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National Health Care Institute

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2024043359

Date 19 December 2024
Subject Package advice for risankizumab (Skyrizi®) for ulcerative colitis

Our reference
2024043359

Dear Ms Agema,

The National Health Care Institute is hereby advising you about the assessment of risankizumab (Skyrizi®) for treating patients with ulcerative colitis (hereinafter "UC"). UC is a chronic inflammation of the intestines that is characterised by periods in which the condition flares up interspersed with periods of remission in which the condition is once again under control. 45,000 people in the Netherlands suffer from ulcerative colitis. The reason for this advice was risankizumab being placed in the lock procedure for expensive medicinal products.

Registered indication
Risankizumab (Skyrizi®) is indicated for treating adult patients with moderate to severe, active UC who have not responded sufficiently or are no longer responding to or were unable to tolerate conventional treatment or a biological treatment.

Claim by the marketing authorisation holder
The value of risankizumab is equivalent to that of the biologicals vedolizumab and ustekinumab and that of the Janus kinase (JAK) inhibitors upadacitinib, tofacitinib and filgotinib after a tumour necrosis factor alpha (TNF-alpha) inhibitor has been unsuccessful.

Package advice
The National Health Care Institute recommends that you include risankizumab (Skyrizi®) in the basic healthcare package for treating adult patients with moderate to severe, active UC who have not responded sufficiently or are no longer responding to or were unable to tolerate a TNF-alpha inhibitor, as long as this introduction does not lead to additional costs. The National Health Care Institute has established that risankizumab for the above indication meets the legal criterion of 'established medical science and medical practice' and that there is equal therapeutic value compared to mirikizumab and vedolizumab. Given the equal value, the starting point for inclusion in the package is an equal price.

The development of this package advice is explained below and we refer to the attached reports for further details.

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General
At your request, the National Health Care Institute assesses whether new 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 and feasibility. 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 treating adult patients with moderate to severe, active UC who have not responded sufficiently or no longer respond to or are unable to tolerate a TNF-alpha inhibitor. Risankizumab has a similar mechanism of action to mirikizumab.

Based on the comparable favourable and unfavourable effects of risankizumab compared to vedolizumab, the National Health Care Institute concludes that risankizumab meets the criterion of established medical science and medical practice for treating adult patients with moderate to severe, active ulcerative colitis who have not responded sufficiently or no longer respond to or are unable to tolerate a TNF-alpha inhibitor. Given that published network meta-analyses show that vedolizumab has a comparable effect to ustekinumab, the National Health Care Institute also sees risankizumab as having an equivalent value to ustekinumab.

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.

[1] Real-world package management 3 (2013). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

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

[3] Cost-effectiveness report (2015). National Health Care Institute, Diemen. Via www.zorginstituutnederland.nl.

Budget impact analysis
The National Health Care Institute estimates that in year 3, after including it in the basic healthcare package, 550 patients per year will be treated with risankizumab for the specified indication. Patients who respond effectively to the induction treatment are classified as responders. These patients can continue their treatment. Non-responders cannot proceed with the treatment.
The costs per patient per year for responders are €25,432 in the first year and €15,028 in the maintenance year. The costs for non-responders (24 weeks of treatment) are €18,496. The costs of comparable treatments per responder patient per year are €14,746. The costs for non-responders to the comparable treatment are €6,805.74 (24 weeks).

By year 3, the total macro costs of risankizumab will be €10.4 million. When substitution of the comparable treatments is taken into account, including risankizumab in the healthcare package leads to additional costs of €2.6 million in year 3 of the BIA. This is driven by the price difference between risankizumab and the standard treatments (vedolizumab, mirikizumab and ustekinumab). Given the equal value, the starting point for inclusion in the package is an equal price.

There is in particular uncertainty about the number of patients who will ultimately be treated with risankizumab. In addition, the availability of biosimilars of ustekinumab could cause a further shift in the treatment landscape. Furthermore, it is possible that the introduction of biosimilars will lead to lower prices. This should be weighed up 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,

Mark Janssen
Chair of the Executive Board

National Health Care Institute

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