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Prior Authorization and Appeals Guide

A resource for navigating the access journey for COBENFY

This guide is designed to provide information about the access process for COBENFY (xanomeline and trospium chloride) for adult patients with schizophrenia.

INDICATION

COBENFY™ (xanomeline and trospium chloride) is indicated for the treatment of schizophrenia in adults.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

COBENFY is contraindicated in patients with:

- urinary retention
- moderate (Child-Pugh Class B) or severe (Child-Pugh Class C) hepatic impairment
- gastric retention
- history of hypersensitivity to COBENFY or trospium chloride. Angioedema has been reported with COBENFY and trospium chloride.
- untreated narrow-angle glaucoma

Please see additional Important Safety Information throughout and U.S. Full Prescribing Information, including Patient Information, here.

Submitting a Prior Authorization (PA) for COBENFY

The CoverMyMeds® portal serves as central location to manage and track your patients' access to COBENFY.

Contact CoverMyMeds® for help with PAs and Appeals

The CoverMyMeds® portal:

1. **Automates the PA processes** for all health plans, providing insurance plan-specific forms and information for submissions
2. **Offers a** system for all submitted requests
3. **Facilitates and communicates** health plan determinations to your office and the designated pharmacy

Steps to submit a PA request

1. **Visit** go.covermymeds.com/provider
2. **Complete and submit the PA request form**
3. **Attach all necessary documentation**

Initiate, transmit, manage, and track the status of PA requests for your commercially insured, Medicare, and Medicaid patients.

The information provided in this Prior Authorization and Appeals Guide and template letters is for informational purposes for patients who have been prescribed COBENFY. These are not intended to substitute for a prescriber's independent clinical decision-making.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS

Risk of Urinary Retention: COBENFY can cause urinary retention. Geriatric patients and patients with clinically significant bladder outlet obstruction and incomplete bladder emptying (e.g., patients with benign prostatic hyperplasia (BPH), diabetic cystopathy) may be at increased risk of urinary retention.

COBENFY is contraindicated in patients with pre-existing urinary retention and is not recommended in patients with moderate or severe renal impairment.

In patients taking COBENFY, monitor for symptoms of urinary retention, including urinary hesitancy, weak stream, incomplete bladder emptying, and dysuria. Instruct patients to be aware of the risk and promptly report symptoms of urinary retention to their healthcare provider. Urinary retention is a known risk factor for urinary tract infections. In patients with symptoms of urinary retention, consider reducing the dose of COBENFY, discontinuing COBENFY, or referring patients for urologic evaluation as clinically indicated.

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covermymeds®

If a PA for COBENFY is denied, CoverMyMeds® can help you navigate the appeal process, from initiation to submission.

VISIT
go.covermymeds.com/provider

CALL
1-866-452-5017

CHAT
covermymeds.com

Live support Monday–Friday, 8 a.m. – 8 p.m. ET

The Patient Access Liaison (PAL): A Dedicated Representative to Support Access for COBENFY

A PAL is a patient-access specialist and a dedicated contact to help guide your understanding of the COBENFY access process. Their role is to:

- Provide education and support after a COBENFY prescribing decision has been made
- Assist your office in navigating the path to insurance coverage for COBENFY
- Provide resources and information you can share with your COBENFY patients, including the support available to them through COBENFY Cares

CoverMyMeds® is a third-party healthcare software company contracted by BMS to provide prior authorization and appeals services to healthcare providers prescribing COBENFY. BMS does not guarantee coverage for COBENFY for PAs and appeals submitted through CoverMyMeds®.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Risk of Use in Patients with Hepatic Impairment: Patients with hepatic impairment have higher systemic exposures of xanomeline, a component of COBENFY, compared to patients with normal hepatic function, which may result in increased incidence of COBENFY-related adverse reactions.

COBENFY is contraindicated in patients with moderate or severe hepatic impairment. COBENFY is not recommended in patients with mild hepatic impairment.

Assess liver enzymes prior to initiating COBENFY and as clinically indicated during treatment.

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Prior Authorization Resources for COBENFY

After you complete the patient's benefits investigation, the health insurance plan may require you to obtain prior authorization for COBENFY by submitting a PA form, letter of authorization (LOA), letter of medical necessity (LOMN).

