AstraZeneca Access 360™

Denial Management Guide

This guide is intended to provide you with resources and best practices to help you navigate the denial of an AstraZeneca medicine.

Providers and patients are encouraged to contact the patient's insurer for detailed instructions on how to appeal or overturn a denial. If you have any questions about this guide, or need guidance on addressing a Denial of Coverage, please contact AstraZeneca Access 360™ or your Field Reimbursement Manager at **1-844-ASK-A360 (1-844-275-2360)**.

Contents

Overview

What is a Denial of Coverage (DOC)?

A Denial of Coverage happens when a patient's claim for coverage or reimbursement is denied by their health insurance provider. Your patient may receive a DOC notification describing why the claim for coverage for a prescribed medicine was not approved.

What can trigger a DOC?

- **NO DOCUMENTATION**

  When the provider fails to respond to a request

- **MEDICALLY UNNECESSARY SERVICE**

  When the services provided are not considered medically necessary by the insurance company

- **INCORRECT CODING**

  When the medical documentation references an incorrect code

- **INSUFFICIENT DOCUMENTATION**

  When the medical documentation that was submitted does not meet the insurance approval requirements

Additional denial reasons include:

- Services not rendered
- Duplicate payment error
- Services not covered
- Unallowable services
- Experimental treatments. Once a drug has received FDA approval and proven to be safe and effective, it is no longer considered experimental. However, some health plans have their own criteria to determine experimental status.

Understanding the differences between DOCs depending on payers and networks

The type of DOC and how the insurers determine a denial can vary from plan to plan. Since not all denials and appeals are the same, it's important to review the patient's plan and terms of coverage before appealing a denial.

DENIALS UNDER MEDICARE

Part B generally covers medicines you get at a doctor's office. Part D covers most medicines used at home.

Sometimes a medicine can be denied because the submitting office tried to get it through the medical coverage versus the pharmacy, or vice versa.

If Medicare or a Medicare health plan denies any medicine benefits, patients can request a coverage determination – a written explanation of the patient's drug-coverage benefits.

The prescribing doctor or the patient can ask for an exception if the medicine is not on the plan's list of covered medicines.

For patients who are asking for a prescription medicine they have not received yet, requests can be made by phone or in writing.

When requesting reimbursement for medicines already bought, the request must be in writing. However, for situations where a patient's life or health could be at greater risk by waiting for a medicine approval, doctors can request an expedited appeal by phone.

For more information regarding Medicare appeals, visit www.medicare.gov/claims-appeals.

About DOC appeals

When an insurer denies a claim for medical services, supplies, or prescriptions, patients have the right to file an appeal. Patients may file an appeal if an insurer:

- Denies a request for coverage or payment of a health care service, supply, or prescription that a patient thinks they should be able to get;
- Denies payment for a health care service, supply, or prescription that a patient has already received;
- Changes the amount a patient is requested to pay for a prescription; or
- Stops covering or paying for part or all of a health care service, supply, or prescription that was always covered and/or paid in the past

The Appeal Process

To put together the most effective appeal, you should be aware of how the process works. Most plans offer internal and external appeals. The internal process is developed and described by the health plan, while an external process might be the result of the health plan's policy or, in many states, mandated by the state. Ultimately, your strategy will depend on the type of appeal you are filing.

GOOD NEWS *Most of the time, denials are overturned as a result of external appeals.*

Types of appeals

In addition to an appeal for a DOC, several other options can be considered prior to creating an appeal.

- **PRE-SERVICE (OR PRE-AUTHORIZATION) APPEAL**
  The plan has denied a submitted request to obtain medical services BEFORE care was provided. This type of denial has prevented the patient from receiving the medicines you have prescribed.

- **POST-SERVICE APPEAL**
  The plan has denied a claim for reimbursement or payment of a medical procedure, meaning the patient may be responsible for 100% of any expenses. An initial appeal should aim to prove that a post-service claim or request for preauthorization DOES meet the insurance guidelines and that it was incorrectly rejected.

- **URGENT CARE (OR EXPEDITED) APPEAL**
  The patient has requested that appeal documents be examined in a timely manner because of medical necessity.

