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Minister of Medical Care and Sports
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2021021804

Date 14 June 2021
Subject GVS advice osilodrostat (Isturisa®)

**National Health Care
Institute**
Care I

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Our reference
2021021804

Dear Ms van Ark,

In your letter of 1 December 2020 (CIBG-20-01214), you requested the National Health Care Institute to carry out a substantive review of whether osilodrostat (Isturisa®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed its substantive assessment. The considerations are included in the GVS report attached to this letter.

Isturisa® is available as a film-coated tablet with 1, 5 or 10 mg osilodrostat (as osilodrostat phosphate) and is registered for the treatment of endogenous Cushing syndrome in adults.

The recommended starting dose is 2 mg osilodrostat twice daily. For patients of Asian origin, a reduced starting dose of 1 mg twice daily is recommended. The dose can be titrated gradually based on individual response and tolerability, with the aim of achieving normal cortisol levels. The maximum recommended dose of osilodrostat is 30 mg twice daily.

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

The outcome of the assessment

The National Health Care Institute has concluded that osilodrostat has an equal therapeutic value compared to metyrapon (Metopirone®), pasireotide (Signifor®) and ketoconazole (Ketoconazole HRA) for the treatment of endogenous Cushing syndrome in adults.

Review of interchangeability

The following medical products prescribed for endogenous Cushing syndrome are considered for interchangeability testing: metyrapon, pasireotide and ketoconazole. Pasireotide is not included in the interchangeability test, because pasireotide is not eligible for clustering with oral medication based on the form of administration (subcutaneous/intramuscular injection).

The National Health Care Institute has concluded that osilodrostat is

interchangeable with ketoconazole and metyrapon. These medicinal products are included in cluster OV04CDAO V in the GVS.

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Advice

The National Health Care Institute advises you to include osilodrostat on List 1A in cluster OV04CDAO V. The standard dose can be set at 10 mg per day.

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Yours sincerely,

Sjaak Wijma
Chair of the Executive Board