An Advocate's Guide to Appealing Prescription Drug Denials

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Housekeeping

- All on mute. Use Questions function for substantive questions and for technical concerns.
- Problems getting on the webinar? Send an e-mail to NCLER@acl.hhs.gov.
- Written materials and a recording will be available at NCLER.acl.gov. See also the chat box for this web address.

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Poll 1

- About what percentage of your services to older adults are being delivered remotely?
  A. Less than 25%
  B. 25%
  C. 50%
  D. 75%
  E. 100%

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Poll 2

- If your clients are still facing challenges related to the COVID-19 pandemic, in what areas are they most impacted?
  A. Health
  B. Economic Security/Income
  C. Housing
  D. Elder Abuse
  E. Other (please share in question box)

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Poll 3

- What additional ways would you like to get information from NCLER?
  A. Short video clips
  B. Podcasts/Audio clips
  C. Longer training sessions
  D. Question & Answer sessions
  E. Other (please share in question box)

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About NCLER

The National Center on Law and Elder Rights (NCLER) provides the legal services and aging and disability communities with the tools and resources they need to serve older adults with the greatest economic and social needs. A centralized, one-stop shop for legal assistance, NCLER provides Legal Training, Case Consultations, and Technical Assistance on Legal Systems Development. Justice in Aging administers the NCLER through a contract with the Administration for Community Living's Administration on Aging.

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About Medicare Rights Center

Based in New York, the Medicare Rights Center is a national, nonprofit consumer service organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Since 1989, Medicare Rights has helped people with Medicare understand their rights and benefits, navigate the Medicare system, and secure the quality health care they deserve.

Key Lessons

- Identify the type of prescription access problem your client is facing and the reason for the denial
- Learn how to assist beneficiaries with the appeals process
- Problem solve to find strategies for accessing needed drugs in a situation where an appeal is unlikely to be successful

Medicare Part D: Prescription Drug Benefit

- Outpatient prescription drug benefit for anyone with Medicare
- Only available from private insurance companies
- Each Medicare drug plan has its own **formulary,** or list of covered drugs
- Only covers drugs on the formulary
- Plans must offer at least two drugs under each type of drug class
- Plans must cover substantially all drugs from a few classes
- A few classes of drugs are excluded from Medicare coverage by law

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Drug Tiers

- Medicare drug plans have a tiering system that determines how much of the cost of a drug a plan member will have to pay
- Generally, the higher the tier, the more expensive the medication
- Each plan sets its own tiers, and plans may change their tiers from year to year

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Part D Appeals

- Part D benefit is operated by private insurance companies that make initial decisions on claims at the pharmacy about whether a beneficiary's prescription will be covered
- Part D insurance companies deny payment for millions of prescriptions every year
- Ability to successfully navigate the appeals process is vital to ensuring affordable access to prescription medication for millions of beneficiaries

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Appeal vs. Grievance

- **Appeal:** Request for plan to cover service or item it has denied
- **Grievance:** Formal complaint filed with plan
- If an individual is experiencing poor customer service or administrative issues with the plan (e.g., taking too long to process an appeal or to provide a refund) they can file a grievance
- Grievance is processed in the same part of the plan that handles appeals, but instead of concerning a coverage issue, the grievance is about a customer service or administrative issue

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The Prescription

- All Part D appeals start with prescription from medical provider
  - Prescription contains important information that will be relevant throughout the appeals process, like name of the medication, dispensing instructions, and condition or illness for which the medication is being prescribed
  - Check that the prescription is correct because erroneous prescription cannot be corrected through the appeals process

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Using the Right Pharmacy

- Most, if not all, Part D plans have networks of pharmacies
- Within those networks, plans normally designate preferred and non-preferred pharmacies
- Individual will have better cost-sharing at preferred pharmacy
- Mail-order pharmacy may have different cost-sharing than retail pharmacy because mail-order pharmacies fill prescriptions for 90 days while traditional pharmacies fill them for 30 days
- Individuals should be aware of how the pharmacy they select will affect their pricing
  - If drug costs are high, it may not be a denial but rather an issue with their pharmacy

