

Cobenfy Prior Authorization

Drug(s) Applied:	Cobenfy (xanomeline tartrate - trospium chloride)
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Criteria:

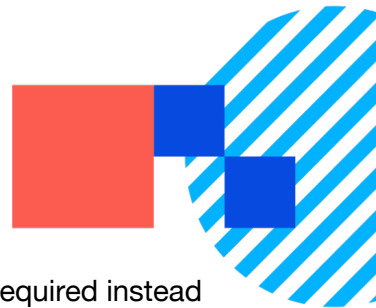
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Approval Criteria

A. **Schizophrenia** as indicated by chart notes within past 90 days

1. Patient's age falls between 18 - 65 years of age **and**
2. Trial and failure of at least 3 months of the following agents*:
 - a) Clozapine unless contraindicated or clinical adverse effects are reported **and**
 - b) An atypical antipsychotic (i.e., maximally tolerated olanzapine, aripiprazole, risperidone) unless contraindicated or clinical adverse effects are reported **and**
3. Schizophrenia is poorly controlled, as documented by one of the following:
 - a) Patient is currently in episode of psychosis at time of visit related to chart notes **or**
 - b) Acute exacerbation requiring hospitalization within the past 2 months **or**
 - c) Relapse requiring hospitalization within the past 2 months, **or**
 - d) Baseline Positive & Negative Syndrome Scale (PANSS) score that falls into the "markedly ill" category (i.e. PANSS total score of at least 95) **and**
4. Documentation of baseline liver function test (LFT) results, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and bilirubin within 1 month prior to starting the requested drug **and**
5. If patient has gastrointestinal obstructive disorders, outside of gastric retention, then the prescriber has provided either clinical justification for appropriate use or attestation that the agent's benefits outweigh the risks **and**
6. Chart notes do not indicate that the patient has **any** of the following:
 - a) Urinary retention
 - b) Moderate to severe hepatic impairment (Child-Pugh Class B or C)
 - c) Gastric retention
 - d) Untreated narrow-angle glaucoma
 - e) Moderate to severe renal impairment (eGFR <60 mL/min) **and**
7. Patient will not use the requested agent with another schizophrenic drug **and**
8. Prescriber is a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO), in Psychiatry and certified with the American Board of Psychiatry and Neurology

Approval Duration: 3 months



*For Texas Fully-Insured members, a trial or failure of one antipsychotic agent is required instead

II. Continued Therapy Approval

A. **Schizophrenia** as indicated by chart notes within past 12 months

1. Patient's age falls between 18 - 65 years of age **and**
2. Patient has been previously approved for the requested agent through the plan's Prior Authorization process or meets the initial therapy criteria above **and**
3. Patient has documented clinical benefit with agent (i.e., decreased relapses and/or acute psychosis episodes, improvement of baseline PANSS score) **and**
4. Patient has had updated liver enzyme & bilirubin and heart rate assessments completed since beginning therapy with the requested agent **and**
5. Chart notes do not indicate that the patient has any of the following:
 - a) Urinary retention
 - b) Moderate to severe hepatic impairment (Child-Pugh Class B or C)
 - c) Gastric retention
 - d) Untreated narrow-angle glaucoma
 - e) Moderate to severe renal impairment (eGFR <60 mL/min) **and**
6. Prescriber is a Doctor of Medicine (MD) or Doctor of Osteopathic Medicine (DO), in Psychiatry and certified with the American Board of Psychiatry and Neurology

Approval Duration: 12 months

Policy Owned by: Curative PBM team