- **MARKETPLACE PLAN APPEAL**
  The Affordable Care Act gives you and the patient the right to appeal a decision made by a state or federal health insurance exchange. This may include decisions surrounding eligibility for specific plans or financial assistance.

- **MEDICARE APPEALS**
  Patients can file a formal appeal if they disagree with their plan's Part B or Part D medicine denial decision. The first level of appeal is to their plan, which is required to send notification of its decision within seven days for a regular appeal and within 72 hours for an expedited appeal. Patients who disagree with this decision can ask for an independent review of their case.

  For Medicare beneficiaries, the Medicare Summary Notice (MSN) will provide details on filing an appeal. Appeals under original Medicare plans must be filed within 120 days of receiving the MSN. Typically, Medicare contractors will reply in writing within 60 days of receiving an appeal.

- **APPEALS TO DENIALS FOR MEDICINES RECEIVED OUTSIDE OF THE NETWORK**
  If you have received a denial of care or a claims denial because care was given from an out-of-network provider, you can attempt to have the original decision overturned through an appeal.

  To start an appeal, confirm that there were no in-network providers in the area where services were sought. Most health plans have rules that state if there is no provider within a certain number of miles from the patient's home, they can see an out-of-network provider at the in-network coverage rate. However, even if the insurer chooses to cover the service(s) at an in-network reimbursement rate, the provider may not consider this payment in full and hold the patient responsible for the difference. For providers who are specialists and there are no other specialists of his/her kind in the network, the patient may have a good argument, and you may be asked to provide any supporting documents that prove why the patient needs to have this care approved and the initial denial overturned.

The Appeal Process

Steps of the appeal process

STEP 01 Review the denial notification to confirm the reason and circumstances that need to be addressed and explained in the appeal letter.

STEP 02 Review the plan's most recent explanation of benefits or contact a representative directly at the health plan to verify where the appeal needs to be sent and by when.

STEP 03 Write an appeal letter. You should be familiar with the format and information required. Additional guidance to help in drafting your appeal letter is included in later sections of this document.

STEP 04 If you or your patient have not received a decision within 30 days, follow up with the payer. Confirm that the appeal letter was received and ask about its status. If the coverage denial was upheld, you can submit another appeal with new information or ask for a supervisor or manager for assistance.

STEP 05 Keep track of the following: dates and methods of any correspondence (by phone, email, and letter); names of insurance agents and claim reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

STEP 06 If the denial is upheld again, ask for a one-time exception or consider filing an insurance complaint with the State's Insurance Commissioner. Payers who hear from the Commissioner will respond promptly to resolve the matter.

STEP 07 If the insurer continues to deny the claim, your patient may request an external appeal (the process varies by state), in which an independent third-party will review the claim and make a final, binding decision.

The Appeal Process

Completing the documents for your appeal

THE APPEAL LETTER

This is the third step of the appeal process referenced on page 6 and can be the most vital. A clear, concise letter that addresses the grounds for disputing the denial will build the foundation of the patient's case. Whether this letter is prepared by you or the patient, we recommend the following:

01 Include a description of the patient's medical condition and the impact it has had on their health.

02 Clearly state why the patient needs the prescribed medicine.

03 Explain why you believe the insurance policy should cover the medicine. For appeals that address only part of the denial, describe just that part to avoid confusion.

04 Present any convincing evidence or cost comparison information to show that the prescribed medical service will save the insurance company on future expenses, such as the management of side effects or readmissions to the hospital.

05 Provide clinical data, such as published journal articles or data on outcomes, which show the benefits and success of the prescribed treatment and/or service.

06 Include contact information for both you and your patient.

07 If the patient submits their own letter in support of the provider's, be sure that the letters work together and make similar statements before sending both to the payer at the same time.

08 Send the letter(s) by certified mail with a request for a return receipt.

09 Keep a hard copy and electronic copy of the letters, the delivery receipt, and a record of all correspondence prior to and following the mailing of your appeal.