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Before Filing Appeal

- Beneficiary goes to pharmacy and learns plan will not cover prescription
  - Pharmacist tries to run the prescription and the plan does not authorize coverage, the pharmacist should provide a form called **Medicare Prescription Drug Coverage and Your Rights**
  - Notice provides instructions on filing an exception request with the plan, which is the first step of the appeal process
  - Notice is not a formal denial; an individual has to file an exception request first before they get an appealable denial
- Beneficiary goes to pharmacy and finds drug is too expensive

Contact the Plan

- Once an individual knows the plan did not authorize coverage, contact the plan and determine why
- Often pharmacist can do this quickly through the plan's pharmacy help desk
  - If not, individual can also call their plan
- Sometimes plan made a mistake that can be fixed at this stage
  - If not, individual should ask the plan exactly why they are not covering the drug and what information they would need in order to change that decision
- At this step it is also a good time to ensure that the pharmacist correctly coded the request and submitted it to the right plan

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Requesting Fast Appeal

- When individual needs drugs as soon as possible, they can request a fast appeal if they or their doctor feel that their health could be seriously harmed by waiting the standard timeline for a decision
- If doctor supports the decision to file an expedited exception request, the plan must follow the expedited timeline
  - Beneficiary can also request an expedited exception request without their doctor's support, but in this case, the plan does not have to follow the expedited timeline
- If the plan denies the request to expedite the process, then plan should notify the individual that they will process the appeal using the standard timeline, and that the individual can file an expedited grievance disputing the decision and refile a new expedited request
- If the plan grants the request to expedite the process, plan should send a decision to the individual within 24 hours of the initial exception request

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Exception Request

- Once individual is at the pharmacy and knows their plan is refusing to cover the medication, individual needs to file a formal exception request to ask the plan to cover their drug
- Individual should file appeal with plan within 60 days of date listed on denial notice
- Plan reviews the appeal and decides if it will cover the drug
  - Standard: Should issue decision within 7 days
  - Expedited: Should issue decision within 72 hours
- Two outcomes
  - Favorable decision: Plan will cover drug
  - Unfavorable decision: Beneficiary can move to the next level of appeal

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Exception Request Tips

- Individual should ask their prescribing doctor for help
  - Doctor should complete a generic Coverage Determination Request form (or contact the plan for a plan-specific version of the form)
- Include additional documentation with the exception request, such as proof of medical need
- Submit appeal in writing
  - Individual can keep a record of what they are submitting, ask for changes (if needed) with the doctors' documentation, and have a paper trail of submitting their requests and subsequent appeals on time

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Formulary Exception Requests: Off Formulary

- **Off-formulary exception request**
- Medicare drug plan may deny coverage for a prescription drug because it believes that the request does not match the plan's formulary
- Get a letter of support from prescribing physician that explains why individual needs the drug and, if possible, how other medications to treat the same condition would be ineffective or harmful to the individual.
- Make sure the letter is complete
  - Letter of support from prescribing doctor is vital to successful formulary exceptions
  - Try to make sure it is accurate, clearly identifies the relevant medications, and is comprehensive

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Formulary Exception Requests: Quantity Limits

- **Quantity limits exception request**
- Plans can limit coverage by a certain amount over a particular period of time
  - Example: Plan may only provide coverage for up to 30 pills per month of a certain type of medication
- To appeal a quantity limits denial, individuals should get assistance from the prescribing doctor in explaining and documenting why a larger quantity of the drug than the plan normally allows is needed

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Formulary Exception Requests: Prior Authorization

- **<u>Prior authorization exception request</u>**
- Plans can require that they authorize a claim ahead of time
- How to request prior authorization differs by plan, so individuals may want to ask their plan how to do so
- Doctors can often call the plan and request prior authorization on behalf of the individual
  - This strategy is helpful because prescribing doctor can also ensure the plan gets any medical documentation it needs

