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**National Health Care Institute**
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**Our reference**
2025023365

Date 30 September 2025
Re: Reassessment GVS advice ofatumumab (Kesimpta®) for multiple sclerosis

Dear Mr Bruijn,

The National Health Care Institute advises you about the reassessment of the clustering of ofatumumab (Kesimpta®) with subcutaneous natalizumab in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 12 August 2025 (CIBG-25-08558).
The National Health Care Institute advises you to maintain the clustering, as ofatumumab and subcutaneous natalizumab are still interchangeable, despite the new data.

Clinical picture
Multiple sclerosis (MS) is a chronic condition in the brain and spinal cord in which the body's own immune system attacks certain nerve cells. The nature and severity of the MS symptoms depend on the location of the inflammation, and the symptoms worsen over time. The inflammatory attacks eventually permanently damage the nerve cells and increase the degree and severity of the symptoms. For example, patients with MS may experience problems with movement, talking, vision, concentration and memory. Periods of inflammatory attacks (=relapse) alternate with periods without symptoms and/or with recovery. With the current treatments, the life expectancy of MS patients is barely different from that of healthy individuals. In the Netherlands, an estimated 36,500 people had MS in 2019. Ofatumumab and natalizumab are indicated for the treatment of MS in patients with active disease.

Therapeutic indication
Ofatumumab (Kesimpta®) is indicated for the treatment of adult patients with relapsing multiple sclerosis (RMS) with active disease defined by clinical or imaging features. The medicinal product is available in a pre-filled syringe or pen containing 20 mg in a 0.4 ml solution (50 mg/ml) for subcutaneous injection.

This medicinal product has been listed on GVS List 1A in the 0L04AABP V cluster with subcutaneous natalizumab for this indication since 1 April 2022. Both medicinal products have additional conditions for reimbursement.

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Current condition for ofatumumab and subcutaneous natalizumab:
*Only for an insured person with active relapsing multiple sclerosis (RMS):*

1. *With continued inflammatory disease activity despite adequate treatment with at least one disease-modulating medicinal product registered for the treatment of MS, or*
2. *Treatment-naïve patients with highly active disease defined by the presence of 2 or more disabling relapses in one year and 1 or more gadolinium-enhanced lesions and/or new T2 lesions and/or significantly larger T2 lesions (≥ 50 percent increase in maximum diameter).*

Claim by the marketing authorisation holder
The marketing authorisation holder requests that ofatumumab is relisted on List 1B of the Health Insurance Regulation on the basis of newly available data. According to the marketing authorisation holder, these data would indicate that ofatumumab (Kesimpta®) is no longer interchangeable with subcutaneous natalizumab for the indication as assessed in 2022: for the treatment of adult patients with relapsing multiple sclerosis (RMS) with active disease defined by clinical or imaging features. The marketing authorisation holder does not request the adaptation of the List 2 conditions.

**Advisory report**
The National Health Care Institute advises you to maintain the clustering of ofatumumab (Kesimpta®) and natalizumab (Tysabri®) on List 1A in cluster 0L04AABP V with the corresponding List 2 conditions.

We have explained below how we reached this advisory report.

Substantive assessment
Background
In February 2022, the National Health Care Institute concluded in a GVS advice that ofatumumab (Kesimpta®) has an equal value compared to the medicinal products cladribine, fingolimod, natalizumab, and ocrelizumab. At the time, the GVS did not include any medicinal products that could be clustered with ofatumumab based on dosage form. Therefore, it was recommended that the medicinal product be placed on List 1B with additional conditions. The assessment of subcutaneous natalizumab in October 2022 concluded that natalizumab and ofatumumab are interchangeable and that both medicinal products can be clustered in a new cluster on List 1A of the GVS. Additional conditions were also recommended for subcutaneous natalizumab. Based on new clinical data, the marketing authorisation holder claims that ofatumumab and subcutaneous natalizumab are no longer interchangeable due to a difference in clinically relevant properties. According to the marketing authorisation holder, the applicability of each of the medicinal products differs.

*Assessment of interchangeability*
The National Health Care Institute has once again reviewed the criteria for interchangeability, taking into account the new information. The National Health Care Institute again concludes that ofatumumab is interchangeable with subcutaneous natalizumab and that both medicinal products can therefore remain clustered on List 1A. The points raised by the marketing authorisation holder are insufficient to conclude that there is a clinically relevant difference in properties between the two medicinal products. Annex 1 refutes the two main arguments put

forward by the marketing authorisation holder.

Should you need any further information, please do not hesitate to contact us.

Yours sincerely,

M.J. Janssen
*Chairperson of the Executive Board*

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