Bristol Myers Squibb®
Access Support®

Exceptions and Appeals Guide

HCP Guide

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The accurate completion of reimbursement or coverage-related documentation is the responsibility of the healthcare provider and patient. Bristol-Myers Squibb and its agents cannot guarantee coverage for any medication or treatment.

Coverage Decisions

Understanding Coverage Decisions and Potential Outcomes

Many health plans require a patient to go through an approval process before starting treatment and throughout treatment. Depending on a patient's insurance status, formulary design, and covered benefits, there may be several possible coverage scenarios for a prescribed specialty medication.

1 COVERED: Prior authorization required

Prior authorization (PA): The patient and HCP need to get approval from the plan in advance before the plan agrees to cover the drug. If required, the HCP will need to provide the health plan with medical history, diagnosis, and treatment plan to show that the treatment selected is medically necessary. The plan will determine if this treatment will be covered

2 COVERED: With restrictions

Step therapy (ST/SE): Requires patients to try a less expensive medication first and fail before their insurance plan will cover a more expensive medication

Non-preferred status: A non-preferred product is a brand-name drug that is not on a health insurance plan's formulary, or list of preferred prescription drugs. Non-preferred drugs are usually more expensive than preferred drugs, and have higher coinsurance or copayments

3 NOT COVERED: Not on formulary

If the product is not on formulary, it is typically not covered. However, the HCP and patient may be able to request a formulary exception

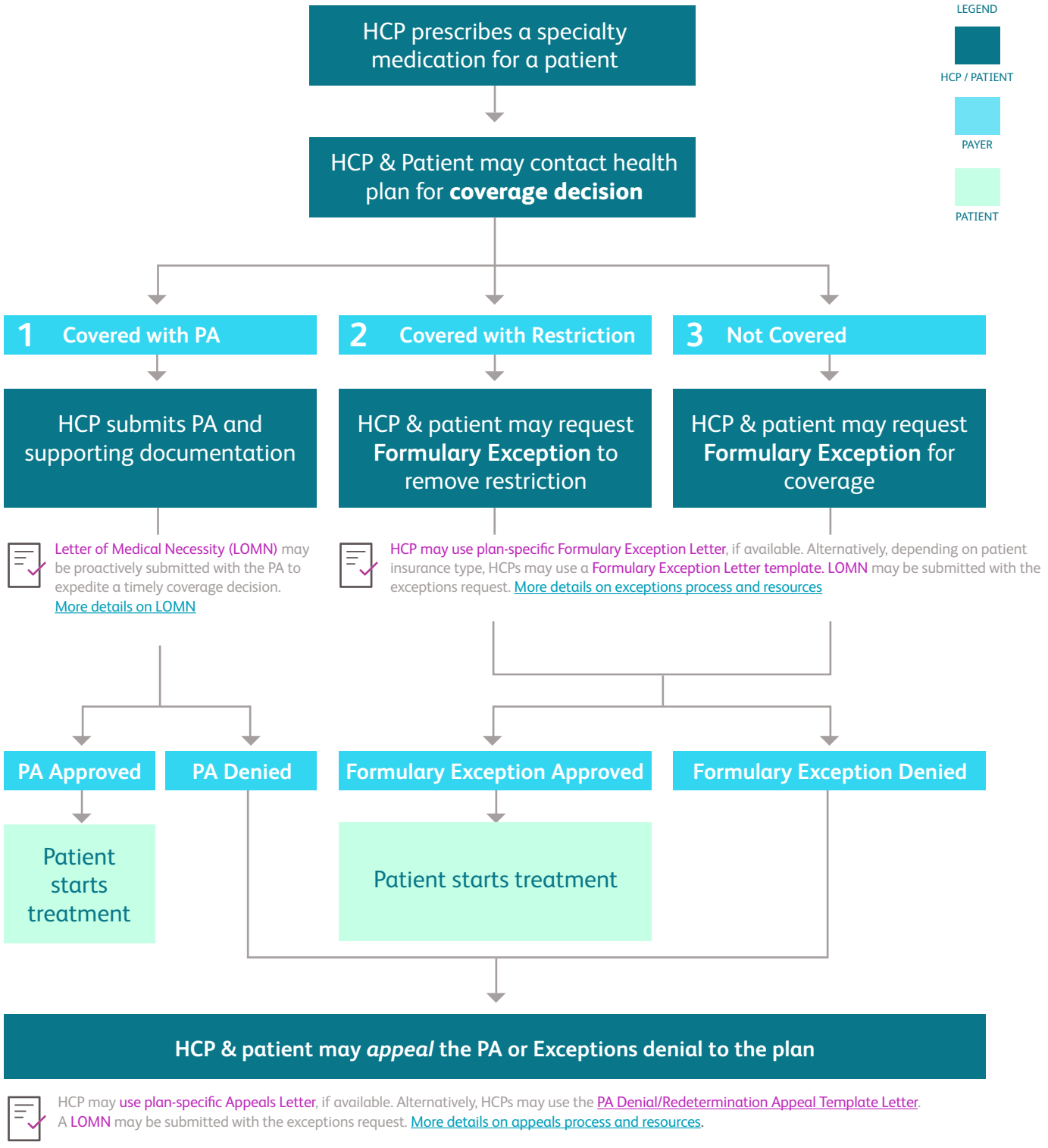
Patients and their doctors may contact a health plan to request a coverage decision to understand plan's coverage of their prescribed medications before starting treatment.

