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Our reference
2020045641

Date 28 October 2020
Subject GVS advice ozanimod (Zeposia®) *2020045641*

Dear Ms van Ark,

In your letter of 7 September 2020 (CIBG-19-09084), you requested Zorginstituut Nederland to assess whether ozanimod (Zeposia®) is interchangeable with a medicinal product that is included in the medication reimbursement system (GVS). The Zorginstituut has recently completed this assessment. The considerations are included in the GVS report attached to this letter.

Ozanimod (Zeposia®) is indicated for the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) with active disease, as defined by clinical characteristics or characteristics visible on imaging. Ozanimod is available as hard capsules; each hard capsule contains 0.23 mg, 0.46 mg or 0.92 mg ozanimod and the recommended maintenance dose is 0.92 mg once a day.

The marketing authorisation holder of ozanimod (Zeposia®) states that ozanimod is interchangeable with dimethyl fumarate and teriflunomide, and can therefore be placed on List 1A of the Health Insurance Regulations (Rzv), in the existing cluster 0N07XXCO V, together with the other products mentioned.

Assessment outcome
Zorginstituut Nederland has come to the final conclusion that in the treatment of RRMS with active disease, ozanimod has a therapeutic value comparable with that of interferon beta-1a, dimethyl fumarate and teriflunomide.

Review of interchangeability
Based on the criteria for interchangeability, it can be concluded that ozanimod (Zeposia®) is interchangeable with the other medicinal products in the GVS cluster 0N07XXCO V, which includes: dimethyl fumarate and teriflunomide.

Advice
On this basis, we recommend that you include ozanimod (Zeposia®) in cluster 0N07XXCO V on List 1A of the GVS. 0.92 mg/day can be applied as the standard dose.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board