NHS
Pan Mersey
Area Prescribing Committee

PITOLISANT HYDROCHLORIDE film-coated tablets (Ozawade®) for excessive daytime sleepiness caused by obstructive sleep apnoea

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of PITOLISANT HYDROCHLORIDE film-coated tablets (Ozawade®) for treating excessive daytime sleepiness caused by obstructive sleep apnoea, in accordance with NICE TA776.

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NICE technology appraisal (TA) 776 (09 March 2022) does not recommend pitolisant hydrochloride (Ozawade®), within its marketing authorisation, to improve wakefulness and reduce excessive daytime sleepiness (EDS) in adults with obstructive sleep apnoea (OSA) whose sleepiness has not been satisfactorily treated by primary obstructive sleep apnoea therapy such as continuous positive airway pressure (CPAP), or who cannot tolerate it.[1]

NICE states that EDS caused by OSA is usually treated with primary obstructive sleep apnoea therapy such as CPAP or mandibular advancement devices. Clinical trial evidence suggests that pitolisant hydrochloride reduces EDS, with and without CPAP, but there is uncertainty about the evidence because of the way the trials were done. It is also uncertain how much pitolisant hydrochloride improves quality of life because of how it was measured in the trials. Because of the uncertainty in the clinical evidence and economic model, the cost-effectiveness estimates are also uncertain. They are likely to be higher than what NICE normally considers an acceptable use of NHS resources, and so pitolisant hydrochloride is not recommended for treating EDS caused by OSA.[1]

Clinicians should continue to follow local pathways for the treatment of OSA and the recommendations in NICE guideline NG202: Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s (20 August 2021).

See separate red statement for the Pan Mersey APC recommendation for prescribing of pitolisant (Wakix®) for the treatment of narcolepsy with or without cataplexy.

Ozawade® is the brand of pitolisant licensed to improve EDS in adults with OSA. The Wakix® brand of pitolisant is not licensed for this indication and should not be used off-label to treat EDS caused by OSA.

References

1. National Institute for Health and Care Excellence. Technology Appraisal 776: Pitolisant hydrochloride for treating excessive daytime sleepiness caused by obstructive sleep apnoea, 09 March 2022. Accessed 15 March 2022.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.