Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over NICE TA956		
Available at	https://www.nice.org.uk/guidance/ta956		
Date of issue	11 March 2024	**Implementation deadline**	30 days – 10 April 2024

Medicine details[1]	
Name and brand name	Etrasimod (Velsipity)
Manufacturer	Pfizer
Mode of action	Sphingosine-1-phosphate receptor agonist.
Licenced indication	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'.
Formulation	Film-coated tablet (tablet)
Dosage	The recommended dose is 2 mg etrasimod taken once daily. Missed dose: If a dose is missed, the prescribed dose should be taken at the next scheduled time; the next dose should not be doubled. Dose interruption: If treatment is interrupted for 7 or more consecutive days, it is recommended to resume treatment with food for the first 3 doses.
Comparison of NICE TA with Summary of Product Characteristics (SmPC)[2]	The NICE TA refers to the dosage within the SmPC which is as listed above i.e. standard dosing for ulcerative colitis, with no dose intensification. This is the current dose considered by NICE as part of this NICE evaluation. Subsequent changes in the licence following NICE publication will need to be considered by the Area Prescribing Committee and will not be routinely funded by local commissioners, as the incremental cost per QALY would not have been considered.

NICE TA recommendations[2]
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.

Decision making framework (DMF)

National guidance and priorities

The ICS has a legal obligation to commission this medicine in line with the NICE TA.

- 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. The implementation deadline is 10 April 2024.

Clinical effectiveness

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.

Patient safety

- The product should be used within its product licence.
- ▼ This is a Black Triangle drug – this medicinal product is subject to reporting of all suspected adverse drug reactions to the MHRA using the Yellow Card Scheme. This will allow timely identification of new safety information.
- Initiation of etrasimod may result in a transient decrease in heart rate and AV conduction delays. Therefore prior to treatment initiation with etrasimod, an electrocardiogram (ECG) should be obtained in all patients to assess for pre-existing cardiac abnormalities. In patients with certain pre-existing conditions, first dose monitoring is recommended. This is also true of ozanimod, other currently available sphingosine-1-phosphate receptor agonist.

Patient factors

- An additional treatment option would be valued by patients. however, there is one other choice within the same class of medicine, ozanimod, which is already in the available pathway, so it does not constitute a novel mode of action or a new line of treatment.
- This medicine is available under a homecare service so will be delivered directly to the patient.

- Patients must adhere to the storage requirements
- Patients would need to be reviewed on a regular basis by the prescribing clinician to ensure concordance, monitor for adverse effects and efficacy.

Environmental impact

- Additional packaging will be generated and will be an environmental impact with regards to waste management – less than for sub cut preparations.
- Homecare deliveries – patients' home (additional carbon – increase air pollution)
- Discharge into wastewater (post metabolism unknown effect)

Equality & diversity

None identified.

Note 1: Drugs approved by NICE for adult conditions will be commissioned in children at specialised paediatric centres if the patient meets the NICE criteria and there is evidence to suggest that the drug is safe and clinically appropriate to use in children as per the NHS England Medicines for Children Policy (see https://www.england.nhs.uk/publication/commissioning-medicines-for-children-specialised-services/ and a Blueteq form is available.

Place in therapy relative to available treatments

This is the second sphingosine-1-receptor agonist available.

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet. Comments to be included in the front sheet.

Cost-effectiveness

The drug cost per Place according to NICE resources does not exceed £100,000.

Section 1: cost of the technology

a. Annual cost per patient (or complete course if shorter)
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).

b. Availability of CAP/PAS price:
Yes.

The company has a commercial arrangement (simple discount patient access scheme). 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.

c. Price relative to comparable medicines:
The comparator is ozanimod - this is the other sphingosine-1-phosphate receptor agonist.

Taking the discounts available on both, etrasimod is the most cost-effective of the two.

Section 2: NICE resource impact statement and template
Number of patients Year 1 and Year 5:

Potential patient numbers per 100,000:

a. NICE resource impact statement
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 56.6 million people).

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

b. NICE resource impact template

Drug costs for Surrey Heartlands:

The cost for this treatment does not exceed the £100,000 per Place threshold.

Commentary:
Due to the SmPC requirement to obtain an ECG prior to initiation, there is currently no prescribing of ozanimod in SH. This is not expected to change with the introduction of etrasimod, given that is has the same requirement.

The Surrey Heartlands Director of Pharmacy and Medicines Optimisation has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Health & Care Professionals Committee at their next meeting. Exception to this will be for any decision made in relation to a NICE Technology Appraisal (which are subject to requiring mandatory funding by commissioners) and other urgent items. The exceptions will be taken to the next Executive Meeting (which meets weekly) for authorisation.

Traffic light recommendation to APC

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme

Yes

Recommended traffic light status and rationale:
RED – Specialist ONLY drugs - treatment initiated and continued by specialist clinicians.

PAD definitions, available at:

FINAL April 2023
Colour classification g

Implementation

NICE TA implementation must be within 30 days of publication.

Actions to implement:

a. Primary care

- This is a National Tariff excluded high-cost drug and is commissioned by ICSs for use in secondary care. There should be no prescribing in primary care.
- Primary care prescribers should be aware that their patient is receiving this medicine and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.

b. Secondary care

- Providers are NHS hospital trusts.
- Trusts to follow internal governance procedures to add to their formulary and initiate homecare.
- The initiation, administration and on-going treatment is managed by secondary care.
- Specialists will be required to notify the high-cost drugs teams of initiation using the Blueteq® system.
- Homecare arrangements will be managed by the trust.

c. ICS

- This technology is commissioned by integrated care systems.
- Pathway has been discussed and approved virtually by the Gastroenterology Network.
    - Inclusion of etrasimod as an option.

d. PAD and Joint Formulary • Remove pathway from all treatments for this condition from PAD and replace with revised pathway. • New PAD profile will be required. • New entry on the JF will be required.
Proposed tick box forms
Blueteq® initiation forms have been developed.

References:

1 European Medicines Agency. Velsipity: EPAR – Product information. Available at: Velsipity, INN-etrasimod arginine (europa.eu) Accessed <27.3.24>

2 NICE Technology Appraisal Guidance: Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over. Available at: https://www.nice.org.uk/guidance/ta956 Accessed <13.3.24>

3 NICE Resource Impact Report: Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over. Available at: https://www.nice.org.uk/guidance/ta956 Accessed <13.3.24>

4 NICE Resource Impact Template: Etrasimod for treating moderately to severely active ulcerative colitis in people aged 16 and over. Available at: https://www.nice.org.uk/guidance/ta956 Accessed <13.3.24>

Declaration of interest:

	Name	Role	Date	Declaration of interests (please give details below)
Prepared by	T. Bahra	Lead MRU Pharmacist	13.3.24	See below
Supported by				
Reviewed by				

Explanation of declaration of interest:
Indirect shareholder as per SH ICB declaration of interests.

Version control sheet:

Version	Date	Author	Status	Comment
1	13.3.24	T. Bahra	Draft	Out for consultation
			Final	Out for clinical comment

Blueteq® form: