Strategies for Obtaining Needed Medications When Health Plans Restrict Access

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Objectives

- Implement Medicare Part D entitlements that guarantee 30 to 120 days of access to restricted medications before a prior authorization is necessary
- Identify important elements that should be included in an explanation of medical necessity to accelerate approval
- Identify the language in the Medicare Part D rule, specific to long-term care, to support a request for coverage
- Differentiate healthcare providers and clinical records that should be consulted in the prior authorization process before the request is submitted

We’ve all had a similar experience …

What Does Medicare Part D Promise?

- Broad Formularies
  - Requires Part D formularies to be broad enough to not discourage enrollment by a group of beneficiaries.
- Part D sponsors will be required to provide *medically necessary prescription drug treatments*
  - Enrollees in the general Medicare population
  - Enrollees who reside in LTC facilities.
    - CMS expects Part D plans to provide coverage of dosage forms of drugs that are widely utilized in the LTC setting.

CMS. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Rev. 18, 01-15-16.

What Is a Part D Covered Drug?

- FDA approved prescription drug, biologic, or biosimilar
  - Not covered by Medicare Part A or B
  - Not specifically excluded from coverage
- **Prescribed for a medically-accepted indication**
  - Any FDA-approved indication
  - An indication included in an approved compendia
    - American Hospital Formulary Service Drug Information
    - DRUGDEX® Information System
  - Part D plans should use utilization management (e.g., prior authorization) for drugs likely to be used for “off-label” or “not medially-acceptable” indications to ensure drugs are only covered for medically-acceptable indications
- On the Part D plan’s formulary or treated as such via coverage determination or appeal

Excluded Drugs

- Agents when used for anorexia, weight loss, or weight gain
- Fertility agents
- Erectile dysfunction agents unless used for FDA-approved, non-ED use
- Cosmetic purposes or hair growth agents
- Cough and colds agents
- Prescription vitamins and mineral products
- Nonprescription drugs.

CMS. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Rev. 18, 01-15-16.

So Why Do Part D Plans Cover Drugs for Off-Label Uses?

But place restrictions on covering drugs that are being used for on-label, medically-appropriate uses …

Utilization Management

- **Prior Authorization** (aka Coverage Exception)
  - Applies to formulary drugs.
  - Limits coverage of a drug to patients who meet certain requirements.
    - *If patient meets coverage criteria, the plan **WILL** cover requested drug.*
- **Step Therapy** (a type of Prior Authorization)
  - Applies to formulary and non-formulary drugs.
  - Must first try a less expensive drug on the plan's formulary, that's been proven effective for most people with the same condition, before the patient can obtain a more expensive drug.
    - *If patient has tried and failed formulary drugs or cannot tolerate them, the plan **WILL** cover requested drug.*
- **Quantity Limits**
  - Applies to formulary drugs, usually set at the highest on-label dosage per day.
  - For safety and cost reasons, plans may limit the amount of prescription drugs they cover over a certain period (usually 30 or 90 days).
    - *If patient has a medically-acceptable need for higher doses, the plan **MAY** cover requested quantity.*
- **Not on Formulary**
  - Applies to non-formulary drugs.
  - Must prove medical necessity and failed attempts or intolerability of formulary drug options.
    - *If patient has a medically-acceptable need for the non-formulary drug, the plan **MAY** cover requested drug.*

CMS. Medicare.gov. https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover/drug-plan-coverage-rules#:~:text=Prior%20Authorization,that%20you%20meet%20certain%20requirements. Accessed September 24, 2024.

Prior Authorization Form (also Formulary Exception Request)

Enrollee's Information

Enrollee's Name _____ Date of Birth _____

Enrollee's Address _____

City _____ State_____ Zip Code _____

Phone _____ Enrollee's Member ID # _____

Complete the following section ONLY if the person making this request is not the enrollee or prescriber:

Requestor's Name _____

Requestor's Relationship to Enrollee _____

Address _____

City _____ State_____ Zip Code _____

Phone _____

Representation documentation for requests made by someone other than enrollee or the enrollee's prescriber:

Attach documentation showing the authority to represent the enrollee (a completed Authorization of Representation Form CMS-1696 or a written equivalent). For more information on appointing a representative, contact your plan or 1-800-Medicare (1-800-633-4227), TTY: 1-877-486-2048, 24 hours per day, 7 days a week.

