NICE National Institute for Health and Care Excellence

NICE guidance

Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over

Technology appraisal guidance
Published: 27 February 2024

www.nice.org.uk/guidance/ta953

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 Etrasimod is recommended, within its marketing authorisation, as an option for moderately to severely active ulcerative colitis in people aged 16 years and over when:

- conventional or biological treatments cannot be tolerated or
- the condition has not responded well enough, or lost response to treatment.

Etrasimod is only recommended if the company provides it according to the commercial arrangement.

1.2 If people with the condition and their clinicians consider etrasimod to be 1 of a range of suitable treatments, after discussing the advantages and disadvantages of all the options, use the least expensive. Take account of administration costs, dosage, price per dose and commercial arrangements.

Why these recommendations were made

Usually, after conventional treatment, people with moderately to severely active ulcerative colitis have advanced treatment, such as a biological medicine or JAK inhibitor. Etrasimod is a sphingosine-1-phosphate receptor agonist, another kind of advanced treatment, which would be offered to the same population.

Clinical trial evidence shows that etrasimod is more effective than placebo for treating moderately to severely active ulcerative colitis. Etrasimod has not been directly compared in a clinical trial with usual treatments. Indirect comparisons suggest that it is likely to work better than adalimumab (a biological treatment) and may be similarly effective to other usual treatments for moderately to severely active ulcerative colitis which has not been previously treated with advanced treatment. For moderately to severely active ulcerative colitis which has previously been treated with advanced treatment, indirect comparisons are highly uncertain and the possibility that treatments differ in terms of their effectiveness for this population could not be ruled out. Based on experience with other treatments used for this population with the same mechanism of action, it was considered likely that etrasimod would also be effective for moderate to severely active ulcerative colitis which has previously been treated with advanced treatment. On balance etrasimod

appeared an effective treatment that would be a welcome additional option for people with moderately to severely active ulcerative colitis.

A cost comparison suggests etrasimod has lower or similar costs to adalimumab and other advanced treatments. So, etrasimod is recommended.

For all evidence see the committee papers.

2 Information about etrasimod

Marketing authorisation indication

2.1 Etrasimod (Velsipity, Pfizer) is indicated for 'people 16 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response, lost response or were intolerant to either conventional therapy, or a biological agent'.

Dosage in the marketing authorisation

2.2 The dosage schedule will be available in the summary of product characteristics for etrasimod.

Price

2.3 The list price of 2 mg etrasimod is £843.84 per pack of 28 tablets (excluding VAT; company submission). The estimated annual cost of treatment is £11,000 (excluding VAT; company submission).

2.4 The company has a commercial arrangement. This makes etrasimod available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

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 3 months of its date of publication. Because etrasimod 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 2 months 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 doctor responsible for their care thinks that etrasimod 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

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by the chair and the vice chair of NICE's highly specialised technologies evaluation committee.

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

Peter Jackson
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 and a project manager.

Albany Chandler
Technical lead

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Technical adviser

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Accreditation