Upon request, BMS Access Support® can help complete a benefit verification on behalf of an enrolled patient to determine coverage and potential out-of-pocket costs for a BMS product.

See next page for what the patient and HCP may do for the coverage scenarios above

Coverage Decisions

Potential Coverage Outcomes



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Coverage Decisions

Considerations for Letter of Medical Necessity (LOMN)

An HCP office may want to proactively include a Letter of Medical Necessity to help explain the rationale and clinical decision-making behind the choice of a specific therapy.

Tips for composing a Letter of Medical Necessity

Seek out the plan's specific guidelines (e.g., obtain any necessary referrals, determine if treatment must be given in a particular setting).

Be aware of all deadlines for appealing a denial or escalating an appeal. Once the HCP office has received the PA approval, check with the plan on the length of the authorization which may vary. Re-authorization may be required.

Be detailed and thorough. Recommended information for an LOMN includes:

- **Current and prior treatment history:** Response to previous therapies (e.g., efficacy, tolerability, comorbidities) if relevant. A written disease summary with medical records is recommended
- **Treatment plan:** Dosage, duration, and treatment escalation schedule, as appropriate
- **Clinical appropriateness:** Medical justification for a specific therapy for this patient
- **Additional documentation:** Denial letter (if used in appeal), Prescribing Information, FDA approval letter, clinical practice guidelines, clinical notes and medical records, diagnostic test results, pathology reports, relevant peer-reviewed articles

Template Letter & Resources to Support Medical Necessity

Click to download:

Sample Letter of Medical Necessity editable template

Letter of Medical Necessity Checklist for considerations on completing LOMN

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Exceptions

Exceptions Overview

What is an Exception?

- A request from a patient or the prescriber for a payer to cover a medication that the insurance plan will not pay for
- An exception request is a type of coverage determination

Who can request an Exception?

- A patient, prescriber, or the patient's representative may request an exception

Reasons to request an Exception

- Ask to pay a lower price for a covered non-preferred drug (tiering exception)
- Ask the plan to cover a prescription drug that is not on formulary (formulary exception)
- Ask the plan to remove a utilization management restriction on a formulary drug (formulary exception), such as:
  - Prior authorization - Quantity limits - Step therapy

Examples of Formulary Exception

- Request to cover a newly approved drug that has not yet been added to the plan formulary
- Request to remove coverage restriction for a "non-preferred" formulary drug so that it is covered at parity as a "preferred" drug

Reminder

For Medicare patients, if a non-formulary drug is approved through formulary exception process, the total patient out-of-pocket cost under Medicare Part D will be capped at $2,000. Patients may also enroll into the Medicare Prescription Payment Plan to manage their OOP drug costs by spreading the payment over the course of the plan year.

Exceptions

Exceptions Process and Template Letters

How to Submit an Exception Request

The prescriber may submit the exception request along with a supporting statement to the health plan, preferably in writing,* using any of the following formats:

- A plan-specific Exceptions Form, if available
- A letter prepared by the HCP
- For patients with Medicare, CMS Model Coverage Determination Request Form

For **formulary exceptions**, the prescriber's supporting statement should indicate that:

The non-formulary drug is necessary for treating the patient's condition because all covered drugs on any tier would:

Not be as effective

and/or

Have adverse effects

- Medicare plans are required to process exception requests **within 24 hours (expedited) or 72 hours (standard)**
- For coverage determination prior to treatment, **the clock starts when the plan receives the HCP's supporting statement**
- HCP office should **make sure to be available during the 24- to 72-hour time period after request submission,** should the plan reach out for additional information. If the HCP office is closed (i.e., weekends, holidays), the request could be denied, and an appeal would then need to be filed

Template Letters & Resources to Support Formulary Exceptions

Click to download:

Formulary Exception Letter editable template

A Letter of Medical Necessity (LOMN) may be submitted with the Exceptions request:

Sample Letter of Medical Necessity editable template

Letter of Medical Necessity Checklist for considerations on completing LOMN

*If submitted Exceptions Request verbally, plan may require the prescriber to follow up in writing

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Navigating Appeals

Types of Denials

Should a health insurance company deny coverage, it is important to understand why and to determine whether an appeal is warranted.

