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2023005393

National Health Care Institute

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Contact
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Date 15 February 2023
Subject Advice tafasitamab (Minjuvi®)

Our reference
2023005393

Dear Mr Kuipers,

In this letter, the National Health Care Institute advises you on tafasitamab (Minjuvi®, TAFA) in combination with lenalidomide (LEN) followed by tafasitamab monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT). The reason for this advice was that tafasitamab was being placed in what is known as the 'lock procedure' for expensive medicinal products.

The National Health Care Institute has concluded that TAFA-LEN meets the statutory criterion of 'established medical science and medical practice' for this indication. Furthermore, the National Health Care Institute has concluded that the therapeutic value of TAFA-LEN is equal to the value of the already reimbursed combination of polatuzumab vedotin (Polivy®, Pola) and bendamustine-rituximab (BR). The National Health Care Institute recommends you to include tafasitamab in the basic health care package, provided that the net price (of the combination of tafasitamab and lenalidomide) after successful price negotiations with the marketing authorisation holder does not exceed the net price of the combination of polatuzumab vedotin and bendamustine-rituximab.

I will explain the advice in more detail below.

General

At your request, the National Health Care Institute assesses whether new care should be part of the health insurance package from the perspective of the health insurance package paid from joint premiums. We consider these both in the scientific sense and in terms of public support. We also review the aspects of efficiency and transparency. The National Health Care Institute assessed TAFA-LEN on the basis of the four package criteria[1]: effectiveness[2], cost-effectiveness[3], necessity and feasibility. The National Health Care Institute is advised in this matter by its Scientific Advisory Board (WAR) for advice on established medical science and medical practice and on cost-effectiveness. Interested parties were

[1] Package management in practice 3 (2013), National Health Care Institute, Diemen

[2] Established medical science and medical practice assessment: updated version (2015). National Health Care Institute, Diemen

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

also consulted in this context.

Comprehensive weighting of package criteria
Established medical science and medical practice
DLBCL is a type of lymphoma. It belongs to the group of non-Hodgkin lymphomas. The standard first-line treatment for DLBCL consists of immuno-chemotherapy with an R-CHOP regimen. Second- and third-line treatment depends (partially) on the patient's age and level of fitness. It can involve chemotherapy, radiation, stem cell transplantation or CAR-T cell-therapy (or a combination of these). Since 2021, if patients are not eligible for stem cell therapy or CAR-T cell therapy, they can be treated with the combination of polatuzumab vedotin with rituximab-bendamustine (Pola-BR).

TAFA-LEN is registered for the treatment of adult patients with R/R DLBCL who are not eligible for ASCT. According to clinical experts, in Dutch clinical practice it could have a place as a secondary-line palliative treatment for patients who are not fit enough for ASCT and as a third-line palliative treatment for patients who, during the secondary-line treatment, do not seem to be fit enough for ASCT nor for CAR-T cell therapy, or for those who cannot wait for manufacturing of patient-specific CAR-T cells.

This letter is confined to the main conclusions. Should you require more detailed information, I would like to refer you to the pharmaco-therapeutic report for the assessment of TAFA-LEN. The substantiation for the TAFA-LEN claim is a phase 2 study which had significant limitations. It was a single-arm, multicentre*, open-label* study. 81 patients participated in this study. There is no data on the effect on quality of life. This study showed an overall survival of 33.5 months after a 42.7-month follow-up period. The physicians' association found the study population sufficiently representative of the Dutch population. Since direct comparisons with BR and Pola-BR were not possible, the National Health Care Institute carried out two *indirect* comparisons with BR and Pola-BR for its assessment. From the outcome of these comparisons, it can be concluded that the effect of TAFA-LEN on overall survival is of such a size that it is likely not less than that of Pola-BR. This means that TAFA-LEN therefore has an equal value to Pola-BR in adult patients with R/R DLBCL, who are not eligible for ASCT, and therefore meets the established medical science and medical practice.

Budget impact
Based on the current list prices, the National Health Care Institute estimates that the use of tafasitamab (Minjuvi®) in the treatment of R/R DLBCL will be accompanied by additional costs charged to the pharmaceutical budget of €8.1 million in the third year after inclusion in the basic health care package. In total, 54 patients will be treated with TAFA-LEN in year 3. The annual treatment costs are €194,563 per patient. However, there is uncertainty about the number of patients, market penetration, the actual duration of treatment in practice and the distribution of the medicinal products that will be substituted.

Cost-effectiveness
Because of the similarities in effectiveness (equal therapeutic value) of TAFA- LEN and Pola-BR, the National Health Care Institute has not carried out a cost-effectiveness analysis.

Final conclusion
Because there is an equal value to the already reimbursed Polivy® (polatuzumab vedotin) and there are no indications that Minjuvi® is preferable to Polivy®, the National Health Care Institute recommends that Minjuvi® is included in the health insurance package, provided that the net price after successful price negotiations with the marketing authorisation holder does not exceed the net price of the existing treatment with Polivy®. We would like to point out that the Insured Package Advisory Committee has recommended that the price for a treatment should be reduced when more resources are available.

Yours sincerely,

Sjaak Wijma,
Chairperson of the Executive Board

National Health Care Institute

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15 February 2023

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