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Date 27 April 2022
Subject Package advice on the lock procedure drug zanubrutinib (Brukinsa®)

Our reference
2022013397

Dear Mr Kuipers

The National Health Care Institute is hereby advising you about the evaluation of zanubrutinib (Brukinsa®) for the treatment of adult patients with Waldenström macroglobulinaemia (WM) who have had at least one previous treatment, or as first-line therapy for patients who are not suitable for chemo-immunotherapy. The reason for this advice was the placement of zanubrutinib in what is known as the lock procedure for expensive medicinal products.

The National Health Care Institute has concluded that zanubrutinib for the treatment of adult patients with WM who have had at least one previous treatment or as first-line therapy for patients who are not suitable for chemo-immunotherapy meets the legal criterion of established medical science and medical practice. The National Health Care Institute has determined that the therapeutic value of this medicinal product is comparable to that of the medicinal product ibrutinib (Imbruvica®), which is already reimbursed.

The National Health Care Institute advises you to include zanubrutinib in the basic health insurance package, provided that the price negotiations successfully deliver a net price that does not exceed that of the existing treatment with ibrutinib. We would like to point out that the Insured Package Advisory Committee has recommended that the price for a treatment should be reduced when several drugs are available for the same indication. In addition, we would like to point out the patent expiry date for ibrutinib (expected in December 2026).

We would like to explain our findings and final conclusion below.

General

At your request, the National Health Care Institute assesses whether new care should be part of the basic health insurance package from the perspective of the basic health care package paid from joint premiums. In this decision, we weigh the matter, both in a scientific sense and from a social basis, and we weigh the aspects of efficiency and transparency. The National Health Care Institute assessed zanubrutinib on the basis of the four package criteria[1]: effectiveness[2],

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

cost-effectiveness[3], necessity and feasibility. The National Health Care Institute is advised by the Scientific Advisory Board (WAR) for advice on established medical science and medical practice and on cost-effectiveness, and the Insured Package Advisory Committee for the social assessment. We also consulted stakeholders during the assessment process.

Integral weighting of package criteria

Established medical science and medical practice

The efficacy and safety of zanubrutinib compared to ibrutinib in WM was studied in a randomised, open-label, direct comparative phase 3 trial (ASPEN). The estimated overall survival (OS) and progression-free survival (PFS) at 18 months were high and comparable in both arms. Based on OS and PFS, zanubrutinib is not inferior to ibrutinib.
Compared to baseline and measured using the EuroQoL 5-Dimension Questionnaire (EQ-5D) and European Organisation for the Research of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30), quality of life improved similarly in both treatment arms. The safety profiles of both zanubrutinib and ibrutinib are acceptable in relation to the effect achieved with the treatment.

Zanubrutinib for the treatment of adult patients with WM who have had at least one previous treatment or as first-line therapy for patients who are not suitable for chemo-immunotherapy meets the criterion of 'established medical science and medical practice' and has comparable therapeutic value to ibrutinib.

Budget impact

The National Health Care Institute estimates that 45 patients per year will be treated with zanubrutinib for this indication in year 3 after inclusion in the package. This results in a cost impact of €2.1 million for zanubrutinib. The use of zanubrutinib in the treatment of adult patients with WM who have had at least one previous treatment, or as first-line therapy for patients who are not suitable for chemo-immunotherapy is not expected to be associated with additional costs or savings.

Ibrutinib has been in use for several years. The health insurance companies have reached joint agreements on the price of ibrutinib for WM. The National Health Care Institute does not know what those agreements involve. The National Health Care Institute only expects no additional costs if the same pricing is assumed for both treatments (i.e. the same pharmacy purchase price); zanubrutinib will therefore lead to additional costs under the current pricing because of the price agreements in place for ibrutinib. After the patent expiry date for ibrutinib (expected in December 2026), zanubrutinib will undoubtedly lead to higher costs.

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

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

Cost-effectiveness
Because of the similarity in effectiveness (equal therapeutic value) of zanubrutinib compared to ibrutinib, which is already reimbursed, a cost-effectiveness analysis has not been considered here.

Package advice
The National Health Care Institute advises you to include zanubrutinib in the basic health insurance package for the stated indication, provided that the price negotiations successfully deliver a net price that does not exceed that of the existing treatment with ibrutinib. Given the equivalent value compared to ibrutinib, which is already being reimbursed, and that there are no indications that either product is preferable to the other, we advise you to take the net price of ibrutinib and the expected patent expiry of ibrutinib in December 2026 into account during the price negotiations. We would like to point out that the Insured Package Advisory Committee has advised the National Health Care Institute in general terms that the price for a treatment should be reduced when several medicinal products are available for the same indication.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board

National Health Care Institute
Care

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27 April 2022

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