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Date 5 July 2021
Subject GVS advice for Mavenclad® – extension of further conditions

Our reference
2021025281

Dear Ms van Ark,

In your letter of 18 May 2021 (CIBG-21-01867), you asked the National Health Care Institute to advise on a reassessment of cladribine (Mavenclad®) in the context of an extension of the List 2 conditions. The National Health Care Institute has now completed the substantive assessment. The considerations are included in the reassessment report and budget impact analysis that are attached to this letter.

Current situation
Cladribine has been included in List 1A of the Healthcare Insurance Regulations (Dutch: "Rzv") in the 0L01BBCO V cluster since March 2018. The List 2 condition reads: *"only for an insured person aged eighteen or older with highly active relapsing-remitting multiple sclerosis (RRMS) who has not responded to treatment with at least one disease-modifying drug (DMD) registered for the treatment of MS."*

Conclusion of the reassessment
The National Health Care Institute has come to the final conclusion that the new data provide sufficient grounds for amending the List 2 conditions for cladribine by including a population to include treatment-naive highly active RRMS patients with at least two relapses in the previous year.

Budget impact analysis conclusion
Taking account of the various assumptions about patient numbers, the current treatment algorithm, dosages, market penetration and patient compliance, an extension of the current indication of cladribine (Mavenclad®) for treating adult patients with highly active RRMS will, in a realistic scenario, entail additional costs charged to the pharmaceuticals budget of €0.7 million in the third year.

Advice
Cladribine is already included in List 1A in the 0L01BBCO V cluster with specific conditions. Based on the considerations mentioned above, we recommend that you modify the List 2 condition for cladribine by adding *"treatment-naive patients who have had 2 or more relapses in the previous year"*, as set out below. This modification of the further conditions is accompanied by additional costs.
The evolution of the use of cladribine in daily practice, like other agents used for

multiple sclerosis, will be analysed regularly. These analyses will be published in the Monitor MS-geneesmiddelen (MS Drug Monitor).

New conditions for cladribine (Mavenclad®)
Only for insured patients aged eighteen or older with highly active relapsing-remitting multiple sclerosis (RRMS)

- *defined as having had 2 or more relapses in the previous year for treatment-naive patients, or*
- *not having responded to treatment with at least one disease-modifying drug (DMD) that is licensed for treating MS*.

Yours sincerely,

Tiana van Grinsven
Acting Chair of the Executive Board

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Care II

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