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Formulary Exception Requests: Step Therapy

- **Step therapy exception request**
- Plans can require an individual to try a different drug (almost always a less expensive one) first before they cover the prescribed drug
- To request an exception, prescribing doctor must provide documentation showing that the individual has either tried the other drug(s) or that it would be unsafe for them to do so

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Tiering Exception

- Individuals can request tiering exception from their drug plan to try and lower the cost of their drug
- Tiering exception is a formal request asking plan to move the drug to lower tier so that it will be more affordable
  - If plan approves the exception, it would normally grant it for the rest of the calendar year, although individuals can request a permanent exception
  - If the request is denied, individual can challenge that decision using the normal Part D appeals process
- Part D plans only have to approve a tiering exception if:
  - There is a drug on the lower tier approved for treating the same condition as the requested drug, and
  - Prescribing doctor provides a supporting statement saying lower tier drug would either not be as effective as requested drug or would have adverse side effects

Tiering Exception Limitations

- Plans do not have to grant tiering exceptions:
  - From a brand-name tier to a generic tier
  - From the specialty tier to a non-specialty tier
  - For drugs that were placed on the formulary after a formulary exception

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Off-Label

- Under federal law, Part D plans must only cover FDA-approved Part D drugs that are prescribed for "medically-accepted indications"
- Medicare has interpreted this narrowly to mean a use that is either:
  - FDA-approved; or
  - Supported by at least one of the two approved compendia, American Hospital Formulary Service-Drug Information (AHFSDI) and DRUGDEX
- Part D plans will deny drugs prescribed for off-label uses

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Off-Label Exception Request

- Determine whether the drug use is off label
  - Get a copy of the FDA label for the drug to ensure the drug is, in fact, not approved by the FDA for the prescribed use
- Check the compendia
  - Ask prescribing doctor to look for support for the use of the drug in the approved compendia (AHFS-DI and DRUGDEX)
  - If the doctor does not have access to the compendia, individuals can contact their local teaching hospitals, libraries (especially medical school libraries), or submit the appeal asking for the plan to review the compendia
- Include supplemental information when possible
  - Most commonly, off-label appeals are only successful when there is an FDA on-label use or there is support in the compendia
  - Include supplemental information showing that support

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Level 1: Request Redetermination

- If an individual's exception request is denied, they can begin the appeals process by requesting a redetermination
- Plan should send them a Notice of Denial of Medicare Prescription Drug Coverage which indicates that their exception request was denied
- Individual files appeal with plan within 60 days of date listed on denial notice
- Plan reviews the appeal and decides if it will cover the drug
  - Standard: Should issue decision within 7 days
  - Expedited: Should issue decision within 72 hours
- Two outcomes
  - Favorable decision: Plan will cover drug
  - Unfavorable decision: Beneficiary can move to the next level of appeal

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Level 2: Request Independent Review

- Individual files an appeal with an Independent Review Entity (IRE) within 60 days of date on unfavorable plan redetermination notice
- IRE reviews case
  - Standard: Should issue decision within 7 days
  - Expedited: Should issue decision within 72 hours
- Two outcomes
  - Favorable decision: Plan will cover drug
  - Unfavorable decision: Beneficiary can move to the next level of appeal

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Level 3: Request Review by Office of Medicare Hearings and Appeals (OMHA)

- Individual submits written request for OMHA appeal within 60 days of receiving the unfavorable reconsideration notice
  - CMS Request for Medicare Hearing form or beneficiary's own written request
  - Must meet amount in controversy: $180 in 2021
- OMHA receives request and sets time and place for hearing
  - Beneficiary receives Notice of Hearing 20 days before hearing
- Beneficiary attends hearing
- OMHA notifies beneficiary of decision by mail
  - Standard: Within **90 days** of hearing request
  - Expedited: Within **10 days** of hearing request

