NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Filgotinib for treating axial spondyloarthritis ID6594

Draft scope

Draft 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 (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. 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.[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] 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.[2] Non-radiographic axial spondyloarthritis affects approximately equal numbers of men and women, whereas ankylosing spondylitis is about 3 times more common in men.[3]

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. NICE recommends the following treatments:

Radiographic axial spondyloarthritis (also 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

Non-radiographic 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.

Intervention(s)	Filgotinib
Population(s)	Adults with active axial spondyloarthritis
Subgroups	If the evidence allows, the following subgroups will be considered: • 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).

Comparators	**For active radiographic axial spondylitis:**
	• TNF-alpha inhibitors including:
	  ○ Adalimumab
	  ○ Certolizumab pegol
	  ○ Etanercept

	○ Golimumab ○ Infliximab • IL-17 inhibitors ○ Secukinumab ○ Ixekizumab ○ Bimekizumab • JAK inhibitors ○ Upadacitinib ○ Tofacitinib **For active non-radiographic axial spondylitis:** • TNF-alpha inhibitors including: ○ Adalimumab ○ Certolizumab pegol ○ Etanercept ○ Golimumab • IL-17 inhibitors ○ Secukinumab ○ Ixekizumab ○ Bimekizumab • JAK inhibitors ○ Upadacitinib
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 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:** 'Tofacitinib for treating active ankylosing spondylitis' (2023) NICE technology appraisal 920 'Bimekizumab for treating axial spondyloarthritis' (2023) NICE technology appraisal 918 'Upadacitinib for treating active non-radiographic axial spondyloarthritis' (2023) NICE technology appraisal 861 'Upadacitinib for treating active ankylosing spondylitis' NICE technology appraisal guidance 829. 'Secukinumab for treating non-radiographic axial spondyloarthritis' (2021) NICE technology appraisal 719 'Ixekizumab for treating axial spondyloarthritis' (2021) NICE technology appraisal 718 'Golimumab for treating non-radiographic axial spondyloarthritis' (2018) NICE technology appraisal 497. 'Secukinumab for active ankylosing spondylitis after treatment with non-steroidal anti-inflammatory drugs or TNF-alpha inhibitors' (2016) NICE technology appraisal 407.

	'TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis' (2016) NICE technology appraisal 383. **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.

Questions for consultation

Where do you consider filgotinib will fit into the existing care pathway for the disease?

Please select from the following, will filgotinib be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would the technology be a candidate for managed access?

Do you consider that the use of filgotinib 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 the treatment will be licenced;
- 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 is considering evaluating this technology through its cost comparison evaluation process.

Please provide 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).

Technologies can be evaluated through the cost-comparison process if they are expected to provide similar or greater health benefits, at a similar or lower cost, compared with technologies that have been previously recommended (as an option) in published NICE guidance for the same indication. Companies can propose cost-comparison topics to NICE at any stage during topic selection and scoping. NICE will route technologies for evaluation through the cost-comparison process if it is agreed during scoping that the process is an appropriate route to establish the clinical and cost effectiveness of the technology.

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

- Is the technology likely to be similar in its clinical effectiveness and resource use to any of the comparators? Or in what way is it different to the comparators?
- Will the intervention be used in the same place in the treatment pathway as the comparator(s)? Have there been any major changes to the treatment pathway recently? If so, please describe.
- Will the intervention be used to treat the same population as the comparator(s)?
- Overall is the technology likely to offer similar or improved health benefits compared with the comparators?
- Would it be appropriate to use the cost-comparison methodology for this topic?

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