Zorginstituut Nederland

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Ministry of Health, Welfare and Sport
PO Box 20350
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2022015656

Date 10 May 2022
Re: GVS advice on pitolisant (Ozawade®)

National Health Care Institute
Care
Medicinal Products

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Case number
2019064947

Our reference
2022015656

Your reference
CIBG-21-02768

Your letter of
8 November 2021

Dear Mr Kuipers,

In a letter of 8 November 2021 (CIBG-21-02768), your predecessor requested the National Health Care Institute to carry out a substantive review of whether pitolisant (Ozawade®) is interchangeable with a product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has completed this assessment.

Pitolisant with the brand name Ozawade® is registered to increase wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP), or who do not tolerate this therapy.

The National Health Care Institute advises you not to include pitolisant (Ozawade®) in the GVS for this indication.

Background
Pitolisant with the Wakix® brand name has already been registered and is being reimbursed for the treatment of adult patients with narcolepsy with and without cataplexy. Both Wakix® and Ozawade® are available as film-coated tablets of 4.5 mg and 18 mg.

The marketing authorisation holder is requesting inclusion of Ozawade® on List 1B of the Health Insurance Regulation for the indication: to increase wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP), or who do not tolerate this therapy.

Weighting of therapeutic value
The effectiveness of pitolisant in adult patients with OSA whose EDS has not been satisfactorily treated with a primary OSA therapy, such as CPAP, or who do not tolerate this therapy has been examined in one randomized comparative study (the HAROSA I study). The results of the HAROSA I study show that pitolisant is likely to have a clinically relevant effect on the subjective outcome parameter

Epworth Sleepiness Scale (ESS), but not a clinically relevant effect on the objective OSLER test. According to the National Health Care Institute, the effectiveness of medicinal products for sleep disorders must be determined on the basis of both a subjective outcome parameter and an objective outcome parameter. Thus, the HAROSA I study only shows an effect on the subjective outcome parameter ESS score. In addition, no clinically relevant effect on the quality of life of these patients is observed. The available data, although sufficient for market registration, does not permit a positive assessment for inclusion in the insured package.

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Advice
The National Health Care Institute has concluded that pitolisant, to increase wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP), or who do not tolerate this therapy, does not meet the established medical science and medical practice. For that reason, the National Health Care Institute advises that pitolisant should not be included in the Medicine Reimbursement System for this indication.

Given that pitolisant under the brand name (Wakix®) is already included in the GVS, the National Health Care Institute recommends that the following List 2 conditions are applied to pitolisant:
Only for an insured person with narcolepsy.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board