



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
PO Box 20350
2500 EJ THE HAGUE

**National Health Care
Institute**

Care
Medicinal Products

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

P. Bloemen

warcg@zinl.nl

Our reference

2024037485

Date 23 October 2024
Re: GVS advice ritlecitinib (Litfulo®) for alopecia areata

Dear Ms Agema,

In the letter of 3 September [CIBG-24-07333], you asked the National Health Care Institute to carry out a substantive review of whether the medicinal product ritlecitinib (Litfulo®) for alopecia areata (AA) is interchangeable with a product included in the health insurance package, in the context of an application for inclusion in List 1B of the Medicine Reimbursement System (GVS).

The National Health Care Institute has now completed that assessment.

At the time of the application for reimbursement and the writing of the assessment by the National Health Care Institute, no interchangeable medicinal product for severe AA was included in the GVS. However, on 31 July of this year, the National Health Care Institute recommended the inclusion of a comparable medicinal product baricitinib (Olumiant®) for adults with severe AA in List 1B of the GVS with List 2 conditions. For this reason, both inclusion on List 1B and inclusion on List 1A in a newly formed cluster with baricitinib have been elaborated in the GVS report (pharmacotherapeutic report and budget impact analysis). Since baricitinib is already included in List 1B of the GVS at the time of writing this letter, the letter only advises on that situation.

AA is an autoimmune disorder characterized by rapid hair loss, especially of the scalp (skull), eyebrows and eyelashes. The disease affects about 2% of the overall population at a certain point in their lives. In practice, the severity of the disease is determined by the quality of life, in addition to the amount of hair loss. Severe AA is associated with emotional and psychosocial problems, including a high prevalence of depression and anxiety. The most recent medical management option for patients with severe AA was an immunosuppressant.

Registered indication: Ritlecitinib is indicated for the treatment of severe AA in adults and adolescents 12 years of age and older and is available in 50 mg hard capsules.

Claim by the marketing authorisation holder: In case of a potential inclusion of baricitinib in List 1B of the GVS at the time of this advice, the marketing authorisation holder claimed an equal value to baricitinib for adult patients with severe AA.

Advice

The National Health Care Institute advises you to include ritlecitinib on List 1A of the GVS in a new cluster to be created with baricitinib for severe AA. The National Health Care Institute recommends that the conditions applicable to baricitinib in List 2 also apply to ritlecitinib. The standard dose of ritlecitinib was determined at 50 mg per day (and for baricitinib at 3 mg per day).

Further conditions for ritlecitinib (and baricitinib) based on criteria set by the physicians' association:

Only on prescription by a dermatologist for an insured person with the main indication being the treatment of severe alopecia areata (AA) in case of:

- *SALT (Severity of Alopecia Tool) score ≥ 50 and*
- *current episode and disease severity of AA less than 8 years;*
- *the regrowth of hair is insufficient despite the use of topical products and at least one systemic immunosuppressant (methotrexate, ciclosporin, prednisone oral or i.m.) at an adequate dose for an appropriate treatment duration, unless there is evidence of contraindications or adverse effects to these products.*

Treatment should be evaluated after 6 months and discontinued if insufficient effectiveness is observed in accordance with the guidelines accepted by the relevant physicians' associations in the Netherlands.

We explain the preparation of this advice below.

Substantive assessment

Assessment of interchangeability

To determine the place of a medicinal product in the GVS, the product's interchangeability with medicinal products already included in the GVS must first be assessed. In this case, the comparison was made with another JAK inhibitor: baricitinib. There is a similar indication, a similar route of administration and no clinically relevant differences in properties. Although the age indication for ritlecitinib is broader than for baricitinib (including 12-18-year-olds), there is no specific dosage form or dose adjustment for this group, and it is therefore indicated for the same age category according to GVS criteria. On the basis of the criteria for interchangeability, it can be concluded that ritlecitinib is interchangeable with baricitinib. On this basis, ritlecitinib (Litfulo®) can be placed on List 1A in a newly formed cluster with baricitinib (see annex GVS report for development).

Therapeutic value

The National Health Care Institute concluded that the therapeutic value of ritlecitinib is comparable with that of baricitinib in the above indication. Both ritlecitinib and baricitinib lead to clinically relevant hair regrowth, compared to placebo. The point estimation of the indirect comparison suggests that there is no clinically relevant difference between the two treatments on this outcome. The risk of severe intervention-related undesirable effects is limited and appears to be similar to placebo and baricitinib. The same applies to the risk of discontinuation of treatment due to undesirable effects. Also, the short-term adverse effects profile does not appear to differ between adults and adolescents and between ritlecitinib and baricitinib. However, there are still uncertainties about the long-term safety of both medicinal products. Long-term safety studies are ongoing or are being initiated.

**National Health Care
Institute**
Care
Medicinal Products

Date
23 October 2024

Our reference
2024037485

Budget impact analysis

In case of advice related to the inclusion in List 1A, a budget impact analysis is usually not required. In view of the two scenarios involved in the preparation of this package advice, the BIA that was drawn up and consulted has been added for information.

Appropriate care

The previous advice on appropriate care for this indication in List 2 applies to both baricitinib and ritlecitinib.

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

Yours sincerely,

Mark Janssen
Chairperson of the Executive Board

**National Health Care
Institute**
Care
Medicinal Products

Date
23 October 2024

Our reference
2024037485