

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

**Risankizumab for people with previously treated moderately to severely active ulcerative colitis**

**Final scope**

**Final remit/evaluation objective**

To appraise the clinical and cost effectiveness of risankizumab within its marketing authorisation for treating moderately to severely active ulcerative colitis in people who have had an inadequate response, lost response, or were intolerant to conventional therapy or 1 or more biologic therapies.

**Background**

Ulcerative colitis is the most common inflammatory bowel disease. The cause of ulcerative colitis is unknown. Hereditary, infectious and immunological factors have been proposed as possible causes. It can develop at any age, but peak incidence is between the ages of 15 and 25 years, with a second, smaller peak between 55 and 65 years. It has been estimated that between 1 in 200 and 1 in 420 people in England have ulcerative colitis, of whom about 52% have moderate to severe disease.<sup>1,2</sup>

Ulcerative colitis can cause inflammation in the inner lining of the large intestine. This is usually restricted to the mucosal surface. The symptoms of ulcerative colitis include bloody diarrhoea, pain, urgency, ulceration, tenesmus, fatigue, and anaemia. Up to 50% of people will experience extra-intestinal manifestations involving joints, eyes, the skin, and liver.<sup>3</sup> Ulcerative colitis is associated with significant morbidity; symptoms can have a debilitating impact on quality of life and daily life, including physical, social, and mental well-being. It is a lifelong disease, and symptoms can recur, or the disease can go into remission for months or even years. Ulcerative colitis can be defined as mild or moderate to severe. Around 50% of people with ulcerative colitis will have at least one relapse per year.<sup>4</sup> About 80% of these are mild to moderate and about 20% are severe.<sup>4</sup> 15-25% of people with ulcerative colitis will require hospitalisation due to acute severe colitis.<sup>5</sup> Complications of ulcerative colitis may include haemorrhage, bowel perforation, stricture formation, abscess formation and anorectal disease. Some people may also develop primary sclerosing cholangitis, osteoporosis, and toxic megacolon. People with long-standing disease have an increased risk of bowel cancer.

The aim of treatment in active disease is to address symptoms of bloody diarrhoea, urgent need to defecate and abdominal pain, and to promote mucosal healing and maintain remission. Initial management depends on clinical severity, extent of disease and the person's preference, and may include aminosalicylates (sulfasalazine, mesalazine, balsalazide or olsalazine), corticosteroids (beclometasone, budesonide, hydrocortisone or prednisolone) and immunomodulators (thiopurines). Options for people whose disease has responded inadequately to conventional therapy or who cannot tolerate or have medical contraindications for such therapies include:

- infliximab, adalimumab and golimumab ([NICE technology appraisal 329](#))

Final scope for the evaluation of risankizumab for people with previously treated moderately to severely active ulcerative colitis

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- vedolizumab ([NICE technology appraisal 342](#))
- tofacitinib ([NICE technology appraisal 547](#))
- ustekinumab (only if a tumour necrosis factor-alpha inhibitor has failed, cannot be tolerated or is not suitable; [NICE technology appraisal 633](#))
- filgotinib ([NICE technology appraisal 792](#))
- ozanimod (only if infliximab is not suitable, or biological treatment is not tolerated or not working well enough; [NICE technology appraisal 828](#))
- upadacitinib ([NICE technology appraisal 865](#)).

For people admitted to hospital with acute severe ulcerative colitis [NICE guideline 130](#) recommends offering intravenous corticosteroids to induce remission and assessing the need for surgery. Surgery may be considered as emergency treatment for severe ulcerative colitis that does not respond to drug treatment. People may also choose to have elective surgery for unresponsive or frequently relapsing disease that is affecting their quality of life. The scope of this appraisal does not include severe ulcerative colitis that is a medical emergency requiring intensive inpatient treatment.

### The technology

Risankizumab (Skyrizi, AbbVie) does not currently have a marketing authorisation in the UK for moderately to severely active ulcerative colitis. It has been studied in clinical trials compared with placebo in people with moderately to severely active ulcerative colitis who have had an inadequate response, lost response, or were intolerant to conventional therapy, 1 or more biologic therapies, or tofacitinib.

