NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Final draft guidance

Guselkumab for treating moderately to severely active ulcerative colitis

1 Recommendations

1.1 Guselkumab can be used as an option for treating moderately to severely active ulcerative colitis in adults when:

- a conventional treatment, biological treatment or Janus kinase (JAK) inhibitor:
  - 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 (see section 2).

1.2 Use the least expensive option of the suitable treatments (including guselkumab, mirikizumab 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

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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.

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.

Why these recommendations were made

TNF-alpha inhibitors are the most used biological treatments for moderately to severely active ulcerative colitis when a conventional treatment has not worked or cannot be tolerated. When a TNF-alpha inhibitor has not worked, or is not tolerated or suitable, potential treatment options include mirikizumab or vedolizumab. Guselkumab is another biological treatment that would be offered to the same population.

Clinical trial evidence shows that guselkumab is more effective than placebo. Guselkumab has not been directly compared in a clinical trial with mirikizumab 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 mirikizumab and vedolizumab. So, guselkumab can be used.

For all evidence, see the committee papers. For more information on NICE's evaluations of mirikizumab and vedolizumab, see NICE's technology appraisal

guidance on mirikizumab for treating moderately to severely active ulcerative colitis and vedolizumab for treating moderately to severely active ulcerative colitis.

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 ulcerative colitis who have had an inadequate response, lost response, or were intolerant to either conventional therapy, a biologic treatment, or a Janus kinase (JAK) inhibitor'.

Dosage in the marketing authorisation

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

Price

2.2 The list price of guselkumab is (excluding VAT; company submission):

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

2.3 The company has a commercial arrangement (simple discount patient access scheme). This makes guselkumab available to the NHS with a discount. The size of the discount is commercial in confidence.

Carbon Reduction Plan

2.4 Information on the Carbon Reduction Plan for UK carbon emissions for Janssen-Cilag will be included here when guidance is published.

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 moderately to severely active ulcerative colitis 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.

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