NICE National Institute for Health and Care Excellence

Resource impact summary report

Resource impact

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Contents

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This summary report is based on the NICE assumptions used in the resource impact template. Users can amend the 'Inputs and eligible population' and 'Unit costs' worksheets in the template to reflect local data and assumptions.

Recommendations

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.

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.

Eligible population for guselkumab

The NHS webpage on ulcerative colitis estimates that 1 in every 227 people in the UK has been diagnosed with ulcerative colitis.

Consultant gastroenterologist opinion estimates that 52% of people with ulcerative colitis

are classified as having moderate to severe disease and 20% have an inadequate response or loss of response or are intolerant to conventional therapy.

Consultant gastroenterologist opinion is that for 50% of these people a TNF-alpha inhibitor will not work, cannot be tolerated or is not suitable.

Table 1 Population expected to be eligible for guselkumab in England

Eligible population and market share	People eligible for guselkumab
Current practice	10,731
Year 1	10,825
Year 2	10,920
Year 3	11,016
Year 4	11,113
Year 5	11,211

The total eligible population shown in the template is for everyone with moderate to severe ulcerative colitis with inadequate response, loss of response or who are intolerant to conventional treatment. But guselkumab can only be used if a TNF-alpha inhibitor has not worked, cannot be tolerated or is not suitable. So this should be considered when inputting the market shares for each treatment option.

Organisations should complete both current and future uptake in the resource impact template based on local practice in order to assess the financial impact.

Treatment options for the eligible population

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 not 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.

The cost comparison suggests the costs for guselkumab are similar to or lower than mirikizumab and vedolizumab.

For more information about the treatments, such as dose and average treatment duration, see the resource impact template.

Financial resource impact (cash items)

The company has a commercial arrangement. This makes guselkumab available to the NHS with a discount.

Users can input the confidential price of guselkumab and amend other variables in the resource impact template.

The payment mechanism for the technology is determined by the responsible commissioner and depends on the technology being classified as high cost.

We expect the resource impact of implementing the recommendations in England will be less than £5 million per year (or approximately £8,800 per 100,000 population, based on a population for England of 57.16 million people).

This is because the technology is a further treatment option, and the overall cost of treatment will be similar for this population.

For further analysis or to calculate the financial impact of cash items, see the resource impact template.

Capacity impact

Guselkumab can be used as either an intravenous induction or a subcutaneous induction, followed by subcutaneous maintenance. Mirikizumab and vedolizumab can initially be administered by intravenous infusion and then subsequent administrations by subcutaneous injection.

The recommended induction dose of guselkumab is either 200 mg administered by

intravenous infusion at week 0, week 4 and week 8 or 400 mg administered by subcutaneous injection (given as 2 consecutive injections of 200 mg each) at week 0, week 4 and week 8.

After completion of the induction dose, the recommended maintenance dose starting at week 16 is 100 mg administered by subcutaneous injection every 8 weeks. Alternatively, for people who do not have adequate therapeutic benefit to induction treatment according to clinical judgement, a maintenance dose of 200 mg administered by subcutaneous injection starting at week 12 and every 4 weeks thereafter, may be considered.

For further analysis, or to calculate the financial capacity impact from a commissioner (national) and provider (local) perspective, see the resource impact template.

Key information

Table 2 Key information

Time from publication to routine commissioning funding	30 days
Programme budgeting category	N/A
Commissioner	Integrated Care Boards
Provider	Secondary care - acute
Pathway position	When conventional or biological treatments cannot be tolerated

About this resource impact summary report

This resource impact summary report accompanies the NICE technology appraisal guidance on guselkumab for treating moderately to severely active ulcerative colitis and should be read with it.

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