<b>Intervention(s)</b>	Risankizumab
<b>Population(s)</b>	People with moderately to severely active ulcerative colitis who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or 1 or more biologic therapies.
<b>Subgroups</b>	<p>If the evidence allows the following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• people who have been previously treated with 1 or more biologic therapies</li> <li>• people who have been previously treated with a JAK inhibitor</li> <li>• people who have not received a prior biologic therapy or a JAK inhibitor.</li> </ul>

<p><b>Comparators</b></p>	<ul style="list-style-type: none"> <li>• TNF-alpha inhibitors (such as infliximab, adalimumab or golimumab)</li> <li>• JAK inhibitors (such as tofacitinib, filgotinib or upadacitinib)</li> <li>• ustekinumab</li> <li>• vedolizumab</li> <li>• ozanimod</li> <li>• etrasimod (subject to ongoing NICE evaluation)</li> <li>• mirikizumab (subject to ongoing NICE evaluation).</li> </ul>
<p><b>Outcomes</b></p>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• rate of and duration of response, relapse and remission</li> <li>• corticosteroid-free remission</li> <li>• rate of endoscopic improvement</li> <li>• rate of hospitalisation</li> <li>• rate of surgical intervention</li> <li>• mortality</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="#">Upadacitinib for treating moderately to severely active ulcerative colitis</a> (2023) NICE technology appraisal guidance 856.</p> <p><a href="#">Ozanimod for treating moderately to severely active ulcerative colitis</a> (2022) NICE technology appraisal guidance 828.</p> <p><a href="#">Filgotinib for treating moderately to severely active ulcerative colitis</a> (2022) NICE technology appraisal guidance 792.</p> <p><a href="#">Ustekinumab for treating moderately to severely active ulcerative colitis</a> (2020) NICE technology appraisal guidance 633.</p> <p><a href="#">Tofacitinib for moderately to severely active ulcerative colitis</a> (2018) NICE technology appraisal guidance 547.</p> <p><a href="#">Vedolizumab for treating moderately to severely active ulcerative colitis</a> (2015) NICE technology appraisal guidance 342.</p> <p><a href="#">Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy</a> (2015) NICE technology appraisal guidance 329.</p> <p><a href="#">Infliximab for acute exacerbations of ulcerative colitis</a> (2008) NICE technology appraisal guidance 163.</p> <p><b>Related technology appraisals in development:</b></p> <p><a href="#">Etrasimod for treating moderately to severely active ulcerative colitis. NICE technology appraisal [ID5091]</a>. Publication date to be confirmed</p> <p><a href="#">Mirikizumab for treating moderately to severely active ulcerative colitis. NICE technology appraisal [ID3973]</a>. Publication date to be confirmed</p> <p><b>Related NICE guidelines:</b></p> <p><a href="#">Ulcerative colitis: management</a> (2019) NICE guideline NG130.</p> <p><a href="#">Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas</a> (2011) NICE guideline 118.</p> <p><b>Related Interventional Procedures:</b></p>

	<p><a href="#">Leukapheresis for inflammatory bowel disease</a> (2005). NICE interventional procedures guidance 126.</p> <p><b>Related quality standards:</b></p> <p><a href="#">Inflammatory bowel disease</a> (2015) NICE quality standard 81.</p>
<p><b>Related National Policy</b></p>	<p>British Society of Gastroenterology (2019) <a href="#">Consensus guidelines on the management of inflammatory bowel disease in adults</a></p> <p>British Society of Gastroenterology (2017) <a href="#">UK guideline on transition of adolescent and young persons with chronic digestive diseases from paediatric to adult care</a></p> <p>The NHS Long Term Plan (2019) <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2013) <a href="#">2013/14 NHS Standard Contract for Colorectal: Complex Inflammatory Bowel Disease (Adult) A08/S/c</a></p>

## References

1. Hamilton B, Green H, Heerasing N, et al. [Incidence and prevalence of inflammatory bowel disease in Devon, UK](#) Frontline Gastroenterology 2021;12:461-470. Accessed April 2023.
2. Crohn's and Colitis UK (2017) [Ulcerative Colitis](#). Accessed April 2023.
3. IBD UK (2021) [Crohn's and Colitis Care in the UK: The Hidden Cost and a Vision for Change](#). Accessed April 2023.
4. National Institute for Health and Care Excellence (2014) [Quality standards and indicators Briefing Paper](#). Accessed April 2023.
5. IBD UK (2023) [Management of acute severe colitis](#). Accessed April 2023.