

## STEP THERAPY POLICY

- POLICY:** Antiepileptics – Oxtellar XR, Trileptal Step Therapy Policy
- Trileptal® (oxcarbazepine tablets and oral suspension – Novartis, generics)
  - Oxtellar XR® (oxcarbazepine extended-release tablets – Supernus)

**REVIEW DATE:** 03/24/2021

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### OVERVIEW

Oxcarbazepine tablets and oral suspension are indicated for use as monotherapy or adjunctive therapy in the treatment of **partial seizures** in adults, as monotherapy in the treatment of partial seizures in patients  $\geq 4$  years of age with epilepsy, and as adjunctive therapy in the treatment of partial seizures in patients  $\geq 2$  years of age.<sup>1</sup> Oxtellar XR is indicated for the treatment of partial seizures in patients  $\geq 6$  years of age.<sup>2</sup>

Oxcarbazepine is an antiepileptic drug (AED) available in immediate- and extended-release formulations.<sup>1,2</sup> Following oral administration, oxcarbazepine is absorbed and extensively metabolized to its pharmacologically active 10-monohydroxy metabolite (MHD), which is responsible for most antiepileptic activity.<sup>1,2</sup> Oxtellar XR administered as a once daily dose is not bioequivalent to the same total dose of the immediate-release formulation given twice daily at steady state.<sup>2</sup>

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

**Automation:** A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

**Step 1:** generic oxcarbazepine tablets, generic oxcarbazepine oral suspension

**Step 2:** Oxtellar XR, Trileptal tablets and oral suspension

### CRITERIA

1. If a patient has tried one Step 1 Product, approve a Step 2 Product.
2. No other exceptions are recommended.

### REFERENCES

1. Trileptal® tablets and oral suspension [prescribing information]. East Hanover, NJ: Novartis; January 2019.
2. Oxtellar XR® extended-release tablets [prescribing information]. Rockville, MD: Supernus Pharmaceuticals, Inc.; December 2018.