The Appeal Process

OTHER DOCUMENTS REQUIRED FOR AN EFFECTIVE APPEAL

- A letter of support indicating the medical reasons why the requested medicine is necessary. Include how well the patient responded to the medicine
- Results of any relevant tests or procedures related to the requested medicine, prior to and following taking the medicine
- Any current medical literature or studies documenting the medical effectiveness of the requested medicines for experimental or investigational treatments
- Peer-reviewed articles from professional journals or magazines that support the treatment being recommended
- A personal description by the patient or their authorized representative describing the need and individual circumstances surrounding the medicine and treatment

Your role after an appeal has been submitted

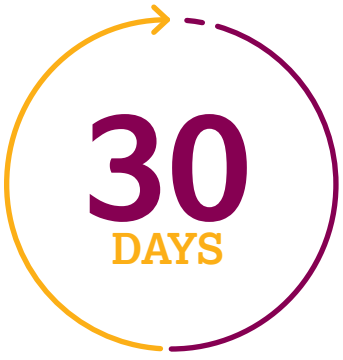
Insurance companies are required to respond to a written appeal letter, and you should receive a notice within 7-10 days of the appeal packet being received. If you do not receive confirmation from the insurance company, contact them to make sure the appeal was received.

INSURERS MUST RESPOND TO AN APPEAL:

Within

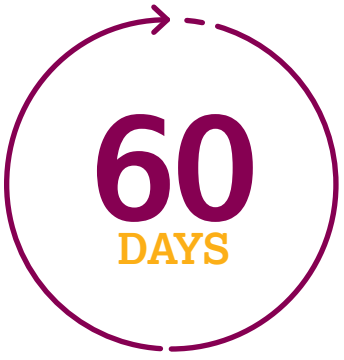
of receipt for urgent care

Within



of receipt for prescriptions not yet received

Within



of receipt for prescriptions already received

For assistance, please call the Access 360 team at 1-844-275-2360, visit www.MyAccess360.com or email Access360@AstraZeneca.com.

The Appeal Process

Depending on the patient's home state and their insurance plan, there are typically three levels of insurance appeals. If your claim is denied due to a particular service being billed or coded incorrectly, your support staff may be able to gather and submit the necessary information on your patient's behalf in order to resolve the issue without the necessity of a formal appeal.

1 FIRST LEVEL APPEAL OR REQUEST FOR RECONSIDERATION

You or your patient may contact the insurance company and request reconsideration. You may also request to speak with the medical reviewer of the insurance plan as part of a "peer-to-peer review" in order to challenge the decision, which could resolve the issue easily.

2 SECOND LEVEL APPEALS

These are typically reviewed by a medical director of the insurance plan who was not involved in the claim decision. The goal of this appeal is to prove that the request should be accepted within the coverage guidelines. There may be an additional level of appeals to determine if the medical care or service is experimental or investigational. First and second level appeals are typically handled by different entities. Depending on the plan, reviews can be external or internal.

3 EXTERNAL REVIEWS

Independent external reviews are conducted by an independent, third-party reviewer in collaboration with a physician who is board-certified in the same specialty as the patient's physician.

Health insurance issuers in all states must participate in an external review process that meets minimum consumer protection standards. Your state may have an external review process that meets or goes beyond these standards. If so, health insurers in your state will follow your state's external review processes, and you will get all of the protections outlined in that process.

Some states may have different regulations for different government plans and commercial insurance plans that vary in the turnaround time for responding to requests for denial appeals. There is also a variance appeals review process for peer-to-peer reviews versus third-party external reviews; and these variances are also specific to each plan.

Peer-to-peer requests for review are conducted by peers in the same field to determine if the request for coverage of a specific medicine and indication meets medical necessity. In these cases, a review may or may not occur with peers who are internal (other doctors who are part of the plan) or external (by doctors in the same field, but affiliated with different plans or associations).

The Appeal Process

The external review process

Within five business days after the insurer has received this external review request, the insurer must complete a preliminary review. This review should confirm that the patient was covered under the plan at the time the medical service was requested or provided and that the denial does not relate to enrollment or eligibility in the group plan. Within an additional business day, the plan will notify you in writing if the appeal is eligible for external review and will provide your appeal documentation to a qualified independent review organization.

The health plan must involve an unbiased, accredited organization that does not receive financial incentives to review your case. The organization assigned to your review is not bound by any decision reached during the plan's internal review process. The insurance plan must provide the Independent Review Organization (IRO) with any documents that were used to make their final adverse determination within five days of you receiving notification that the IRO has accepted your review.

