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Contact
Ms M.J.S. de Vries

2022045178

Date 23 December 2022
Subject GVS advice solriamfetol (Sunosi®)

Our reference
2022045178

Dear Mr Kuipers,

In your letter of 2 August 2022 (CIBG-22-04193), you asked the National Health Care Institute to assess whether the medicinal product solriamfetol (Sunosi®) is interchangeable with another product that is included in the Medicine Reimbursement System (GVS). The National Health Care Institute, advised by the Scientific Advisory Board (WAR), has now completed this assessment. The considerations are included in the GVS report attached to this letter.

Background
Solriamfetol is indicated to improve wakefulness and reduce excessive daytime sleepiness in adult patients with narcolepsy (with or without cataplexy) or obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP). Solriamfetol is available as 75 mg and 150 mg film-coated tablets. For narcolepsy, the recommended starting dose is 75 mg once daily, upon awakening; a starting dose of 150 mg may be considered. For OSA, the recommended starting dose is 37.5 mg once daily upon awakening. Depending on clinical response, the dose can be titrated, with a recommended maximum daily dose of 150 mg once daily.

The marketing authorisation holder is asking that the registered indications be included on List 1A of the Healthcare Insurance Regulations.

Assessment of interchangeability
To determine the place of a medicinal product in the GVS, the product's interchangeability with medicinal products already included in the GVS must first be assessed.

On the basis of the criteria for interchangeability, the National Health Care Institute has concluded that solriamfetol and pitolisant (Wakix®) are interchangeable.

Assessment of therapeutic value
Narcolepsy
Solriamfetol meets the established medical science and medical practice for the treatment of excessive daytime sleepiness and to improve wakefulness in adult

patients with narcolepsy (with or without cataplexy). Based on the data, the National Health Care Institute concludes that the medicinal product has an equal value compared to pitolisant and modafinil.

OSA
Solriamfetol meets the established medical science and medical practice for the treatment of excessive daytime sleepiness and to improve wakefulness 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). Based on the data, the National Health Care Institute concludes that the medicinal product has an added therapeutic value compared to standard care. Treatment of these patients with solriamfetol can be considered, provided that other causes for EDS are excluded by a medical specialist/somnologist.

Budget impact analysis
Since no medical treatment is currently available for OSA, the inclusion of solriamfetol on the GVS List 1A will be accompanied by additional costs charged against the pharmaceutical budget of €9 million, taking into account assumptions about the patient numbers, market penetration and dose used.

Advice
The National Health Care Institute advises you to place solriamfetol (Sunosi®) on List 1A of the Health Insurance Regulation in a newly to be formed cluster with pitolisant (Wakix®). The standard dose is 150 mg per day for solriamfetol and 18 mg per day for pitolisant. The National Health Care Institute recommends that the following reimbursement condition be included for solriamfetol:

Solriamfetol condition:
Only for insured persons aged 18 or older, for the treatment of excessive daytime sleepiness (EDS) and the improvement of wakefulness in patients

1. *with narcolepsy or*
2. *with obstructive sleep apnoea (OSA) whose EDS, despite optimal OSA therapy such as continuous positive airway pressure (CPAP)*, a *mandibular repositioning device (MRA) and sleep position training (SPT), persists, and*
    a. *have been referred to a medical specialist and treated in accordance with the protocol accepted by the relevant physicians' assocations, and*
    b. *other causes of EDS have been excluded by a medical specialist/somnologist.*

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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