Administrative

- Incorrect/incomplete information
- Submission deadline missed

May be resolved through plan customer service and/or submitting corrected paperwork

Coverage

- Non-covered benefit
- PA or precertification required
- Changes in coverage
- Diagnosis not covered in the health plan

Clinical

- Lack of medical necessity
- Not medically appropriate

May warrant a medical appeal to challenge denials based on coverage criteria, formulary placement, other coverage limitations, and clinical necessity

Template Letters & Resources to Support Appeals

Click to download:

Prior Authorization Denial / Redetermination Appeal Template Letter

Commercial Claim Denial Appeal / Redetermination Template Letter

Peer-to-Peer Medical Review Checklist to support the patient's treatment rationale

A Letter of Medical Necessity (LOMN) may be submitted with the Exceptions request:

Sample Letter of Medical Necessity editable template

Letter of Medical Necessity Checklist for considerations on completing LOMN

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Navigating Appeals

Appeals Checklist

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

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

2 Gather the commonly required documents

- ☐ A copy of the denial letter
- ☐ Prepare a Letter of Appeal with concise rationale for the plan to reconsider the decision
- ☐ Other potential clinical documentation
- ☐ A Letter of Medical Necessity (LOMN) for the named patient

3 Submit the appeal

- ☐ Confirm the 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 plan that should receive the appeal
- ☐ Review the appeal submission for accuracy and completeness per plan requirements
- ☐ Verify how the plan will communicate the appeals decision

4 Follow up

- ☐ Keep track of submission date and the plan's decision time frame
- ☐ Follow up as needed if you do not hear back in a timely manner
- ☐ Be sure to document all discussions and correspondence with plan representatives regarding the denial
- ☐ You may consider requesting a peer-to-peer review with a clinician from the plan where you can explain the clinical need and rationale to cover the previously denied treatment

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Navigating Appeals

Appeals Process: Commercial

Commercial Appeals

There are usually 2 options for **commercial health insurance** appeals.

OPTION 1: Internal Review

LEVEL 1

Request for reconsideration directly from the health insurance plan

Download **Commercial Claim Denial Appeal / Redetermination Template Letter** here.

LEVEL 2

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

Download **Peer-to-Peer Medical Review Checklist** here.

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

Appeals Process: Medicaid

Medicaid Appeals

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 determination may be appealed

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Navigating Appeals

Appeals Process: Medicare

The Medicare Advantage and Prescription Drug Plan appeals process has 5 successive levels after coverage determination.

Coverage determination timing: 72 hours (standard) / 24 hours (expedited)

1 Redetermination by the Plan Sponsor

Request for reconsideration of a coverage denial, i.e., a second look at the request

Download **Medicare Redetermination Request Form** by clicking here.

Timing
- Standard Process: 7 days
- Expedited Process: 72 hours

IF DENIED

2 Reconsideration by the Independent Review Entity (IRE)

Review by an independent third party if the redetermination is unsuccessful

Download **Medicare Reconsideration Request Form** by clicking here.

Timing
- Standard Process: 7 days
- Expedited Process: 72 hours

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 ≥$190

Download **Request for a Medicare Hearing by an Administrative Law Judge** by clicking here.

Timing
- Standard Process: 90 days
- Expedited Process: 10 days

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

Timing
- Standard Process: 90 days
- Expedited Process: 10 days

IF DENIED

5 Review by a Federal District Court

Last level of appeal a patient can request The patient's OOP / AIC must be ≥$1,900

Resources and Support

Educational Resources

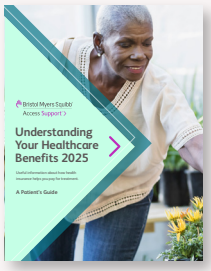
Resources	
Medicare Prescription Drug Exceptions and Appeals Parts C and D Enrollee Grievance, Coverage Determinations, and Appeals Guidance effective 1/1/2025	Learn More
Coverage Determination by the Part D Plan Sponsor Request for a Medicare Prescription Drug Coverage Determination	Learn More
Redetermination by the Part D Plan Sponsor Request for Redetermination of Medicare Prescription Drug Denial (for use beginning 1/1/2025)	Learn More
Reconsideration by the Part D Independent Review Entity Request for Reconsideration of Medicare Prescription Drug Denial (for use beginning 1/1/2025)	Learn More
Forms for HHS Office of Medicare Hearings and Appeals (OMHA) Request for a hearing by an Administrative Law Judge and other pre-hearing forms	Learn More
Appointment of Representative Form Note: The prescriber may request a coverage determination, redetermination or Independent Review Entity reconsideration on the enrollee's behalf without having to be an appointed representative.	Learn More

A patient may review educational resources by visiting

www.BMSAccessSupport.com

Understanding Your Healthcare Benefits

Click here for information on how health insurance works and ways BMS Access Support can help



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Resources and Support

BMS Access Support®

Looking for support? We're here for you.

Patient access support, reimbursement resources, and financial support options may be available through **BMS Access Support®**

Call a Patient Access Specialist at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday

Visit **www.BMSAccessSupport.com**

Schedule a meeting with a BMS Access and Reimbursement Manager on the BMS Access Support website

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