Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	October 11, 2024 March 18, 2025, April 4, 2025

Cobenfy™ (xanomeline and trospium chloride)

LENGTH OF AUTHORIZATION: Up to one year

THIS MEDICATION MAY RECEIVE APPROVAL UNDER TWO CRITERIA

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.

ALTERNATE REVIEW CRITERIA

- Clinical documentation of medical necessity because:
    - The patient has a diagnosis of schizophrenia, schizotypal or delusional disorder and meets the following:
        - The drug product or medication of a similar drug class is prescribed for the treatment of schizophrenia or schizotypal or delusional disorders; **-AND-**
        - Prior authorization has been granted previously for the prescribed drug; **-AND-**
        - The medication was dispensed to the patient during the previous 12 months

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Documentation of improved 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/