Pitolisant (daytime sleepiness in obstructive sleep apnoea, after prior therapy)

Resolution of: 21 April 2022 valid until: unlimited
Entry into force on: 21 April 2022
Federal Gazette, BAnz AT 07 07 2022 B2

Therapeutic indication (according to the marketing authorisation of 22 July 2021):

Ozawade is indicated to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adult patients with obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP).

Therapeutic indication of the resolution (resolution of 21 April 2022):

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Adults with excessive daytime sleepiness (EDS) due to obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP)

Appropriate comparator therapy:

An optimised standard therapy for underlying obstructive sleep apnoea.

Extent and probability of the additional benefit of pitolisant compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adults with excessive daytime sleepiness (EDS) due to obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP)

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	∅	No data available.
Side effects	n.a.	There are no assessable data.

Explanations:
↑: statistically significant and relevant positive effect with low/unclear reliability of data
↓: statistically significant and relevant negative effect with low/unclear reliability of data
↑↑: statistically significant and relevant positive effect with high reliability of data
↓↓: statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: There are no usable data for the benefit assessment.
n.a.: not assessable

2. Number of patients or demarcation of patient groups eligible for treatment

Adults with excessive daytime sleepiness (EDS) due to obstructive sleep apnoea (OSA) whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP)

approx. 200,000 – 400,000 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Ozawade (active ingredient: pitolisant) at the following publicly accessible link (last access: 4 April 2022):

https://www.ema.europa.eu/en/documents/product-information/ozawade-epar-product-information_en.pdf

Treatment with pitolisant should only be initiated and monitored by doctors experienced in treating patients with obstructive sleep apnoea.

4. Treatment costs

Annual treatment costs:

Adults with excessive daytime sleepiness (EDS) due to sleep apnoea whose EDS has not been satisfactorily treated by, or who have not tolerated, OSA primary therapy, such as continuous positive airway pressure (CPAP) ventilation

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Pitolisant	€ 4,807.17 – € 9,768.62
+ optimised standard therapy	Different from patient to patient
Appropriate comparator therapy:	
Optimised standard therapy	Different from patient to patient

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 April 2022)

Costs for additionally required SHI services: not applicable