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Case number
2023034813

Our reference
2024003286

Your reference
3637932-1051210-GMT

Your letter of
17 August 2023

Date 16 February 2024
Re: Request additional advice Sunosi solriamfetol List 2 for OSA

Dear Ms Dijkstra,

On 16 August 2023, following our advice on the inclusion of solriamfetol (Sunosi®) in the GVS, your predecessor requested that the List 2 indication conditions for the indication OSA (obstructive sleep apnoea) be refined before deciding on the inclusion of this indication in the GVS.

In the meantime, we have discussed, with representatives from the physician's association, patients and health insurers, a tightening of the conditions mentioned, and I would like to inform you about the outcome and the subsequent additional advice.

Background
On 23 December 2022, the National Health Care Institute advised your predecessor to include the medicinal product solriamfetol (Sunosi®) in List 1A of the GVS for the treatment of EDS (excessive daytime sleepiness) in patients with narcolepsy and patients with OSA under the following reimbursement conditions:

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) with whom 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. who have been referred to a medical specialist and treated in accordance with the protocol accepted by the relevant professional groups, and
b. where other causes of EDS have been excluded by a medical specialist/somnologist.

Solriamfetol was then included by your predecessor in List 1A of the Rzv as of 1 March 2023, but only for the indication narcolepsy (List 2 No. 156).
Before deciding on the reimbursement of solriamfetol for patients with OSA, your predecessor asked the National Health Care Institute to formulate, in consultation with the stakeholders, better verifiable criteria and/or agreements for appropriate use for the already used optimal OSA therapy. This request is based on the fact

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that there is a risk of inappropriate use, where the group of potential users of solriamfetol for OSA is significant.

Considerations for tightened indication conditions
In coordination with representatives from the physician's association, patients and health insurers, we recommend that an additional reimbursement condition be included with regard to the centres where the initial prescription of solriamfetol must be prescribed, i.e. a sleep centre accredited by the Netherlands Association for Sleep Medicine (SVNL). This is verifiable and contributes to appropriate use, as these centres have the right expertise to ensure that optimal OSA therapy is initiated and other causes of EDS are excluded.
In this respect, we advise that the reimbursement condition should also include an evaluation of the treatment after 12 months in the SVNL-accredited sleep centre. This will further promote appropriate use.

In addition, we recommend that the examples of *'optimal OSA therapy' and 'other causes of EDS'* be removed from the above condition. Although it is technically possible to establish objectively verifiable criteria for previously initiated diagnostics and treatment, we believe that these aspects are sufficiently ensured by the condition of prescribing the initial prescription at an SVNL-accredited sleep centre. This is based on the conviction that the accredited sleep centre can be expected to monitor compliance with these indication conditions and thus to ensure appropriate use.

We also advise to remove the criterion *'has been referred to a medical specialist and treated in accordance with the protocol accepted by the relevant physicians' associations*. In our opinion, this element is sufficiently addressed in the tightened indication criteria by the proposed criterion *'who have received optimal OSA therapy and for whom other causes for EDS have been excluded'*.

Finally, the consulted parties were in favour of including in the condition the expertise required from the prescriber for appropriate use: *a specialist physician with specific expertise in sleep-wake disorders*. This expertise is, according to the parties, necessary, among other things, for ensuring '*optimal OSA therapy*' and excluding '*other causes for EDS*'. Although this criterion is not objectively verifiable, it does clarify the expertise that stakeholders consider necessary to secure appropriate use. It is up to the SVNL-accredited sleep centre to apply this condition in practice.

Advice
Based on the above considerations, we advise the following refined reimbursement conditions for solriamfetol for the indication OSA. We assume that this advice, in consultation with the stakeholders, strikes an optimal balance between objectivity/verifiability on the one hand and effectiveness in securing appropriate use on the other.

<u>Conditions of solriamfetol for OSA</u>
Only for an insured person who meets the following criteria:
- *Diagnosed with OSA*
- *Aged 18 years or older*
- *With residual symptoms of excessive daytime sleepiness (EDS) requiring treatment to improve the rate of wakefulness*

- *Who is receiving optimal OSA therapy and for whom other causes for EDS have been 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. 12 months after the start of the solriamfetol treatment, the SVNL-accredited sleep centre should assess whether it is appropriate to continue the use of solriamfetol.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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