Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

To the Minister of Medical Care and Sport
PO Box 20350
2500 EJ THE HAGUE

2021030997

Date 3 September 2021
Subject GVS advice roxadustat (Evrenzo)

National Health Care Institute
Care
Medicinal Products

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Contact
Dr T.H.L. Tran
T +31 (0)6 120 014 12

Our reference
2021030997

Dear Ms van Ark,

In your letter of 15 June 2021 (CIBG-21-01970), you requested National Health Care Institute to assess, using the parallel procedure CBG-ZIN, the reimbursement application of the medicinal product roxadustat (Evrenzo®) for inclusion in the GVS. In the parallel procedure CBG-ZIN, the reimbursement process was started while the registration process had not yet been completed. Medicinal products that go through this parallel procedure, rather than the current sequential procedure, will become available to patients more quickly. The EMA registration of roxadustat (Evrenzo®) was published on the EMA website on 24 August 2021. This is normally the time when a reimbursement dossier can be submitted. Due to the parallel procedure, the National Health Care Institute can now rule on the reimbursement immediately after registration. The National Health Care Institute has since completed its assessment. The considerations are included in the GVS report attached to this letter, with the pharmaco-therapeutic report and the budget impact analysis.

Evrenzo® is available as tablets with 20, 50, 70, 100 or 150 mg roxadustat and is registered for the treatment of symptomatic anaemia in chronic kidney damage (CNS) in adult patients. The recommended starting dose for patients not previously treated with ESAs (erythropoiesis stimulating agents) is 70 mg three times a week for patients with a body weight of <100 kg and 100 mg three times a week for patients with a body weight of >100 kg. For patients switching from ESAs to roxadustat, the recommended starting dose of roxadustat is determined based on the ESA's last administered dose, in accordance with the table in the Summary of Product Characteristics (SmPC).

The market authorisation holder is asking for inclusion on List 1B of the Health Insurance Regulation.

National Health Care Institute
Care
Medicinal Products

Date
3 September 2021

Our reference
2021030997

Assessment outcome
Roxadustat is the first reversible inhibitor of the enzyme hypoxia inducible factor-prolyl hydroxylase (HIF-PH). This enzyme plays an important role in the production of red blood cells. The ESAs, as well as roxadustat, have also been registered for the treatment of symptomatic anaemia in CNS. The different ESAs registered are darbepoetin alfa, methoxy polyethylene glycol-epoetin beta and epoetin, which are included in cluster 0B03XAAP V on List 1A in the GVS.
In the GVS, the classification of medicinal products into groups of interchangeability distinguishes between, among other things, medicinal products administered through injection and non-injection medicinal products. For this reason, roxadustat, which is administered orally, is not interchangeable with darbepoetin alfa, methoxy polyethylene glycol-epoetin beta and epoetin administered by injection (subcutaneous or intravenous).

Therapeutic value
The National Health Care Institute has concluded that, in the treatment of adult patients with symptomatic anaemia in case of chronic kidney damage, roxadustat complies with the established medical science and medical practice and has an equal value compared to erythropoietic growth factors (ESAs) in non-dialysis patients and dialysis patients in both an Hb correction setting and an ESA conversion setting.

Budget impact analysis
The total cost of roxadustat is expected to be €4,154,138 in the third year after inclusion in the health insurance package. Taking into account the equal therapeutic value, the level of substitution per ESA and the market penetration, inclusion of roxadustat (Evrenzo®) on List 1B of the GVS for the treatment of adult CNS patients with anaemia will be accompanied by additional costs of €0, charged to the pharmaceutical budget.

It is relevant to mention that both roxadustat and ESAs will be transferred to the intramural budget as of 1 January 2022. From then on, the budget impact analysis will no longer apply.

Pharmaco-economic analysis
Based on the estimated budget impact, the product is exempt from pharmaco-economic analysis.

Advice
The National Health Care Institute advises that you include roxadustat (Evrenzo®) on List 1B, on the basis of the considerations above.

Yours sincerely,

Sjaak Wijma
Chair of the Executive Board