NICE National Institute for Health and Care Excellence

NICE guidance

Guselkumab for previously treated moderately to severely active Crohn's disease

Technology appraisal guidance
Published: 28 August 2025

www.nice.org.uk/guidance/ta1095

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

1 Recommendations

1.1 Guselkumab can be used as an option for previously treated moderately to severely active Crohn's disease in adults, when:

- conventional or biological treatment:
  - has not worked (that is, the condition has not responded well enough or lost response to treatment), or
  - cannot be tolerated, and
- a tumour necrosis factor (TNF)-alpha inhibitor has not worked, cannot be tolerated or is not suitable.

Guselkumab can only be used if the company provides it according to the commercial arrangement.

1.2 Use the least expensive option of the suitable treatments (including guselkumab, risankizumab and vedolizumab), having discussed the advantages and disadvantages of the available treatments with the person with the condition. Take account of administration costs, dosages, price per dose and commercial arrangements.

1.3 These recommendations are not intended to affect treatment with guselkumab that was started in the NHS before this guidance was published. People having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS healthcare professional consider it appropriate to stop.

What this means in practice

Guselkumab must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. Guselkumab must be funded in England within 30 days of final publication of this guidance.

There is enough evidence to show that guselkumab provides benefits and value for money, so it can be used routinely across the NHS in this population.

NICE has produced tools and resources to support the implementation of this guidance.

Why these recommendations were made

Usual treatment for moderately to severely active Crohn's disease when conventional treatments stop working or are unsuitable is biological treatment, which can include TNF-alpha inhibitors or ustekinumab. If these do not work well enough, stop working or are not tolerated, or if TNF-alpha inhibitors are unsuitable, people can then have risankizumab or vedolizumab. Guselkumab would be offered to the same population as risankizumab and vedolizumab.

Clinical trial evidence shows that guselkumab increases the likelihood of disease remission and endoscopic response compared with placebo. It has not been directly compared in a clinical trial with risankizumab or vedolizumab, but indirect comparisons suggest that it is likely to work as well as these.

A cost comparison suggests the costs for guselkumab are similar to or lower than risankizumab and vedolizumab. So, guselkumab can be used.

For all evidence see the committee papers. For more information on NICE's evaluation of risankizumab and vedolizumab, see NICE's technology appraisal guidance on risankizumab for previously treated moderately to severely active Crohn's disease and vedolizumab for treating moderately to severely active Crohn's disease after prior therapy.

2 Information about guselkumab

Marketing authorisation indication

2.1 Guselkumab (Tremfya, Janssen-Cilag) is indicated for 'the treatment of adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or biologic treatment'.

Dosage in the marketing authorisation

2.2 The dosage schedule is available in the summary of product characteristics for guselkumab.

Price

2.3 The list price of guselkumab is (excluding VAT; company submission).

- £4,500 for a 200 mg solution for infusion vial
- £2,250 for a 200 mg pre-filled pen
- £2,250 for a 100 mg pre-filled pen

2.4 The company has a commercial arrangement. This makes guselkumab available to the NHS with a discount. The size of the discount is commercial in confidence.

Carbon Reduction Plan

2.5 For information, Janssen-Cilag did not disclose its Carbon Reduction Plan for UK carbon emissions.

3 Implementation

3.1 Section 7 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication. Because guselkumab has been recommended through the cost-comparison process, NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.

3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.

3.3 When NICE recommends a treatment 'as an option', the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has previously treated moderately to severely active Crohn's disease and the healthcare professional responsible for their care thinks that guselkumab is the right treatment, it should be available for use, in line with NICE's recommendations.

4 Evaluation committee members and NICE project team

Evaluation committee members

This topic was considered as a cost comparison evaluation by the lead team of the highly specialised technologies evaluation committee, which includes the chair and vice chair. The highly specialised technologies evaluation committee is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

Chair

Paul Arundel
Chair, highly specialised technologies evaluation committee

Iolo Doull
Vice-chair, highly specialised technologies evaluation committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Sammy Shaw
Technical lead

Michelle Green
Technical adviser

Jennifer Upton
Project manager

Janet Robertson
Associate director

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