This guide is intended to provide you with resources and best practices to ensure you have all the tools you need to navigate the denial of an AstraZeneca medicine efficiently with a favorable outcome.

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

- Service not rendered
- Service not covered
- Duplicate payment error
- Unallowable service
- 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 Denial of Coverage 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 D

Medicare Part D is the federal government’s prescription drug benefit program that helps pay the cost of prescription drugs and prescription drug insurance premiums.

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 medications or if the patient contends that they should pay less for a more expensive drug because they can’t take any of the less expensive drugs for the same condition.

Requests for plan exceptions can be made by phone or in writing for patients who are asking for a prescription drug they haven’t received yet.

When requesting reimbursement for drugs 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 medication approval from their plan, doctors can request an expedited appeal by phone.

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What providers can do after a DOC

When a denial is issued, the payer usually provides a letter that includes all the appeal options and instructions. You should review the denial notice to confirm the trigger of the denial and begin a trouble-shooting strategy and proper response to the denial. Sometimes a drug can be denied because the submitting office tried to get it through the medical coverage versus the pharmacy, or vice versa.

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/paid in the past.

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The Appeals 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

45% of the time, denials are overturned as a result of external appeals.

Types of appeals

In addition to an appeal for denial of coverage, several other options can be considered prior to creating an appeal.

Pre-service (or pre-authorization) appeal

In this case, 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 medications you have prescribed.
Types of appeals (continued)

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 Part D plan’s 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 medications 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.

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
Find the location where the appeal must be sent and know the deadlines for submitting all materials.

STEP 04
Write an appeal letter. You should be familiar with the format and information required. Several sample letters are at the end of this document, and more detail on appeals letters appears below.

STEP 05
If you or your patient haven’t 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 could resubmit another appeal with new information or ask for a Supervisor or Manager for assistance.

STEP 06
Keep track of the following: dates and methods of any correspondence (by phone, email and written); names of insurance agents and claim reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

STEP 07
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 have to hear from the Commissioner will respond promptly to resolve the matter.

STEP 08
If the insurer continues to deny the claim, your patient may request an external appeal (the process varies by state law), in which an independent third-party will review the claim and make a final, binding decision.

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Completing the documents of your appeal

The appeal letter

This is the first and most vital step of the appeal process. 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 life.

02 State plainly why the patient needs the prescribed medications. Patient letters should be pleasant, brief and not convey any frustration regarding the initial denial.

03 Explain why you believe the insurance policy covers the medications. 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 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 shows the benefits and success of the prescribed treatment/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 hardcopy and electronic copy of the letters, the delivery receipt and a record of all correspondence prior to and following mailing your appeal.

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 medication
- Results of any relevant tests or procedures related to the requested medicine, prior to and following taking the medication
- 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

Request a timely response from the insurance provider based on the guidelines that the plan must follow. 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 72 hours of receipt for urgent care
- Within 30 days of receipt for prescriptions not yet received
- Within 60 days of receipt for prescriptions already received

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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.

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.

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 level appeals are made through a Pharmacy Benefit Manager (PBM) and second level appeals go through the medical side of the same plan. Both appeals are handled by different entities. Depending on the plan, reviews can be external or internal.

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.

Effective January 1, 2012, health insurance issuers in all states must participate in an external review process that meets minimum consumer protection standards as outlined in the Affordable Care Act. 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 turn-around 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).

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The external review process
Within five business days after the insurer has received this external review request, it must complete a preliminary review to 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 denial of coverage, 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.

Remember the clock is ticking on any appeal
After the Denial of Coverage, 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 Appeals 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, 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 coverages. Patients can contact the insurance company/payer to verify the following:

- Prescription coverage, copays and limits
- What types of approvals and pre-approvals are 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, based on per dose, year or treatment cycle?

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Getting a Denial of Coverage 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.

Here is a brief guide to the appeals process:

Access 360 can help you navigate a denial. Our appeal support services can help:

• Receive Denial of Coverage 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 and appeal letter. Note deadlines and specific documents required that will need to be included
• Craft a well-written appeals letter that clearly describes the desired outcome and focuses statements on supporting that outcome

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Example 1:
Request for medicine X 3 mg/kg and Medicine Y 1 mg/kg every 3 weeks combination followed by Medicine Y 3 mg/kg every 2 weeks for metastatic melanoma to the genital region & lymph node
- Diagnosis code: C43.72, C79.82, C77.4
- Insurance: Anthem
- Cost of therapy: $XXX,XXX
- Level of evidence: NCCN level of evidence 2A
- Anthem clinical policy

Initial thoughts?
- Case meets NCCN and Anthem Clinical policy guidelines
- Concern for reimbursement? None
- What happened next? Denied for Experimental and Investigational usage

Final outcome
Submitted an appeal that contained:
- Infusion orders and pharmacy records
- Nursing administration and performance status assessment
- Prescriber clinical records
- Authorization for treatment from AIM pharmacy specialty services
- Current lab and scan results
- Appeal successful and reimbursement granted

Reference: ICLIO Webinar: Coverage and Reimbursement Case Studies

Example 2:
Request for medicine Y 2 mg/kg every 3 weeks for metastatic melanoma to lymph node
- Diagnosis code: C77.9
- Insurance: Medicaid
- Cost of therapy: $XXX,XXX
- Level of evidence: FDA approved, NCCN supported level 1, Clinical policy for payer

Initial thoughts?
- Case should be approved without issues
- Concern for reimbursement? None
- What happened next...The case was DENIED.

Final outcome
- Clinical policy was outdated with therapy
- Peer to peer needed to be performed
- No call received from the payer after the peer scheduled
- Contacted the pharmacy director to get a reconsideration due to outdated policy


Example 3:
Request for medicine Z 3 mg/kg every 2 weeks for metastatic melanoma to lymph node
- Diagnosis code: C43.72, C77.8
- Insurance: Original Medicare
- Cost of therapy: $XXX,XXX
- Level of evidence: FDA approval, NCCN supported Level 1, LCD supported diagnosis

Initial thoughts?
- Case should be approved without issues
- No ABN needed
- Concern for reimbursement? None
- What happened next...Denied for medical necessity & units of service exceed acceptable maximum

Final outcome
Submit an appeal that contained:
- Infusion orders and pharmacy records
- Nursing administration and performance status assessment
- Prescriber clinical records
- Authorization for treatment from AIM pharmacy specialty services
- Current lab and scan results
- Medicare Redetermination Request Form
- Appeal successful and reimbursement granted

Why? Coding? C43.72, C77.8 Dose? Patient weight 160 kg = 480 mg dose 13

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Connecting with AstraZeneca Access 360 is easy. Contact us to learn more:

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