

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Risankizumab for previously treated active psoriatic arthritis

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of risankizumab 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 In around 70% of people psoriasis precedes psoriatic arthritis.² The prevalence of psoriatic arthritis in England in 2018 was estimated to be around 83,700 adults.^{2,3} Men and women are equally likely to develop psoriatic arthritis with the peak onset being between the ages of 30 and 50 years.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, which can affect any part of the body but is most commonly found on the extensor surfaces of the elbows and knees, the 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, apremilast, ixekizumab, secukinumab 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 [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 [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 [340](#)). Biosimilar products for some of the biological therapies are available for use in the NHS.

The technology

Risankizumab (Skyrizi, AbbVie) is an anti-interleukin-23 (IL-23) antibody drug that reduces inflammation by blocking the action of IL-23 protein. Risankizumab is administered by subcutaneous injection.

Risankizumab does not currently have a marketing authorisation in the UK for treating active psoriatic arthritis. It has been studied in clinical trials alone compared with placebo in adults with psoriatic arthritis whose disease has not responded adequately to biological therapies or conventional synthetic DMARDs or for whom biological therapies or conventional synthetic DMARDs are not tolerated or for whom conventional synthetic DMARDs are contraindicated.

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

Intervention(s)	Risankizumab
Population(s)	Adults with psoriatic arthritis whose disease has not responded adequately to previous biological therapies or conventional synthetic DMARDs, or for whom biological therapies or conventional synthetic DMARDs are not tolerated or for whom conventional synthetic DMARDs are contraindicated.

<p>Comparators</p>	<p>For people who have only received 1 previous conventional disease modifying anti-rheumatic drug (DMARD)</p> <ul style="list-style-type: none"> • Conventional DMARDs <p>For people whose disease has not responded adequately to at least 2 conventional DMARDs:</p> <ul style="list-style-type: none"> • Biological DMARDs (with or without methotrexate including etanercept, adalimumab, infliximab, golimumab, certolizumab pegol, ixekizumab and secukinumab) • Apremilast • Tofacitinib • Guselkumab (<i>subject to ongoing NICE appraisal</i>) • Upadacitinib (<i>subject to ongoing NICE appraisal</i>) <p>For people whose disease has not responded adequately to conventional DMARDs and 1 or more TNF-alpha inhibitors:</p> <ul style="list-style-type: none"> • Ustekinumab • Secukinumab • Certolizumab pegol • Tofacitinib • Ixekizumab • Best supportive care • Guselkumab (<i>subject to ongoing NICE appraisal</i>) • Upadacitinib (<i>subject to ongoing NICE appraisal</i>) <p>For people in whom TNF-alpha inhibitors are contraindicated or not tolerated:</p> <ul style="list-style-type: none"> • Ustekinumab • Secukinumab • Ixekizumab • Tofacitinib • Best supportive care • Guselkumab (<i>subject to ongoing NICE appraisal</i>) • Upadacitinib (<i>subject to ongoing NICE appraisal</i>)
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<p>Outcomes</p>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • 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.
<p>Economic analysis</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. The availability of any managed access arrangement for the intervention will be taken into account.</p>

<p>Other considerations</p>	<p>If evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> • the reason for previous treatment failure (for example due to lack of efficacy, intolerance or adverse events) • mechanism of action or number of previous treatments • presence or severity of concomitant psoriasis (no psoriasis, mild, moderate or severe psoriasis) • presence or severity of axial involvement <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>Related NICE recommendations and NICE Pathways</p>	<p>Related Technology Appraisals</p> <p>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).</p> <p>Golimumab for the treatment of psoriatic arthritis (2011). NICE Technology Appraisal 220 (moved to the static list).</p> <p>Ustekinumab for treating active psoriatic arthritis (2015). NICE Technology Appraisal 340 (moved to the static list).</p> <p>Certolizumab pegol and secukinumab for treating active psoriatic arthritis following inadequate response to disease modifying anti-rheumatic drugs (2017) NICE Technology Appraisals 445. Review date: 2020.</p> <p>Apremilast for treating active psoriatic arthritis (2017) NICE Technology Appraisal 433 Review date: 2020.</p> <p>Ixekizumab for treating active psoriatic arthritis following inadequate response to disease-modifying anti-rheumatic drugs (2018) NICE Technology Appraisals 537. Review date: 2021.</p> <p>Tofacitinib for treating active psoriatic arthritis after inadequate response to DMARDs (2018) NICE Technology Appraisals 543. Review date: 2021.</p> <p>Risankizumab for treating moderate to severe plaque psoriasis (2019) NICE Technology appraisal guidance 596. Review date: 2022.</p> <p>Terminated appraisals</p> <p>Abatacept for treating psoriatic arthritis after DMARDs (terminated appraisal) (2019) NICE Technology Appraisals</p>

	<p>568.</p> <p>Appraisals in development</p> <p>Guselkumab for treating active psoriatic arthritis after inadequate response to DMARDs NICE technology appraisal guidance [ID1658] Publication date to be confirmed.</p> <p>Upadacitinib for treating active psoriatic arthritis after inadequate response to DMARDs NICE technology appraisal guidance [ID2690] Publication expected August 2021.</p> <p>Related Guidelines</p> <p>Spondyloarthritis in over 16s: diagnosis and management (NG65) Published in February 2017. Last updated: June 2017</p> <p>Psoriasis: assessment and management (2012). NICE clinical guideline 153. Last updated: September 2017</p> <p>Related Quality Standards</p> <p>Spondyloarthritis (2018) NICE Quality Standard 170.</p> <p>Psoriasis (2013). NICE Quality Standard 40.</p> <p>Related NICE Pathways</p> <p>NICE Pathway: Spondylarthritis. Pathway last updated November 2020.</p> <p>NICE Pathway: Psoriasis. Pathway last updated November 2020.</p>
<p>Related National Policy</p>	<p>The NHS Long Term Plan, 2019. NHS Long Term Plan</p> <p>NHS England (2018/2019) NHS manual for prescribed specialist services (2018/2019) Chapter 5, Adult highly specialist rheumatology services</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domains 2 to 5. https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</p>

Questions for consultation

Is risankizumab expected to be used in combination with other treatments?

Is the population defined appropriately? Is the population expected to include people with psoriatic arthritis for whom topical therapies or biologic DMARDs are contraindicated?

Have all relevant comparators for risankizumab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for active psoriatic arthritis after inadequate response or intolerance to conventional or biological DMARDs?

How should best supportive care be defined?

Are the outcomes listed appropriate?

Are the subgroups suggested in 'other considerations appropriate?

Are there any other subgroups of people in whom risankizumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider risankizumab will fit into the existing NICE pathway, [spondyloarthritis](#)?

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 risankizumab 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.

Do you consider risankizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of risankizumab can result in any potential significant and 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 Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at <http://www.nice.org.uk/article/pmg19/chapter/1-Introduction>).

NICE has published an addendum to its guide to the methods of technology appraisal (available at <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/methods-guide-addendum-cost->

[comparison.pdf](#)), which 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. Psoriasis Association (2018) [Psoriasis Arthritis](#). Accessed July 2020
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 (2019) [Population estimates mid-year 2018](#). Accessed July 2020