



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport  
P.O. Box 20350  
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2024029851

Date 19 March 2025  
Re: GVS advice oral methylprednisolone (Methylprednisolon ACE®) for the treatment of multiple sclerosis

**National Health Care**

Institute  
Care  
Medicinal Products

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**Contact**

Ms N. Stam

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**Our reference**

2024029851

Dear Ms Agema,

The National Health Care Institute advises you on the inclusion of oral methylprednisolone (Methylprednisolon ACE®) for acute relapses of multiple sclerosis in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 13 January 2025 (CIBG-24-07729).

**Registered indication**

Oral methylprednisolone (Methylprednisolon ACE®) is indicated for short-term treatment of acute relapses of multiple sclerosis (MS).

Oral methylprednisolone is available in 100 mg tablets

**Claim by the marketing authorisation holder**

The marketing authorisation holder requests the inclusion in List 1B of the Health Insurance Regulation for the registered indication.

**Advice**

The National Health Care Institute recommends that oral methylprednisolone (Methylprednisolon ACE®) for the short-term treatment of acute relapses be included in List 1B of the GVS. The inclusion is not associated with additional costs to be charged to the pharmaceutical budget.

We explain the preparation of this advice below.

**Substantive assessment**

*Assessment of interchangeability*

Based on the criteria for interchangeability, the National Health Care Institute concluded that oral methylprednisolone is not interchangeable with other medicinal products included in the GVS. Oral methylprednisolone is not interchangeable with any other product in the GVS due to its method of administration and high dosage, which give it another main indication. On this basis, oral methylprednisolone cannot be placed on List 1A. The National Health Care Institute has therefore assessed whether oral methylprednisolone can be included in List 1B.

### *Therapeutic value*

There is extensive experience with intravenous administration of methylprednisolone for the short-term treatment of acute MS relapses. Intravenous methylprednisolone is already reimbursed for MS treatment. The professional association states in its guideline 'Multiple Sclerosis (2023)' that, based on multiple randomised controlled studies, oral methylprednisolone is as effective and safe as intravenous methylprednisolone. Oral methylprednisolone tablets are currently magistral preparations and are being reimbursed. The manufacturer of this re-delivery from compounding pharmacies has now registered the medicinal product.

Based on these considerations, the National Health Care Institute concludes that oral methylprednisolone for the treatment of acute MS relapses complies with the established medical science and medical practice. Oral methylprednisolone is therefore eligible for inclusion in List 1B.

### *Budget impact analysis*

The National Health Care Institute estimates that 977 patients per year will be treated with oral methylprednisolone for the above indication in year 3 after inclusion in the package. This number is based on information from the GIP database on the average annual number of prescriptions from 2021 to 2023 for the re-delivery of methylprednisolone tablets/capsules from compounding pharmacies.

The pharmacy purchase price (AIP) of oral methylprednisolone (Methylprednisolon ACE®) is €10.87 per 100 mg tablet. The AIP of the registered tablets is the same as that of the re-delivery from compounding pharmacies. A treatment consists of a three-day course with a daily dose of 1000 mg. As such, a total of 30 tablets are needed for one course. This amounts to €326.10 per course. This results in macro costs of € 318,599.70 in the third year.

When complete substitution of the re-delivery of methylprednisolone from compounding pharmacies is taken into account, there is a neutral budget impact.

Should you need any further information, please do not hesitate to contact us. The assessment report is attached (marginal test).

Yours sincerely,

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

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Care  
Medicinal Products

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