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Contact
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2023034007

Our reference
2023042057

Date 11 October 2023
Re: GVS advice fenfluramine (Fintepla®)

Dear Mr Kuipers,

This is a corrected version of the letter already sent on August 31, 2023 (reference 2023034007), in which the advice to include the previously concluded financial arrangement for cannabidiol has been added.

In your letter of 30 May 2023 (CIBG-23-05536), you requested the National Health Care Institute to assess the reimbursement application of the medicinal product fenfluramine (Fintepla®) for inclusion in the Medicine Reimbursement System (GVS). The National Health Care Institute has now completed the substantive assessment. The considerations are included in the GVS report attached to this letter.

Fenfluramine is a serotonin-releasing agent, stimulating multiple subtypes of 5-HT receptors by releasing serotonin. It may reduce seizures by acting as an agonist on specific serotonin receptors in the brain. The precise mode of action of fenfluramine in Dravet syndrome and Lennox-Gastaut syndrome is unknown. Each ml contains 2.2 mg of fenfluramine (as fenfluramine hydrochloride). It is available as an oral solution (120 ml or 360 ml bottle, incl. dosing syringes for 3 ml and 6 ml).

Fenfluramine is registered for the treatment of seizures associated with Dravet Syndrome and Lennox-Gastaut Syndrome as an add-on therapy to other anti-epileptic medicines for patients 2 years of age and older. The starting dose (first week) is 0.1 mg/kg body weight taken twice daily. Thereafter, if tolerated, the dose should be increased to the maintenance dose of 0.35 mg/kg twice daily. The maximum recommended dose is 26 mg per day. In combination with stiripentol (for Dravet syndrome only), the starting dose is 0.2 mg/kg body weight twice daily, with a maximal recommended dose of 17 mg per day.

Assessment of interchangeability
Based on the criteria for interchangeability, it can be concluded that fenfluramine is interchangeable with cannabidiol (Epidyolex®), which is also registered as an adjunctive treatment in therapy-resistant Lennox-Gastaut Syndrome or therapy-resistant Dravet Syndrome. Cannabidiol is currently listed on List 1B of the GVS with a reimbursement condition. The standard dose of fenfluramine can be

determined at 16 mg and that of cannabidiol at 700 mg.

National Health Care Institute
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Date
31 August 2023

Our reference
2023034007

Advice
We advise you to include fenfluramine on List 1A of the GVS in a new cluster to be formed with cannabidiol. We would like to point out that a financial arrangement has been concluded for cannabidiol (Epidyolex®) to secure the accessibility and affordability of the healthcare package. We have no insight into the agreements made, but the basic principle when including a treatment with a therapeutic value comparable with that of the standard treatment in the insured package is that the net price of the new treatment should not exceed the net price of the comparative treatment. We, therefore, recommend negotiations for fenfluramine (Fintepla®).

The List 2 condition applicable to cannabidiol also applies to fenfluramine. The wording of item 153 of List 2 in the Rzv can be amended as follows.

153. Cannabidiol and fenfluramine

Condition:

Only for an insured person aged two years and over who use this medicinal product as adjunctive therapy for seizures associated with Lennox-Gastaut syndrome (LGS) or Dravet syndrome (DS). The treatment must be discontinued if the seizure frequency has not decreased by at least 30% after 6 months on the maintenance dosage.
Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board