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Advice document
SMC2655

etrasimod film-coated tablets (Velsipity®)

Pfizer Ltd

10 May 2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

etrasimod (Velsipity®) is accepted for use within NHSScotland.

Indication under review: for the treatment of patients 16 years of age and older with moderately to severely active ulcerative colitis (UC) who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.

Etrasimod offers an additional treatment choice in the therapeutic class of sphingosine 1-phosphate (S1P) receptor modulators.

This advice applies only in the context of approved NHSScotland Patient Access Scheme (PAS) arrangements delivering the cost-effectiveness results upon which the decision was based, or PAS/ list prices that are equivalent or lower.

Vice Chair
Scottish Medicines Consortium

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1. Clinical Context

1.1. Medicine background

Etrasimod is an S1P receptor modulator that targets the S1P1, S1P4 and S1P5 receptors. Treatment should be initiated under the supervision of a physician experienced in the management of ulcerative colitis. The recommended dose is 2 mg taken orally once daily. It is recommended that etrasimod be administered with food for the first 3 days to attenuate potential transient heart rate lowering effects related to initiation of treatment. Etrasimod can then be taken with or without food. Refer to the Summary of Product Characteristics for further information.[1]

1.2. Relevant comparator(s)

Ozanimod (Zeposia®) is another S1P receptor modulator, which targets S1P1 and S1P5 receptors. It is accepted for use within NHSScotland 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 or a biologic agent (SMC2478).

Other comparators include Janus-associated kinase (JAK) inhibitors (tofacitinib, filgotinib, upadacitinib), an integrin inhibitor (vedolizumab), tumour necrosis factor (TNF)-alpha inhibitors (infliximab, adalimumab, golimumab) and an interleukin inhibitor (ustekinumab).

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

There is no direct evidence comparing etrasimod with relevant comparators.

The submitting company conducted a network meta-analysis (NMA) to compare the efficacy of etrasimod to comparators (ozanimod, tofacitinib, filgotinib, upadacitinib, vedolizumab, infliximab, adalimumab, golimumab and ustekinumab) in adults with moderately to severely active ulcerative colitis with and without prior exposure to biologic therapy. They concluded that etrasimod is an efficacious treatment for patients with moderately to severely active ulcerative colitis and is comparable to currently available therapies used in the advanced treatment of ulcerative colitis. The findings also demonstrated that the incidence of serious infections during the induction phase was expected to be low for patients treated with etrasimod and comparable to placebo and its comparators.

Other data were also assessed but remain confidential*

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment

SMC is unable to publish the estimated patient numbers as the company considered that these were commercial in confidence.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

Other data were also assessed but remain confidential*

References

1. Pfizer Ltd. Etrasimod 2 mg film-coated tables (Velsipity®) Summary of product characteristics. Electronics Medicines Compendium https://www.medicines.org.uk/.

This assessment is based on data submitted by the applicant company up to and including 15 April 2024**.**

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.