UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2360-1
Program	Prior Authorization/Medical Necessity
Medication	Cobenfy™ (xanomeline and trospium chloride)
P&T Approval Date	1/2025
Effective Date	4/1/2025

1. Background:

Cobenfy is FDA approved for the treatment of schizophrenia. This program requires a member to try three atypical antipsychotics before providing coverage for Cobenfy.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Cobenfy** will be approved based on **ONE** of the following criteria:

   a. **BOTH** of the following:

      1) Diagnosis of schizophrenia

      -AND-

      2) History of failure, contraindication, or intolerance to **three** of the following (please document drug, date and duration of trial):

         (a) aripiprazole (generic Abilify)
         (b) olanzapine (generic Zyprexa)
         (c) quetiapine IR or ER (generic Seroquel or Seroquel XR)
         (d) risperidone (generic Risperdal)
         (e) ziprasidone (generic Geodon)

   -OR-

   b. Treatment with Cobenfy was initiated at a recent behavioral inpatient admission (discharge within the past 3 months) and the member is currently stable on therapy. (Please document date of discharge from inpatient admission).

   -OR-

   c. Member is new to the plan and currently stabilized on Cobenfy (as evidenced by coverage effective date of less than or equal to 120 days)

Authorization will be issued for 12 months.

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B. Reauthorization

1. **Cobenfy** will be approved for continuation of therapy based on the following criterion:

   a. Documentation of a positive clinical response to therapy

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and Prior Authorization/Notification may also be in place.

4. References:

1. Cobenfy [package insert]. Princeton, NJ: E.R. Squibb & Sons, LLC. September 2024.
2. American Psychiatric Association. Practice Guideline for the Treatment of Patients with Schizophrenia Third Edition. Available at: https://psychiatryonline.org/doi/10.1176/appi.books.9780890424841

Program	Prior Authorization/Medical Necessity - Cobenfy
Change Control	
1/2025	New program.