Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

2025028952

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Contact
K. Watson
warcg@zinl.nl

Our reference
2025028952

Date 12 December 2025
Re: Advice lock procedure medicinal product upadacitinib (Rinvoq®) for giant cell arteritis

Dear Mr Bruijn,

The National Health Care Institute advises you in this letter about the assessment of upadacitinib (Rinvoq®) for the treatment of giant cell arteritis. The reason for this advice was the placement of upadacitinib in the lock procedure for expensive medicinal products. The National Health Care Institute advises you not to include upadacitinib in the basic healthcare package for giant cell arteritis. Although the marketing authorisation holder requested that upadacitinib be included in the Medicine Reimbursement System (GVS) for extramural medicinal products, your Ministry informed the marketing authorisation holder on October the 13th 2025 that upadacitinib is not eligible for this. Upadacitinib is considered to be medical specialist care and, as such, falls within the scope of intramural funding.[1]

Giant Cell Arteritis is an autoimmune disease in which the immune system attacks the body itself, causing inflammation of the large and medium-sized arteries (‘*systemic vasculitis*’). This can lead to narrowing and even occlusion of the affected arteries. This causes a reduced supply of oxygen in the underlying tissues. Headache, jaw pain when chewing, and loss of vision are the main symptoms. Giant cell arteritis occurs primarily in people over 50 and is treated long-term with high doses of corticosteroids[2]. In the Netherlands, approximately 7500 people suffer from giant cell arteritis.

Registered indication
Upadacitinib is indicated for the treatment of giant cell arteritis in adult patients.

Upadacitinib is also registered for rheumatoid arthritis, psoriatic arthritis, axial spondyloarthritis, ankylosing spondylitis, atopic dermatitis, ulcerative colitis and Crohn's disease. These indications are not taken into consideration here. Upadacitinib is reimbursed for certain types of Crohn's disease since May 2024.[3]

[1] See the letter Directorate-General on Curative Care dated 13 October, 2025; reference: 4239355-1089788-GMT.

[2] According to the professional association, 75 – 80% of patients with giant cell arteritis have a recurrence of the disease, with more than 50% of patients being treated for more than 5 years.

[3] Government Gazette No. 15245 (8 May 2024)

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
12 December 2025

Our reference
2025028952

Claim by the marketing authorisation holder
'Upadacitinib has a similar therapeutic value to the current treatment with tocilizumab (the standard treatment in the Netherlands) for the treatment of giant cell arteritis in adult patients who have an inadequate response or contraindication to methotrexate (MTX), or experience side effects due to MTX.'

Package advice

The National Health Care Institute advises you not to include upadacitinib in the basic healthcare package for the treatment of giant cell arteritis. The National Health Care Institute has determined that upadacitinib does not meet the legal criterion of 'established medical science and medical practice' for this indication.

We explain the preparation of this package advice below.

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[4]: effectiveness[5], cost-effectiveness[6], necessity[7] and feasibility[8]. The Scientific Advisory Board (WAR) advises the National Health Care Institute on the (scientific) basis and the conclusion of the assessment. Stakeholders are consulted during the process.

Since upadacitinib does not meet the legal criterion of 'established medical science and medical practice' for the above indication, a comprehensive weighting of the four package criteria and advice from the Insured Package Advisory Committee (ACP) is not warranted.

Substantive assessment
Effectiveness
Established medical science and medical practice
No direct comparative study has been conducted with upadacitinib and tocilizumab. The effectiveness and safety of both upadacitinib and tocilizumab have been studied in separate randomised, placebo-controlled, double-blind studies (RCTs) in patients ≥ 50 years with giant cell arteritis with a background treatment of a glucocorticoid tapering regimen. Neither study specifically looked at whether patients had previously been treated with methotrexate. These studies differ too much in design and patient enrolment to reliably indirectly compare the effectiveness of these agents on the basis of their study results, in order to test

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

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

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

[7] 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).

[8] 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 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).

the claim of equal value. The National Health Care Institute, supported by the WAR, concludes that the study results can only be used to assess whether there is a clinically relevant added value for each medicinal product compared to placebo.

In this context, the National Health Care Institute has assessed the effects of upadacitinib and tocilizumab separately on the crucial outcome parameters of sustained remission, cumulative glucocorticoid dose, quality of life and adverse effects. According to the National Health Care Institute, supported by the WAR, 'sustained remission' was ultimately both clinically and for the final assessment the most relevant outcome parameter in relation to the often long-term treatment of giant cell arteritis. However, also on the basis of their individual study results on these outcome parameters relative to placebo, it cannot be reliably established that upadacitinib is equivalent to tocilizumab in terms of clinical effectiveness for giant cell arteritis. Based on these findings, upadacitinib does not meet the criterion of established medical science and medical practice.

Should you need any further information, please do not hesitate to contact us. The pharmacotherapeutic report is attached.

Yours sincerely,

M.J. Janssen
Chair of the Executive Board

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
12 December 2025

Our reference
2025028952