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National Health Care Institute
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Medicinal Products

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2022004796

Our reference
2022004796

Date 10 February 2022
Subject GVS advice ofatumumab (Kesimpta®)

Dear Mr Kuipers,

In the letter of 8 November 2021, the State Secretary of Medical Care and Sport requested the National Health Care Institute to carry out a substantive review of whether ofatumumab (Kesimpta®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has completed this assessment. The considerations are included in the GVS report attached to this letter.

Ofatumumab (Kesimpta®) is registered for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features. Ofatumumab is available as a solution for injection in a pre-filled pen. Each pre-filled pen contains 20 mg ofatumumab.
The recommended dose is 20 mg ofatumumab administered by subcutaneous injection with:
- initial doses in weeks 0, 1 and 2, followed by
- monthly maintenance doses from week 4.

The market authorisation holder is asking for inclusion on List 1B of the Health Insurance Regulation.

Review 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. Ofatumumab (Kesimpta®) is not interchangeable with any products in the GVS.

Therapeutic value
The National Health Care Institute has concluded that ofatumumab, as secondary disease-modulating therapy (DMD), has a therapeutic value that is equal to the other secondary DMDs cladribine, fingolimod, natalizumab and ocrelizumab in adult patients with:
- Active RMS with continuous inflammatory disease activity despite adequate treatment with at least one disease-modulating medicinal product;
- Treatment-naive patients with very active disease defined by the presence of

two or more disabling relapses in one year and 1 or more gadolinium-stained lesions and/or new T2 lesions and/or significantly increasing T2 lesions (≥ 50 percent increase in maximum diameter).

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Budget impact analysis
The cost of maintenance treatment with ofatumumab is €20,086 per year. Taking account of assumptions about patient numbers, market penetration, patient compliance, substitution, etc., the expected budget impact of ofatumumab is €0.3 million in the third year after inclusion in the package.

Pharmaco-economic analysis
Based on the estimated budget impact, the product is exempt from pharmaco-economic analysis.

Advice
Based on the above considerations, the National Health Care Institute advises that you include ofatumumab (Kesimpta®) on List 1B.

If the application of ofatumumab (Kesimpta®) is included in the package, the National Health Care Institute recommends the following reimbursement conditions:

Condition ofatumumab (Kesimpta®):
Only for an insured person with active relapsing multiple sclerosis (RMS):
a) with persistent inflammatory disease activity despite adequate treatment with at least one disease-modifying medicinal product that is licensed for treating MS, or
b) Treatment-naive patients with very active disease defined by the presence of two or more disabling relapses in one year and 1 or more gadolinium-stained lesions and/or new T2 lesions and/or significantly increasing T2 lesions (≥ 50 percent increase in maximum diameter).

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board