A **LOA** is used to request explicit approval from a health plan for a medication prescribed to the named member patient. It can accompany the submission of a PA form and include information about the patient's diagnosis, medical history, and treatment plan.

A **LOMN** is commonly submitted when a PA is required to help expedite a timely coverage decision, and usually when appealing an access denial.

Sample template letters[a] for COBENFY may be able to assist you in the process of requesting coverage for a patient prescribed COBENFY.

SAMPLE LOA

These sample letters are accessible here.

SAMPLE LOMN

These sample letters are accessible here.

Did you know?

When a new treatment enters the market, authorization and/or formulary inclusion typically takes time to increase. In the initial stages where there may be gaps or lapses in coverage, submitting a Letter of Medical Exception, also known as a formulary exception, may help a patient receive approval for COBENFY use ahead of a formulary determination.

[a]The information provided in this Prior Authorization and Appeals Guide and template letters is for informational purposes for patients who have been prescribed COBENFY. These are not intended to substitute for a prescriber's independent clinical decision-making.

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider (HCP) and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Risk of Use in Patients with Biliary Disease: In clinical studies with COBENFY, transient increases in liver enzymes with rapid decline occurred, consistent with transient biliary obstruction due to biliary contraction and possible gallstone passage.

Please see additional Important Safety Information throughout and U.S. Full Prescribing Information, including Patient Information, here.

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Prior Authorization Checklist

In addition to accurately and thoroughly completing the health insurance plan's PA form, it is helpful to add detailed information—as the provider deems appropriate—in the LOA and/or LOMN. This may include

- ✓ Key clinical notes regarding the diagnosis of schizophrenia and its severity
- ✓ The patient's age, condition, and medical history
- ✓ The patient's comprehensive treatment history, and response to previous therapies, eg, efficacy and tolerability
- ✓ Appropriate ICD-10-CM diagnostic code(s)

NOTE: PA requests should include at least one ICD-10-CM diagnosis code as appropriate to the decision to prescribe COBENFY, supported by the patient's medical/treatment history.

ICD-10-CM Code[1]	Description[1]
F20.0	Schizophrenia
F20.8	Other Schizophrenia
F20.9	Schizophrenia, Unspecified

Bristol Myers Squibb and its representatives cannot recommend a diagnostic code for a specific case or patient. The diagnostic code must be determined independently by the patient's healthcare provider and should reflect the patient's record. The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement.

- ✓ Provider's professional opinion clearly and concisely explaining the decision to treat with COBENFY, which may be supported by the following:
  - COBENFY indication per full Prescribing Information
  - Peer-reviewed journal articles, established clinical pathways, and/or nationally recognized guidelines

ICD-10-CM=International Classification of Diseases, 10th revision, Clinical Modification;

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Risk of Use in Patients with Biliary Disease (cont.): COBENFY is not recommended for patients with active biliary disease such as symptomatic gallstones. Assess liver enzymes and bilirubin prior to initiating COBENFY and as clinically indicated during treatment. The occurrence of symptoms such as dyspepsia, nausea, vomiting, or upper abdominal pain should prompt assessment for gallbladder disorders, biliary disorders, and pancreatitis, as clinically indicated.

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Submitting an Appeal for COBENFY

Should a health insurance company deny coverage for COBENFY for your adult patient with schizophrenia, it is important to understand why and to determine whether an appeal is warranted.

Administrative

- Incorrect/incomplete information
- Diagnosis not covered in the health plan
- Submission deadline missed

Coverage

- Non-covered benefit
- PA or precertification required
- Changes in coverage

Clinical

- Lack of medical necessity
- Not medically appropriate

Some administrative appeals can be resolved by the health insurance plan's customer service and/or by submitting a corrected PA form.

You may choose to submit a medical appeal to challenge denials based on coverage criteria, formulary placement, other coverage limitations, and clinical necessity.

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the HCP and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Risk of Use in Patients with Biliary Disease (cont.): Discontinue COBENFY in the presence of signs or symptoms of substantial liver injury such as jaundice, pruritus, or alanine aminotransferase levels more than five times the upper limit of normal or five times baseline values.

Decreased Gastrointestinal Motility: COBENFY contains trospium chloride. Trospium chloride, like other antimuscarinic agents, may decrease gastrointestinal motility. Administer COBENFY with caution in patients with gastrointestinal obstructive disorders because of the risk of gastric retention. Use COBENFY with caution in patients with conditions such as ulcerative colitis, intestinal atony, and myasthenia gravis.

