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Cobenfy Prior Authorization

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

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

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*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