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Level 3: Request Review by OMHA

- Three outcomes
  1. Favorable decision
  2. Unfavorable decision
  3. OMHA does not make decision within 90 days
- Advocacy tip: do not be intimidated
  - Individuals who really need coverage for their medication may be afraid to file an OMHA appeal or think it is not worth their time
  - Process is specifically set up to help Medicare beneficiaries without legal counsel navigate the hearings themselves
  - Unless individual's appeal is totally without merit, it is often worth filing an appeal with OMHA even if the beneficiary does not have a legal advocate assisting them

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Level 4: Request Review by Medicare Appeals Council

- Individual requests Council review within 60 days of receiving unfavorable OMHA decision
- Appeal must reference the parts of the OMHA decision with which the beneficiary disagrees and explain why they disagree
- Council reviews existing written record
  - Individuals or their legal advocates can submit briefs to supplement the record
- Council reviews appeal
  - Standard: Should issue decision within **90 days**
  - Expedited: Should issue decision within **10 day**
- Three outcomes
  - Favorable decision: Plan will cover drug
  - Unfavorable decision: Beneficiary can choose to move to the next level of appeal
  - Council does not make decision within 90 days

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Level 5: Request Review in Federal District Court

- Individual requests Judicial Review in local U.S. Federal District Court within 60 days of receiving unfavorable Council decision
  - Must meet amount in controversy: $1,760 in 2021
- Federal District Court reviews appeal
  - No time frame for decision
- Two outcomes
  - Favorable decision: Plan will cover drug
  - Unfavorable decision: Beneficiary will have to pay for the drug

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Tips for Appealing (1 of 2)

- Keep copies and never send originals
  - In Medicare Rights' experience, it can be helpful to keep a copy of all documents sent and received during the appeals process. Medicare Rights advises its clients to never send the original copies of important documents.
- Follow appeal deadlines
- Request language and disability accommodations
  - Individuals with limited English proficiency or disabilities that affect their ability to communicate with their plan have a right to reasonable accommodations, such as materials in an alternative language or format.
  - Individual or their representative must request accommodation from the plan.
  - If request is ignored or denied, individual can file a grievance with the plan or a complaint online or with 1-800- MEDICARE.

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Tips for Appealing (2 of 2)

- Document
  - Take notes when anyone speaks to the plan (e.g., the plan employee's name, their phone number, the date/time of the call, and what was said). Keep track of when the doctor submits the request and copies of what they submitted.
- If needed, expedite
  - If prescribing doctor believes that individual's health could be seriously harmed by waiting the standard timeline for appeal decisions (plan has 72 hours to make a decision), they can request a fast appeal (plan has 24 hours to make a decision).

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Part B vs. Part D appeals

- Part B and Part D both cover outpatient prescription drugs
  - Part B drugs: Administered by doctor
  - Part D: Self-administered
- Part B and Part D drug denials do not use same appeal process
- Part B drug denials
  - Appeal using Original Medicare or Medicare Advantage appeal process
- Part D drug denials
  - Appeal using Part D appeal process
- Possible coverage problems
  - Part B drug billed to Part D

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Safety Edits

- Safety edits are stops put on coverage requests where the patient's safety may be threatened if the prescription is filled
  - Commonly found on opioids
- Soft edits: Pharmacist can use a code to override the catch
- Hard edit: Plan will have to provide prior authorization or make a coverage determination before the claim goes through
  - Pharmacist can attest to medical necessity and request an expedited determination

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Resolving Safety Edits

- Confer with the pharmacist about the cause of the edit and what is needed to override the edit
  - Pharmacists are provided with information on the edit when they attempt to send the claim to the Part D plan
  - If they need more information, pharmacist can also contact the plan through the plan's pharmacy help desk
- Determine whether pharmacist can override (soft edit) or needs to submit a coverage determination (hard edit)
  - Hard edit: submit the request by having the doctor fill out a Coverage Determination Request form along with the supplemental information (or contact the plan for a plan-specific version of the form)