Please see additional Important Safety Information throughout and U.S. Full Prescribing Information, including Patient Information, here.

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Appeals Submission Considerations

For plan-specific instructions, required forms, and deadlines to submit an appeal, contact the health insurance plan or search the provider portion of the health insurance plan's website for:

- Grievances and appeals
- Denials and appeals
- Appeals and disputes

Most health insurance plans have similar rules for filing:

- ✓ The request must commonly be made in writing: in a Letter of Appeal, an appeals form, or both
- ✓ There must be a supporting statement from the provider explaining the medical reason for the appeal
- ✓ The steps in the appeals process must be followed in order
- ✓ Timelines for each level of appeal must be met

Important tips when appealing a denial:

- Be sure to **document all discussions and correspondence** with the health insurance plan's representatives regarding the denial
- You may consider requesting a peer-to-peer review with a clinician from the health plan where you can explain the clinical need and rationale for the plan to cover the previously denied treatment

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Risk of Angioedema: Angioedema of the face, lips, tongue, and/or larynx has been reported with COBENFY and trospium chloride, a component of COBENFY. In one case, angioedema occurred after the first dose of trospium chloride. Angioedema associated with upper airway swelling may be life-threatening. If involvement of the tongue, hypopharynx, or larynx occurs, discontinue COBENFY and initiate appropriate therapy and/or measures necessary to ensure a patent airway. COBENFY is contraindicated in patients with a history of hypersensitivity to trospium chloride.

Please see additional Important Safety Information throughout and U.S. Full Prescribing Information, including Patient Information, here.

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Appeals Checklist

1. If the denial was not due to incorrect or incomplete information, confirm:

- ✓ The patient's benefit coverage level
- ✓ The health insurance plan's requirements, appeals processes, and deadlines
- ✓ Any applicable state and federal guidelines

2. Gather the commonly required documents

- ✓ Patient authorization and notice of release of information (PAN) or HIPAA release form
- ✓ A copy of the patient's health plan and/or prescription card (front and back)
- ✓ A copy of the denial letter
- ✓ A Letter of Appeal that gives a concise rationale for the health insurance plan to overturn the decision

Consider including the following information:

- The patient's relevant medical history
- Diagnosis that is specific to the COBENFY indication
- The patient's current and prior treatment history, including dose and duration, if relevant. Include
  - The patient's response to previous therapies, eg, efficacy, tolerability, comorbidities
  - Medical records, chart notes (NOTE: A written summary with medical records is recommended)
  - Information on clinical fitness and how it relates to the patient's need for the treatment

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Risk of Use in Patients with Narrow-angle Glaucoma: Pupillary dilation may occur due to the anticholinergic effects of COBENFY. This may trigger an acute angle closure attack in patients with anatomically narrow angles. In patients known to have anatomically narrow angles, COBENFY should only be used if the potential benefits outweigh the risks and with careful monitoring.

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- ✓ Other potential clinical documentation
  - COBENFY clinical trials data/publications
  - Relevant peer-reviewed journal articles
- ✓ A LOMN for COBENFY for the named patient
  - Depending on the patient/situation, include a summary of medical necessity in the Letter of Appeal instead

3. Submit the appeal

- ✓ Confirm the health insurance plan's appeals deadline for the specific level of appeal being submitted and file the appeal as soon as possible ahead of the deadline
- ✓ Verify the appropriate contact person at the health insurance plan that should receive the appeal
- ✓ Review the appeal submission for accuracy and completeness per the health insurance plan's requirements
- ✓ Verify how the health insurance plan will communicate the appeals decision

4. Follow up

- ✓ Keep track of submission date and the health insurance plan's decision time frame
- ✓ Follow up as needed if you do not hear back in a timely manner
- ✓ Keep the patient and provider informed of any decision or delay

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the HCP and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

Submitting an Appeal for COBENFY

Commercial appeals for COBENFY[2]

There are usually 2 options for **commercial health insurance** appeals, depending on the state and health insurance plan.

