

# Trospium-Xanomeline (COBENFY) Criteria for Use November 2024

VA Pharmacy Benefits Management Services, VA National Formulary Committee

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information.

## Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive trospium/xanomeline

- Moderate or severe renal impairment (eGFR < 60 ml/min)
- Mild (Child-Pugh Class A), moderate (Child-Pugh Class B), or severe (Child-Pugh Class C) hepatic impairment
- Untreated narrow-angle glaucoma
- Active biliary disease (e.g., symptomatic gallstones)
- Uncontrolled hypertension
- Concomitant condition with risk of urinary retention (e.g., neurogenic bladder, benign prostatic hyperplasia, bladder outlet obstruction, diabetic cystopathy) ^1
- Concomitant condition with risk of bowel obstruction (e.g., gastric retention, inflammatory bowel disease, intestinal atony, neurogenic bowel) ^1

## Inclusion Criteria^2

ALL of the following must be fulfilled to meet criteria.

- Diagnosis of schizophrenia
- Prescriber is a VA/VA Community Care psychiatrist
- Insufficient response or intolerance to trials of three of the following antipsychotics categories: partial dopamine agonism (e.g., aripiprazole), low dopamine affinity (e.g., olanzapine) and moderate to high dopamine affinity (e.g., risperidone) ^3, ^4
- Inadequate response, intolerance, or patient determined not to be a candidate for clozapine

1. Tropium has anticholinergic effects and can increase risk of urinary and gastric retention.
2. Liver enzymes, bilirubin, and heart rate should be assessed prior to initiation and as clinically indicated during treatment
3. Adherent to, and achieved a target dose consistent with the effective doses specified in the FDA label for at least 6 weeks
4. If intolerance is due to metabolic effects, efforts to mitigate these effects have been attempted with an adequate trial of at least 2 of the following:
  - MOVE program participation
  - Metformin
  - Topiramate

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