

## Xanomeline-trospium (COBENFY) Safety Edit

### Goal(s):

- Promote safe use of xanomeline-trospium in combination with other mental health drugs for schizophrenia.

### Length of Authorization:

Up to 12 months

### Requires PA:

- Xanomeline-trospium
- Auto-approval requests for people with a claim for xanomeline-trospium in the last 6 months

**Covered Populations:** FFS and CCO enrolled patients (pharmacy claims only).

### Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is xanomeline-trospium prescribed for an FDA-approved indication?	<b>Yes:</b> Go to #3	<b>No:</b> Pass to RPh. Deny; medical appropriateness
3. Is the intent to prescribe xanomeline-trospium in conjunction with another antipsychotic medication?	<b>Yes:</b> Go to #4	<b>No:</b> Go to #5
4. Is there documentation or provider attestation that the benefits of therapy (e.g. symptom improvement, social function, number of hospitalizations, etc) outweigh potential risks of combination treatment (e.g. hepatic impairment, biliary disease, gastrointestinal and anticholinergic effects, etc)?	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness

## Approval Criteria

<p>5. Is there documentation or provider attestation that the patient does not have any of the following conditions?</p> <ul style="list-style-type: none"><li>• Concurrent antidepressant that inhibits CYP2D6 (e.g., bupropion, fluoxetine, paroxetine, or duloxetine)</li><li>• Urinary retention (e.g., benign prostatic hyperplasia, diabetic cystopathy)</li><li>• Untreated narrow-angle glaucoma</li><li>• Impaired gastric motility (e.g., gastrointestinal obstructive disorders)</li><li>• Mild, moderate or severe hepatic impairment, biliary disease, or elevated liver function tests</li><li>• Moderate or severe renal impairment or estimated glomerular filtration rate (eGFR) &lt;60 mL/min</li></ul>	<p><b>Yes:</b> Approve for 12 months</p>	<p><b>No:</b> Pass to RPh. Deny; medical appropriateness</p>
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*P&T/DUR Review: 8/25; 2/25 (SS)  
Implementation: 3/10/25*