OPTION 1: Internal Review

Level 1

Request for reconsideration directly from the health insurance plan

Level 2

Peer-to-peer review over the phone with a medical reviewer at the health insurance plan to help resolve the issue

IF DENIED

OPTION 2: Independent External Review

Request for a third-party physician group or Independent Review Organization (IRO) review of the appeal if the internal reviews are unsuccessful

Medicaid appeals for COBENFY[3,4]

Medicaid appeals vary, as each state Medicaid and Medicaid Managed Care Organization (MCO) sets its own appeals systems.

Federal regulations provide certain rights to Medicaid members for claims denials, including a fair hearing and an expedited appeals review process. Although not standardized across states, most appeals processes are similar:

- Notifications and requests should be made in writing
- Explanation for the denial must be provided to the beneficiary
- The process consists of successive steps with specific time frames
- Adverse coverage determinations may be appealed

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Anticholinergic Adverse Reactions in Patients with Renal Impairment: Trospium chloride, a component of COBENFY, is substantially excreted by the kidney. COBENFY is not recommended in patients with moderate or severe renal impairment (estimated glomerular filtration rate (eGFR) <60 mL/min). Systemic exposure of trospium chloride is higher in patients with moderate and severe renal impairment. Therefore, anticholinergic adverse reactions (including dry mouth, constipation, dyspepsia, urinary tract infection, and urinary retention) are expected to be greater in patients with moderate and severe renal impairment.

Please see additional Important Safety Information throughout and U.S. Full Prescribing Information, including Patient Information, here.

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Medicare appeals for COBENFY[5]

The Medicare Part D appeals process has 5 successive levels.

1 Redetermination by the Part D Plan Sponsor

Request for reconsideration of a coverage denial, ie, a second look at the request

IF DENIED

2 Reconsideration by the Independent Review Entity (IRE)

Review by an independent third party if the redetermination is unsuccessful

IF DENIED

3 Hearing by an Administrative Law Judge (ALJ)

May be requested if the patient does not agree with the IRE

The patient's out-of-pocket (OOP) expense, known as the amount in controversy (AIC), must be ≥$180

IF DENIED

4 Review by a Medicare Appeals Council

May be requested if the patient disagrees with the ALJ

There is no minimum OOP/AIC required to file the appeal

IF DENIED

5 Review by a Federal District Court

Last level of appeal a patient can request

The patient's OOP/AIC must be ≥$1,840

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the HCP and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Central Nervous System Effects: Trospium chloride, a component of COBENFY, is associated with anticholinergic central nervous system (CNS) effects. A variety of CNS anticholinergic effects have been reported with trospium chloride, including dizziness, confusion, hallucinations, and somnolence. Monitor patients for signs of anticholinergic CNS effects, particularly after beginning treatment or increasing the dose. Advise patients not to drive or operate heavy machinery until they know how COBENFY affects them. If a patient experiences anticholinergic CNS effects, consider dose reduction or drug discontinuation.

Please see additional Important Safety Information throughout and U.S. Full Prescribing Information, including Patient Information, here.

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Extra Help for Medicare Members

The Medicare Part D Extra Help program, also known as Low Income Subsidy (LIS), helps eligible Medicare Part D members with limited income and assets pay their premiums, deductibles, and/or prescription co-payments.[6]

In 2025, most eligible members will pay[6]:

		2024 prescription drug cost-share	
$0	premiums		In January of 2024, the IRA eliminated the partial subsidy, and all eligible members would receive the full (100%) subsidy.[7]
$0	deductibles		
$12.15	maximum for each covered brand-name drug	$11.20	
$4.90	for generic drugs	$4.50	

Eligibility for extra help

The Social Security Administration (SSA), which administers the Extra Help program, is required to notify patients receiving Social Security benefits that they are eligible for the Extra Help program/benefits.[8]

Members automatically qualify if they[8]:

- Have Medicare Part A and/or Part B and SSI
- Have Medicare and Medicaid (dually eligible)
- Are enrolled in a Medical Savings Program (MSP)

How to apply for Extra Help

Medicare Part D members can apply for Extra Help through the SSA.[9]

1-800-772-1213

www.socialsecurity.gov/extrahelp

At a local SSA office

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Most Common Adverse Reactions (≥5% and at least twice placebo): nausea, dyspepsia, constipation, vomiting, hypertension, abdominal pain, diarrhea, tachycardia, dizziness, and gastroesophageal reflux disease.

