NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Guselkumab for treating moderately to severely active ulcerative colitis (ID6237)

Final scope

Remit/evaluation objective

To appraise the clinical and cost effectiveness of guselkumab within its marketing authorisation for treating moderately to severely active ulcerative colitis.

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. At least 1 in every 227 people in the UK has been diagnosed with ulcerative colitis,[1] around 296,000 people.[2] Ulcerative colitis can be defined as mild, moderate or severe. It is estimated that 52% of diagnoses are moderate to severe disease.

Ulcerative colitis can cause inflammation in the inner lining of the large intestine. This is usually restricted to the mucosal surface. This usually affects the rectum and extends proximally throughout the colon. The symptoms of ulcerative colitis include bloody diarrhoea, pain, urgency, tenesmus (a persistent, painful urge to pass stool even when the rectum is empty), fatigue, and anaemia. About 30% of people will have extra-intestinal manifestations involving joints, eyes, skin, and liver.[3] 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 wellbeing. It is a lifelong disease, and symptoms can recur, or the disease can go into remission for months or even years.

Around 50% of people with ulcerative colitis will have at least 1 relapse per year.[4] About 80% of these are mild to moderate and about 20% are severe.[4] About 15% to 25% of people with ulcerative colitis will need to be admitted to hospital for acute severe colitis.[5] 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 and then 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), biological treatments, JAK inhibitors (tofacitinib and upadacitinib) and the S1P inhibitor, ozanimod. An immunosuppressant (such as mercaptopurine or azathioprine) may be considered if aminosalicylates fail to maintain remission (see NICE's guideline on the management of ulcerative colitis).

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NICE has recommended several treatments for moderately to severely active ulcerative colitis:

- infliximab, adalimumab and golimumab in adults whose disease has responded inadequately to conventional therapy including corticosteroids and mercaptopurine or azathioprine, or who cannot tolerate, or have medical contraindications for, such therapies (NICE technology appraisal guidance 329)
- vedolizumab (NICE technology appraisal guidance 342)
- tofacitinib in adults when conventional therapy or a biological agent cannot be tolerated or the disease has responded inadequately or lost response to treatment (NICE technology appraisal guidance 547)
- ustekinumab in adults when conventional therapy or a biological agent cannot be tolerated, or the disease has responded inadequately or lost response to treatment and only if a tumour necrosis factor (TNF) alpha inhibitor has failed, cannot be tolerated or is not suitable (NICE technology appraisal guidance 633)
- filgotinib in adults when conventional or biological treatment cannot be tolerated, or if the disease has not responded well enough or has stopped responding to these treatments (NICE technology appraisal guidance 792)
- ozanimod in adults when conventional treatment cannot be tolerated or is not working well enough and infliximab is not suitable, or biological treatment cannot be tolerated or is not working well enough (NICE technology appraisal guidance 828)
- upadacitinib in adults when conventional or biological treatment cannot be tolerated, or if the condition has not responded well enough or has stopped responding to these treatments (NICE technology appraisal guidance 856)
- mirikizumab in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or lost response to treatment and only if a TNF-alpha inhibitor has not worked or cannot be tolerated or is not suitable (NICE technology appraisal guidance 925)
- etrasimod in people 16 and over when conventional or biological treatments cannot be tolerated or the condition has not responded well enough, or lost response to treatment (NICE technology appraisal guidance 956)
- risankizumab in adults when conventional or biological treatment cannot be tolerated, or the condition has not responded well enough or has lost response to treatment and only if a TNF-alpha inhibitor has not worked or cannot be tolerated or is not suitable (NICE technology appraisal guidance 998).

For people admitted to hospital with acute severe ulcerative colitis, NICE's guideline on the management of ulcerative colitis recommends offering intravenous corticosteroids to induce remission and to assess 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.

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The technology

Guselkumab (Tremfya, Johnson & Johnson) does not currently have a marketing authorisation in the UK for ulcerative colitis. It is being 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 a conventional therapy, a biological treatment, or a Janus kinase (JAK) inhibitor (tofacitinib).

Intervention(s)	Guselkumab
Population(s)	Adults with moderately to severely active ulcerative colitis that have had an inadequate response, lost response to, or were intolerant to conventional therapy and/or a biological treatment or a JAK inhibitor
Comparators	• Conventional therapies, without biological treatments • TNF-alpha inhibitors (adalimumab, golimumab, infliximab) • JAK inhibitors (filgotinib, tofacitinib, upadacitinib) • Interleukin inhibitors (mirikizumab, risankizumab, ustekinumab) • Integrin receptor inhibitors (vedolizumab) • Sphingosine l-phosphate receptor modulators (etrasimod, ozanimod)
Outcomes	The outcome measures to be considered include: • rates of and duration of response, relapse and remission • endoscopic healing • endoscopic remission combined with histological improvement • mortality • measures of disease activity • rates of hospitalisation (including re-admission) • rates of surgical intervention • corticosteroid-free remission • medicine adherence • 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

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	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:** Risankizumab for previously treated moderately to severely active ulcerative colitis (2024) NICE technology appraisal guidance 998 Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over (2024) NICE technology appraisal guidance 956 Mirikizumab for treating moderately to severely active ulcerative colitis (2023) Technology appraisal guidance 925 Upadacitinib for treating moderately to severely active ulcerative colitis (2023) Technology appraisal guidance 856 Ozanimod for treating moderately to severely active ulcerative colitis (2022) Technology appraisal guidance 828 Filgotinib for treating moderately to severely active ulcerative colitis (2022) Technology appraisal guidance 792 Ustekinumab for treating moderately to severely active ulcerative colitis (2020) Technology appraisal guidance 633 Tofacitinib for treating moderately to severely active ulcerative colitis (2018) Technology appraisal guidance 547 Vedolizumab for treating moderately to severely active ulcerative colitis (2015) Technology appraisal guidance 342 Infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy (2015) Technology appraisal guidance 329

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	Related NICE guidelines: Ulcerative colitis: management (2019) NICE guideline NG130 **Related interventional procedures:** Leukapheresis for inflammatory bowel disease (2005) NICE interventional procedures guidance 126 **Related quality standards:** Inflammatory bowel disease (2015) NICE quality standard 81
Related National Policy	The NHS Long Term Plan (2019) NHS Long Term Plan NHS England (2023) Manual for prescribed specialist services (2023/2024) Chapter 106A. Specialist colorectal surgery services (adults) NHS England (2013) 2013/14 NHS Standard Contract for Colorectal: Complex Inflammatory Bowel Disease (Adult). A08/S/c

References

1. Crohn's & Colitis UK 2024 Ulcerative colitis [accessed January 2025].
2. NHS UK 2022 Ulcerative colitis [accessed January 2025].
3. NICE CKS 2024 Ulcerative colitis [accessed January 2025].
4. NICE 2015 Inflammatory bowel disease NICE quality standard 81 [accessed January 2025].
5. IBD UK Management of acute severe colitis [accessed January 2025].

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