



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
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2025026177

Date 5 November 2025
Re: GVS advice pitolisant (Ozawade®) for sleep apnoea (reassessment)

**National Health Care
Institute**

Research, Development and
Medicinal Products
Medicinal Products Team

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Contact

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Our reference

2025026177

Dear Mr Bruijn,

The National Health Care Institute advises you on the expansion of the additional condition of pitolisant (Ozawade®) for the treatment of patients with excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea. This advice was prompted by your request in the letter of 15 July 2025 (CIBG-25-08443).

People with obstructive sleep apnoea stop breathing several times a night, which disturbs their sleep pattern. As a result, patients can often experience sleepiness, fatigue and irritability during the day. This has a particular impact on the daily functioning and quality of life of patients. In the Netherlands, there are approximately 500,000 patients with excessive daytime sleepiness due to obstructive sleep apnoea. These patients are treated initially with non-medical treatments, such as (combined) lifestyle interventions and continuous positive airway pressure (CPAP) therapy. Patients who continue to have symptoms despite these treatments can receive medication. At the moment, solriamfetol is the only medicinal product reimbursed for this.

Licensed indication(s)

Pitolisant (Ozawade®) is indicated to increase alertness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) where EDS has not been adequately treated with a primary OSA therapy, such as continuous positive airway pressure (CPAP), or who do not tolerate this therapy. The medicinal product is available in 4.5 mg and 18 mg tablets

Pitolisant is also registered for patients with narcolepsy under the brand name Wakix®. For this indication, pitolisant is already being reimbursed and included in the Medicine Reimbursement System (GVS) on list 1A in cluster 0N06BACO with solriamfetol (Sunosi®). The current reimbursement condition for pitolisant is as follows:

Only for an insured person with narcolepsy.

Claim by the marketing authorisation holder

Pitolisant (Ozawade®) has an equivalent value compared to solriamfetol (Sunosi®) for the registered indication.

The marketing authorisation holder is requesting an expansion of the reimbursement conditions for pitolisant.

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Advisory report

The National Health Care Institute advises you to amend the additional conditions of pitolisant, in line with the additional conditions of solriamfetol, in List 2 of the GVS as follows:

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Only for the treatment of excessive daytime sleepiness (EDS) and the improvement of the degree of wakefulness in a patient

1. *with narcolepsy or*
2. *diagnosed with obstructive sleep apnoea (OSA), and*
 1. *with residual symptoms of excessive daytime sleepiness (EDS) requiring treatment to improve the degree of wakefulness and*
 2. *receiving optimal OSA therapy, and*
 3. *for whom other causes for EDS are excluded.*

The initial prescription should be prescribed at an SVNL-accredited sleep centre and by a specialist physician with specific expertise in sleep-wake disorders. Twelve months after the start of the pitolisant treatment, the SVNL-accredited sleep centre should assess whether it is appropriate to continue the use of pitolisant.

We have explained below how we reached this advisory report.

Substantive assessment

Therapeutic value

In 2022, the National Health Care Institute concluded that pitolisant did not meet the established medical science and medical practice. The data available at the time from the HAROSA I study showed that pitolisant had an effect on reducing daytime sleepiness, but that there did not appear to be a clinically relevant effect on improving alertness and quality of life compared to placebo. In the meantime, new study data from the randomised, placebo-controlled HAROSA III study and a meta-analysis of the HAROSA I and III studies have become available. These have been assessed by the National Health Care Institute.

The National Health Care Institute now concludes, based on an indirect comparison, that pitolisant has an equal value in the said indication compared to standard treatment with solriamfetol. Both medicinal products have a similar effect in reducing daytime sleepiness and improving alertness. Both pitolisant and solriamfetol also seem to have some effect on the quality of life, although the evidence for this is limited. Furthermore, there do not appear to be any relevant differences in adverse effects between pitolisant and solriamfetol.

Budget impact analysis

Due to the equal value and the fact that pitolisant is already clustered on List 1A with solriamfetol, which can already be used for this indication, the adjustment of the additional condition is expected to be budget-neutral. The professional group has indicated that the prescription of solriamfetol is very limited. There are no reasons to believe that this number will increase as a result of the introduction of pitolisant.

Should you need any further information, please do not hesitate to contact us.

The assessment report is attached as an annex (pharmacotherapeutic report).

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

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