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To the Minister of Health, Welfare and Sport
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National Health Care Institute
Care
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Our reference
2023053757

Date 3 April 2025
Re: Package advice lock procedure medicinal product etrasimod (Velsipity®) for ulcerative colitis

Dear Ms Agema,

The National Health Care Institute advises you on the assessment of etrasimod (Velsipity®) for the treatment of patients with ulcerative colitis (UC). Ulcerative colitis is a chronic colon inflammation characterised by periods of disease flare-ups alternating with periods of remission when the disease is somewhat controlled. 45,000 people in the Netherlands suffer from ulcerative colitis. This advice was prompted by the placement of etrasimod in the package lock for expensive medicinal products.

Registered indication
Etrasimod (Velsipity®) is indicated for the treatment of patients aged 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.

Claim by the marketing authorisation holder
Etrasimod (Velsipity®) for the treatment of adult patients (≥ 16 years) with moderately to severely active ulcerative colitis who have had an inadequate response with, lost respons to, or were intolerant to a TNF-α blocker has an equivalent value to ozanimod and vedolizumab. Because vedolizumab and ustekinumab have an equivalent value in this population, etrasimod also has an equivalent value to ustekinumab.

Package advice
The National Health Care Institute advises you to include etrasimod (Velsipity®) for the treatment of adult patients (≥ 16 years) with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to a TNF-α blocker in the basic healthcare package provided that its introduction does not lead to additional costs. The National Health Care Institute has established that etrasimod meets the legal criterion of 'established medical science and medical practice' and that there is an equal value to treatment with vedolizumab and ozanimod. Given the equal value, the starting point for inclusion in the package is an equal price.

We explain the preparation of this package advice below.

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General
At your request, the National Health Care Institute assesses whether care should be part of the standard health insurance package from the perspective of the basic healthcare package paid from joint premiums.

The National Health Care Institute assesses on the basis of the four package criteria[1]: effectiveness[2], cost-effectiveness[3], necessity[4] and feasibility[5]. Stakeholders were consulted during the process.

Comprehensive weighting of package criteria
Effectiveness
Established medical science and medical practice
The first line of treatment of moderate to severe UC consists of treatment with mesalazine and/or thiopurines. In case of insufficient effect, a TNF-alpha inhibitor is given. In case of insufficient effect of the TNF-alpha inhibitor, the healthcare provider may consider a higher dose of the TNF-alpha inhibitor, switching to another TNF-alpha inhibitor, or switching to another group of medicinal products. The medicinal products that can be used after TNF-alpha inhibitors are vedolizumab, ustekinumab, JAK inhibitors (upadacitinib, tofacitinib and filgotinib), mirikizumab and ozanimod. The professional association has indicated that there are no preferred products after the use of a TNF-alpha inhibitor and that the price determines the selection. Currently, vedolizumab and ustekinumab are the most common treatments. Based on data from recently published network meta-analyses, a number of these products, including ustekinumab and vedolizumab, have similar effectiveness after TNF-alpha inhibitors. The Minister has recently included mirikizumab in the basic healthcare package for the treatment of adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were' intolerant to a TNF-alpha inhibitor. The National Health Care Institute has recently issued positive advice for risankizumab with a similar indication.

Based on the comparable beneficial and adverse effects of etrasimod compared to vedolizumab and ozanimod, the National Health Care Institute concludes that etrasimod complies with the established medical science and medical practice for the treatment of adult patients (>16 years) with moderately to severely active UC who have had an inadequate response with, lost response to, or were' intolerant to a TNF-alpha inhibitor. Given that vedolizumab has similar effects to ustekinumab in published meta-analyses, the National Health Care Institute also considers etrasimod to be equivalent to ustekinumab.

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[1] Real-world package management 4 (2023). National Health Care Institute, Diemen. Via http://www.zorginstituutnederland.nl.

[2] Assessment of the established medical science and medical practice (2023). National Health Care Institute. Via http://www.zorginstituutnederland.nl.

[3] Healthcare cost-effectiveness report (2024) National Health Care Institute, Diemen. Via http://www.zorginstituutnederland.nl.

[4] Necessity is related to both the medical need due to the severity of a disease for the patient (burden of disease) and the need to insure something. See the report on real-world package management 4 (2023).

[5] The package criterion of feasibility deals with whether it is feasible or sustainable to include a specific form of care in the basic healthcare package. It is therefore mainly a test of a number of implementation aspects, such as the healthcare organisation, the support base, ethical and legal aspects, budget impact, etc. See the report on real-world package management 4 (2023).

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Cost-effectiveness
Due to its equal value, the National Health Care Institute has not assessed its cost-effectiveness. However, it is not known whether the treatments it has been compared to are cost-effective.

Budget impact analysis
The National Health Care Institute estimates that 101 patients per year will be treated with etrasimod for the above indication in year 3 after inclusion in the package. The total costs per patient per year are €10,128.75. This results in macro costs of €789,663 in the third year. When also taking into account ozanimod substitution, this results in €390,990 in savings in year 3.

In particular, there is uncertainty about the number of patients and the market distribution of etrasimod and ozanimod. This could actually cause the budget impact to be either higher or lower.

Since etrasimod is equivalent to ustekinemab and vedolizumab, the introduction should not result in additional costs compared to these products. Biosimilars have already been registered for ustekinumab. Introduction of these biosimilars leads to competition and thus lower (secret) prices. This price decrease and the negotiated prices should be taken into account when applying the principle of 'equal value, equal price'.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as annexes (pharmacotherapeutic report and budget impact analysis).

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board