The IRO normally considers the following documents as appropriate:

- Medical records
- Attending physician's recommendations
- Reports from appropriate health care professionals and other documents submitted by the plan, and statements issued by the providers and their patients
- The terms or language of the health plan
- Appropriate practice guidelines
- Clinical review criteria developed and used by the plan

After the IRO has received the initial request for external review, it must provide written notice of the final decision within 45 calendar days. If the decision was to reverse or overturn the plan's DOC, the plan must immediately provide coverage or payment for the claim. In cases involving an expedited external review, the IRO must notify the patient about the decision as quickly as medical conditions or circumstances require, but no more than 72 hours after the IRO receives the request for expedited review.

Timely Filing Deadlines Are Critical

REMEMBER: THE CLOCK IS TICKING ON ANY APPEAL

After the DOC, you and your patient have a limited amount of time to respond with a standard set of appeal steps. The notification of denial will provide you with information on how to appeal and how much time you have to submit an Appeal Letter and support documents.

Denial Prevention Tips

What you can do to prevent a DOC

Considering that some claims are denied by insurance carriers for multiple reasons, you should help your patients understand how their insurance coverage works.

You can also do a prior authorization, which is a review process where health plan specialists ensure that a medicine is needed and will be used properly. In addition to collecting basic patient information, you must submit details regarding medical history, diagnosis, and proposed treatment plans.

What your patients can do to prevent a DOC

To get the most benefit from their health plans, patients should stay on top of their coverage. Patients can contact the insurance company and/or payer to verify the following:

- Prescription coverage, copays, and limits
- What are the types of approvals and pre-approvals needed by their health plan?
- Who at the doctor's office will be helping with these processes?
- What do they need from the patient to get these processes started?
- How are out-of-pocket costs for each medicine determined? Is there a cap on out-of-pocket costs, and if so, is it per dose, year, or treatment cycle?

How Access 360 Can Help

Getting a DOC notification can be discouraging, but there are certain steps that you can take to appeal that decision. Denials are often overturned, but this takes time and attention on the part of you and your patient.

Contact your Access 360 team for help with this process.

Here is a brief guide to the appeal process:

ACCESS 360 APPEAL SUPPORT SERVICES CAN HELP:

- Receive DOC notification
- Review the reason(s) for the denial in the Explanation of Benefits or remittance or Medicare Summary Notice
- Verify the patient's plan's most current benefits and the terms of coverage for their plan
- Note any and all areas where there may be a misunderstanding by the payer or obvious errors where the patient is entitled to prescription benefits
- Review the payer's process for submitting an appeal letter. Note deadlines and specific documents required that will need to be included
- Craft a well-written appeal letter that clearly describes the desired outcome and focuses statements on supporting that outcome
- Gather supporting documents, outside articles and studies, payment authorizations, a description of the need for the medicine, and the reason why this medicine is unique for the patient to get the results they need
- Make copies of these materials and submit them according to the directions of the payer
- Follow up within 10 days to verify that the appeal package has been received
- Follow up again if you have not received a decision on the appeal within a month

You may also request to speak with the medical reviewer of the insurance plan as part of a "peer-to-peer review."

Payers are required to make a decision on the appeal and notify the patient. If they still deny the coverage, a second appeal can be filed to the medical director of the insurance plan who was not involved in the claim decision. In some cases, a second appeal can require an outside party for an impartial, external review.

If the second appeal is denied, you can request a one-time exception or consider filing an insurance complaint with the State's Insurance Commissioner.

DENIAL OF COVERAGE APPEAL STEPS:

1. Receive DOC
2. Review the DOC for explanation of denial
3. Verify patient's benefits and coverage
4. See sample letters on myaccess360.com
5. Send letter with supporting documentation
6. Follow up

For assistance, please call the Access 360 team at 1-844-275-2360, visit www.MyAccess360.com or email Access360@AstraZeneca.com.

Connecting with AstraZeneca Access 360™ is easy

The AstraZeneca Access 360™ program provides personal support to connect patients to affordability programs and streamline access and reimbursement for select AstraZeneca medicines.

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