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Our reference
2022025210

Date 25 October 2022
Subject Letter report natalizumab SC (Tysabri®)

Dear Mr Kuipers,

In your letter of 27 September 2022 (CIBG-22-04456), you asked the National Health Care Institute for advice on the place of the medicinal product natalizumab for subcutaneous administration (natalizumab SC) (Tysabri®) in the Medicine Reimbursement System (GVS).

Marketing authorisation holder proposal
The marketing authorisation holder claims that natalizumab SC (Tysabri®) has a comparable therapeutic value to the already admitted medicinal product ofatumumab (Kesimpta®), and states that natalizumab SC is interchangeable with ofatumumab. Consequently the marketing authorisation holder claims that natalizumab SC can be placed on List 1A of the Health Insurance Regulation (Rzv) in a new to be formed cluster with ofatumumab.

The assessment can be found in the corresponding GVS report attached.

Registered indication
Natalizumab SC is an alternative formulation of natalizumab IV and has recently been approved by the EMA and registered as an extension under the brand name Tysabri®.

Natalizumab SC is available as a 150 mg solution for injection in a pre-filled syringe. The recorded indication is the same as that of natalizumab IV and reads:

For the treatment of adult patients with highly active relapsingremitting multiple sclerosis (RRMS) for the following patient groups:
- Patients with highly active disease despite a full and adequate treatment with at least one diseasemodifying therapy (DMT).

or
- Patients with rapidly evolving severe RRMS, defined by 2 or more disabling relapses in one year, and with 1 or more gadolinium enhancing lesions on brain Magnetic Resonance Imaging (MRI) or a significant increase in T2 lesions load as compared to a previous recent MRI.

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Natalizumab SC is already available as an add-on inpatient medicine along with the medicinal product natalizumab for intravenous administration (natalizumab IV) under the brand name Tysabri®.
The request for the inclusion of natalizumab SC in the GVS is a request for the entire registered indication and is in accordance with the current add-on status.

Outcome of assessment (see GVS report in annex)
Based on the available data and PK/PD analyses, it can be concluded that natalizumab SC and natalizumab IV (both registered under the brand name Tysabri®) are therapeutically interchangeable.

Assessment of interchangeability
On the basis of the criteria for interchangeability, natalizumab SC is interchangeable with ofatumumab.

Advice
The National Health Care Institute advises you to place natalizumab SC (Tysabri®) on List 1A of the Health Insurance Regulation (Rzv) in a new to be formed cluster with ofatumumab. The standard dose of natalizumab SC and that of ofatumumab can be set at 10.7 mg and 0.66 mg per day respectively.

We also recommend the following List 2 condition for natalizumab SC:

Condition:

Only for an insured person with highly active relapsing-remitting multiple sclerosis (RRMS):

1) with highly active disease despite a full and adequate treatment with at least one diseasemodifying therapy (DMT).
2) with rapidly evolving severe RRMS, defined by 2 or more disabling relapses in one year, and with 1 or more gadolinium enhancing lesions on brain Magnetic Resonance Imaging (MRI) or a significant increase in T2 lesions load as compared to a previous recent MRI.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

Annex: GVS report on natalizumab SC (Tysabri®)