



AMANTADINE ER
Gocovri, Osmolex ER (amantadine ER)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Gocovri, an extended release amantadine, is indicated for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy with or without concomitant dopaminergic medications. Osmolex ER is another formulation of extended release amantadine, and similarly can be used to treat Parkinson's disease or drug induced extrapyramidal reactions in adult patients. Motor problems and dyskinesia are significant complications of levodopa therapy used to treat patients with Parkinson's disease (PD) and increases in frequency the longer patients are treated with levodopa for Parkinson's disease. Currently, treatment of dyskinesia related to Parkinson's disease includes adjusting levodopa doses and dosing schedule, adding additional medications to treat Parkinson's disease (thereby allowing for a decrease in the dose needed of levodopa), and lastly adding a medication to specifically treat dyskinesia (amantadine) (1-3).

Regulatory Status

FDA approved indication(s):

Gocovri is indicateds: (1)

- For the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications
- As adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes

Osmolex ER is indicated for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions in adult patients (2).

Adverse reactions reported include: falling asleep during activities of daily living and somnolence, suicidality and depression, hallucinations/psychotic behavior, dizziness and orthostatic hypotension, and impulse control/compulsive behaviors. Additionally, the use of these medication are contraindicated in patient with end-stage renal disease (eGFR below 15 mL/min/1.73 m²) as this medication is primarily excreted renally (1-2).

Safety and effectiveness in pediatric patients have not been established (1-2).



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Summary

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Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Gocovri and Osmolex ER while maintaining optimal therapeutic outcomes.

References

1. Gocovri [package insert]. Emeryville, CA: Adamas Pharma, LLC.; January 2021.
2. Osmolex ER [package insert]. Bridgewater, NJ: Vertical Pharmaceuticals LLC.; March 2021.
3. Daniel Tarsy et al. Medical management of motor fluctuations and dyskinesia in Parkinson disease. UpToDate. September 30, 2021.