Compounded Drugs

- Compounded drug: combination medication created by mixing or altering drug ingredients to create a custom medication for a particular patient
- Part D plans can choose to cover the costs associated with the Part D-drug component of a compounded drug, but will not cover compounds made from bulk powders, as these are not considered Part D drugs
- Only costs associated with those components (like labor costs from mixing drug) that satisfy the definition of a Part D drug are allowable costs under Part D

Resolving Compounded Drug Denial

- Determine whether the plan chooses to cover compounded drugs
  - Not all plans cover compounded drugs, so individual may want to check their plan materials or contact the plan to determine whether an appeal is viable or whether they should switch plans or medications
- Determine which parts of the drug should be covered
  - Even if plan covers portions of the compounded drug, it is likely it will not have to cover all portions
  - Even drugs that are normally covered are not covered if they are used in their bulk powder form (which is very common in compounding)

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Accessing Drugs Outside Appeals Process

- Transition refills
- Switching plans
- Switching drugs
- Paying out-of-pocket

Transition Refills

- Usually a one-time, 30-day supply of a prescribed drug
- Part D plans are required to cover and allow access to transition refill even if it is not on their formulary or even if there is a plan restriction on the drug.
- Beneficiaries who are in a long-term care facility, such as a nursing home, will be provided with all available refills during their first 90 days in the plan, instead of a one-time fill.
- The purpose of the refill "is to promote continuity of care and avoid interruptions in drug therapy." Thus, transition refills can only be requested within the first 90 days of coverage under a new plan.

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Switching Plans

- A helpful solution for many individuals facing issues accessing prescription medications is to simply switch plans. How quickly an individual can switch plans depends on their situation.
- Every Medicare beneficiary can switch plans during Fall Open Enrollment (which occurs each year from October 15 to December 7).
- Throughout the year, individuals may also be eligible for various Special Enrollment Periods (SEP). For example, individuals can qualify for SEPs when they move, if they become eligible for Medicaid, or if their Part C or Part D plan is ending.

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Extra Help

- Extra Help (also called the Low-Income Subsidy or LIS) is a federal program that helps pay for some of the out-of-pocket costs of Medicare prescription drug coverage.
  - It only provides cost-sharing assistance for drugs that are on an individual's formulary, so it is not generally helpful when an appeal is lost, except that it does provide an SEP for anyone who has Extra Help.
  - This SEP can be used once per calendar quarter during the first three quarters of the year (January through March, April through June, and July through September).

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Switching Drugs

- Medicare Rights counsels people in this situation to ask their provider about any generic forms or a similar drug on the plan’s formulary and for any samples they might be able to provide to help the person at least have a few doses while they search for a longer-term solution.

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Paying Out-of-Pocket (1 of 2)

- When everything else fails, a Medicare beneficiary can pay out-of-pocket for their medication
- There are a few ways to help reduce the price of medication that is not covered
  - Most of these require that the pharmacist bill the individual without submitting claim to the Part D plan
- Prescription assistance programs that can be found through:
  - NeedyMeds, Medicine Assistance Tool, and Rx Assist
  - Contacting organizations and foundations designed to assist people with specific medical conditions
    - Many of these programs focus on the uninsured, so they may not be available for someone with Part D
- Pharmacies may offer special promotions for certain drugs that will lower the cost
  - Some pharmacies also have discount programs for generics

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Paying Out-of-Pocket (2 of 2)

- Shop around for better prices on medications by contacting local pharmacies or using database, such as GoodRx
- Some manufacturers of drugs offer patient assistance programs for the uninsured
  - Often, people with Part D coverage cannot take advantage of these, but, on occasion, manufacturers will sometimes provide assistance
- Many localities have charity programs that provide assistance affording medication

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