NICE UPDATE

NICE expands access to ONTOZRY® with approval for secondary care initiation[1]

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Adverse events and product complaints should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard for the UK. Adverse events and product complaints should also be reported to Angelini Pharma on (UK) +44 2034889643 or UKIReporting@angelinipharma.com

Indication for United Kingdom: ONTOZRY® is indicated for the adjunctive treatment of focal–onset seizures with or without secondary generalisation in adult patients with epilepsy who have not been adequately controlled despite treatment with at least 2 anti–epileptic medicinal products.[2]

Prescribing information and adverse event reporting information can be found by scanning the QR code or click here if you are viewing on a digital device.

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THINK SEIZURE FREEDOM

Every Seizure Matters

56% OF PATIENTS

achieved a ›50% reduction in seizure frequency with **ONTOZRY® 200 mg/day vs. 26% of patients** with placebo when added to SOC* over 12 weeks of fixed dose, double-blind treatment.†[2,3]

21% OF PATIENTS

achieved seizure freedom (100% reduction in seizure frequency) with **ONTOZRY® 400 mg/day vs. 1% of patients** with placebo when added to SOC.*‡[2,3]

ONTOZRY® IS GENERALLY WELL TOLERATED,

with a dose-dependent treatment-emergent adverse event profile.[2]

The most common adverse reactions are of mild-to-moderate severity: somnolence, coordination and gait abnormalities, and headache.§[2,4]

* In the randomly assigned population at baseline, the median number of previous anti-seizure medications (ASMs) taken at any time before the start of the study was 3 (range 2–4); these might or might not have been ongoing during the study. 74% of patients (n=322/437) were taking 2–3 concomitant ASMs during the study.[3]

† Responder rates for seizure frequency reductions of ›50% from baseline during the maintenance phase were 26% (n=26/102) for the placebo group compared with 56% (n=55/98; OR 3.74 [95% CI 2.06–6.80]; p<0.0001) for the ONTOZRY® 200 mg dose group.[3]

‡ Responder rates for seizure frequency reductions of 100% during the 12-week maintenance phase were 1% (n=1/102) for the placebo group, 4% (n=4/102) for the ONTOZRY® 100 mg group, 11% (n=11/98; p=0.0022) for the ONTOZRY® 200 mg group and 21% (n=20/95; p<0.0001) for the ONTOZRY® 400 mg group.[3]

§ Grouped terms: Somnolence: somnolence, fatigue, sedation and hypersomnia; Coordination and gait abnormalities: dizziness, vertigo, balance disorder, ataxia, gait disturbance and abnormal coordination.[2]

Following a review by NICE, ONTOZRY® can now be initiated in non-tertiary settings, providing more flexibility in patient management[1]

THE UPDATED NICE TECHNOLOGY APPRAISAL FOR ONTOZRY®

Cenobamate is recommended as an option as an add-on treatment for focal onset seizures with or without secondary generalised seizures in adults with drug-resistant epilepsy that has not been adequately controlled with at least 2 antiseizure medicines.[1,2]

It is recommended only as a second-line add-on treatment if:[1]

- it is used after at least 1 first-line add-on treatment has not controlled seizures, and other first-line add-on treatments are contraindicated or not tolerated, and
- treatment is started by a healthcare professional with expertise in epilepsy, after which treatment can be continued in primary care

The full NICE guidance is available at: www.nice.org.uk/guidance/ta753

This update from NICE is based on a review of current clinical practice and experience with ONTOZRY®, considering its clinical and cost-effectiveness, safety profile, and the need to **improve patient access.**[1] **As a result, ONTOZRY® can now be initiated in secondary care and then transferred to primary care.**

THIS CHANGE IS EXPECTED TO:[1,5]

Decrease delays in initiating treatment

Reduce potential health inequalities

Increased equitable access to treatment

References:

1. NICE Technology appraisal guidance. TA753. Cenobamate for treating focal onset seizures in epilepsy. Published: 15 December 2021. Last updated: 6 May 2025. Available from: www.nice.org.uk/guidance/ta753 (accessed May 2025).
2. ONTOZRY® Summary of Product Characteristics. United Kingdom and European Union.
3. Krauss GL, et al. Lancet Neurology. 2020;19(1):38–48.
4. Sperling MR, et al. Epilepsia. 2020;61:1099–108.
5. Pinho-Gomes AC, et al. Lancet Neurol. 2022 Jun;21(6):504-505.

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