors including:<ul style="list-style-type: none"><li>- Upadacitinib</li></ul></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>• fatigue</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 Services perspective.</p> <p>The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.</p> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
<p><b>Other considerations</b></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="#">‘Tofacitinib for treating active ankylosing spondylitis’</a> (2023) NICE technology appraisal 920</p> <p><a href="#">‘Bimekizumab for treating axial spondyloarthritis’</a> (2023) NICE technology appraisal 918</p>

	<p><a href="#">‘Upadacitinib for treating active non-radiographic axial spondyloarthritis’</a> (2023) NICE technology appraisal 861</p> <p><a href="#">‘Upadacitinib for treating active ankylosing spondylitis’</a> NICE technology appraisal guidance 829.</p> <p><a href="#">‘Secukinumab for treating non-radiographic axial spondyloarthritis’</a> (2021) NICE technology appraisal 719</p> <p><a href="#">‘Ixekizumab for treating axial spondyloarthritis’</a> (2021) NICE technology appraisal 718</p> <p><a href="#">‘Golimumab for treating non-radiographic axial spondyloarthritis’</a> (2018) NICE technology appraisal 497.</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.</p> <p><a href="#">‘TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis’</a> (2016) NICE technology appraisal 383.</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>
--	--

## References

1. National Axial Spondyloarthritis Society. *About Axial SpA*. Available from: [About Axial SpA | National Axial Spondyloarthritis Society](#) Accessed November 2025
2. Tofacitinib for treating active ankylosing spondylitis TA920. *Resource Impact template*. Available at [Tools and resources | Tofacitinib for treating active ankylosing spondylitis | Guidance | NICE](#) Accessed November 2025
3. NHS: *Ankylosing Spondylitis Overview*. Available at <https://www.nhs.uk/conditions/ankylosing-spondylitis/> Accessed November 2025