Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 11, 2024

Cobenfy™ (xanomeline and trospium chloride)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Patient must have a diagnosis of schizophrenia; **AND**
- Patient must have a trial and failure of a preferred medication to treat schizophrenia including a trial of Vraylar (cariprazine) **AND** Caplyta (lumateperone tosylate) with a minimum 30-day treatment period; **AND**
- Patient must have baseline tests including heart rate, liver enzymes, and bilirubin prior to starting treatment.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of positive clinical response; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g. urinary retention, angioedema, increased heart rate); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 50 mg/20 mg, 100 mg/20 mg, 125 mg/30 mg capsules (xanomeline/trospium chloride).
- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/