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COBENFY Cares: Support with Patients in Mind

COBENFY cares

COBENFY Cares™ is a program designed to support patients who have been prescribed COBENFY™. Our team of Champions is available **24 hours a day, 7 days a week, 365 days a year (24/7/365)** to offer them another source of support while taking COBENFY.*

COBENFY Cares Champions can:

- Provide patients with information about schizophrenia
- Introduce the resources available to support patients through COBENFY Cares and help them enroll at cobenfycares.com
- Answer commonly asked questions about COBENFY based on the Prescribing Information
- Help your patients follow the medication schedule you prescribed
- Refer care partners to resources available to them at cobenfy.com
- Offer support in English, Spanish, or other languages via translation services

[a]COBENFY Cares Champions are available to provide support to patients who have been prescribed COBENFY. Champions do not provide medical advice or care. COBENFY Cares Champions are provided as a service by Bristol Myers Squibb. Patients should discuss any questions about their medical conditions and treatment options with their healthcare providers.

Financial Support

- Enroll eligible, commercially insured patients in the COBENFY Co-Pay Assistance Program and support co-pay card activation
- Identify possible independent financial support options for patients with affordability concerns

Access Support

- Help facilitate prompt initiation of COBENFY treatment through CoverMyMeds®
- Prior authorization and appeals support through CoverMyMeds®

An Additional Source of Support

Call COBENFY Cares at 1-877-COBENFY (1-877-262-3639).

Our Champions are available **24 hours a day, 7 days a week, 365 days a year (24/7/365)**.

Pharmacy support is available at 1-833-415-4346, **24 hours a day, 7 days a week (24/7/365)** (excluding holidays). Learn more at www.cobenfycares.com

IMPORTANT SAFETY INFORMATION (CONT.)

WARNINGS AND PRECAUTIONS (CONT.)

Use in Specific Populations:

- Moderate or Severe Renal Impairment: Not recommended
- Mild Hepatic Impairment: Not recommended

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Support To Help Your Adult Patients with Schizophrenia Start On Their Treatment With COBENFY

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CHAT
covermymeds.com

Live support Monday–Friday, 8 a.m. – 8 p.m. ET

The accurate completion of reimbursement- or coverage-related documentation is the responsibility of the HCP and patient. Bristol Myers Squibb and its agents make no guarantee regarding reimbursement for any service or item.

References: 1. ICD-10-CM/PCS MS-DRG v37.0 definitions manual. Centers for Medicare & Medicaid Services. October 10, 2024. https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0328.html **2.** Engaging with insurers: Appealing a denial. Patient Advocate Foundation. Accessed October 10, 2024. https://education.patientadvocate.org/wp-content/uploads/2022/07/Engaging-with-Insurers.-Appealing-a-Denial.pdf **3.** Understanding Medicaid fair hearings. Medicaid.gov. Accessed October 10, 2024. https://www.medicaid.gov/resources-for-states/downloads/mdcid-fair-hrings-prtnr-rsurce.pdf **4.** Federal requirements and state options: Appeals. Medicare and CHIP Payment and Access Commission. July 2018. Accessed October 10, 2024. https://www.macpac.gov/publication/federal-requirements-and-state-options-appeals/ **5.** *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance Effective July 19, 2024.* Centers for Medicare & Medicaid Services. Accessed October 10, 2024. https://www.cms.gov/medicare/appeals-and-grievances/mmcag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf **6.** Announcement of calendar year (CY) 2025 Medicare Advantage (MA) capitation rates and Part C and Part D payment policies. Centers for Medicare & Medicaid Services. April 1, 2024. Accessed October 10, 2024. https://www.cms.gov/files/document/2025-announcement.pdf **7.** HI 03001.020 Eligibility for Extra Help (prescription drug Low-Income Subsidy). Social Security Administration. April 9, 2024. Accessed October 10, 2024. https://secure.ssa.gov/poms.nsf/lnx/0603001020 **8.** Program Operations Manual System (POMS): HI 03001.005 Medicare Part D Extra Help (Low-Income Subsidy or LIS). Social Security Administration. April 9, 2024. Accessed October 10, 2024. https://secure.ssa.gov/poms.nsf/lnx/0603001005 **9.** Understanding the Extra Help with your Medicare Prescription Drug Plan. Social Security Administration. February 2024. Accessed October 10, 2024. https://www.ssa.gov/pubs/EN-05-10508.pdf

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