Name of prescription drug you are requesting (if known, include strength and quantity requested per month):

Type of Coverage Determination Request

- ☐ I need a drug that is not on the plan's list of covered drugs (formulary exception).*
- ☐ I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (formulary exception).*
- ☐ I request prior authorization for the drug my prescriber has prescribed.*
- ☐ I request an exception to the requirement that I try another drug before I get the drug my prescriber prescribed (formulary exception).*
- ☐ I request an exception to the plan's limit on the number of pills (quantity limit) I can receive so that I can get the number of pills my prescriber prescribed (formulary exception).*
- ☐ My drug plan charges a higher copayment for the drug my prescriber prescribed than it charges for another drug that treats my condition, and I want to pay the lower copayment (tiering exception).*
- ☐ I have been using a drug that was previously included on a lower copayment tier, but is being moved to or was moved to a higher copayment tier (tiering exception).*
- ☐ My drug plan charged me a higher copayment for a drug than it should have.
- ☐ I want to be reimbursed for a covered prescription drug that I paid for out of pocket.

***NOTE: If you are asking for a formulary or tiering exception, your prescriber MUST provide a statement supporting your request. Requests that are subject to prior authorization (or any other utilization management requirement), may require supporting information. Your prescriber may use the attached "Supporting Information for an Exception Request or Prior Authorization" to support your request.**

Additional information we should consider *(attach any supporting documents)*:

Important Note: Expedited Decisions

If you or your prescriber believe that waiting 72 hours for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 72 hours could seriously harm your health, we will automatically give you a decision within 24 hours. If you do not obtain your prescriber's support for an expedited request, we will decide if your case requires a fast decision. You cannot request an expedited coverage determination if you are asking us to pay you back for a drug you already received.

☐ **CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 24 HOURS**
(If you have a supporting statement from your prescriber, attach it to this request).

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that documentation supporting this information is available for review if requested by the health plan sponsor, or, if applicable, a state or federal regulatory agency. I understand that any person who knowingly makes or causes to be made a false record or statement that is material to a claim ultimately paid by the United States government or any state government may be subject to civil penalties and treble damages under both the federal and state False Claims Acts. *See, e.g.*, 31 U.S.C. §§ 3729-3733.

Signature of person requesting the coverage determination (the enrollee, or the enrollee's prescriber or representative):

_____ **Date:**_____

Type of Coverage Determination Request

FORMULARY and TIERING EXCEPTION requests cannot be processed without a prescriber's supporting statement. PRIOR AUTHORIZATION requests may require supporting information.

☐ **REQUEST FOR EXPEDITED REVIEW: By checking this box and signing below, I certify that applying the 72 hour standard review timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.**

Prescriber's Information

Name _____

Address _____

City _____ State _____ Zip Code _____

Office Phone_____ Fax _____

Prescriber's Signature _____ **Date**_____

Diagnosis and Medical Information

Medication:	Strength and Route of Administration:	Frequency:
New Prescription OR Date Therapy Initiated:	Expected Length of Therapy:	Quantity:
Height/Weight:	Drug Allergies:	Diagnosis:

Rationale for Request

☐ **Alternate drug(s) contraindicated or previously tried, but with adverse outcome, e.g., toxicity, allergy, or therapeutic failure** Specify below: (1) Drug(s) contraindicated or tried; (2)

Type of Coverage Determination

- ❑ I need a drug that is not on the plan's list of covered drugs (Non-formulary Exception)
- ❑ I have been using a drug that was previously included on the plan's list of covered drugs, but is being removed or was removed from this list during the plan year (Non-formulary Exception)
- ❑ I request prior authorization for the drug my prescriber has prescribed (Prior Authorization)
- ❑ I request an exception to the requirement that I try another drug before I get the drug my prescriber prescribed (Step-Therapy Exception)
- ❑ I request an exception to the plan's limit on the number of pills (quantity limit) I can receive so that I can get the number of pills my prescriber prescribed (Quantity Limit Exception)
- ❑ My drug plan charges a higher copayment for the drug my prescriber prescribed than it charges for another drug that treat my condition, and I want to pay the lower copayment (Tiering Exception)
- ❑ I have been using a drug that was previously included on a lower copayment tier, but is being moved to or was moved to a higher copayment tier (Tiering Exception)
- ❑ My drug plan charged me a higher copayment for a drug than I should have.
- ❑ I want to be reimbursed for a covered prescription drug that I paid for out of pocket.

NOTE: If you are asking for a formulary or tiering exception, your PRESCRIBING PHYSICIAN must provide a statement to support your request. You cannot ask for a tiering exception for a drug in the plan's Specialty Tier. In addition, you cannot obtain a brand name drug at the copayment that applies to generic drugs.

https://www.cms.gov/files/document/modelcoveragedeterminationrequestformpdf

Expedited Decision

Patient or Prescriber

- If you, or your prescribing physician, believe that waiting for a standard decision (which will be provided within 72 hours) could seriously harm your life or health or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescribing physician asks for a faster decision for you,or supports you in asking for one by stating (in writing or in a telephone call to us) that he or she agrees that waiting 72 hours could seriously harm your life or health or ability to regain maximum function, we will give you a decision within 24 hours. If you do not obtain your physician's support, we will decide if your health condition requires a fast decision.

☒ I need an expedited coverage determination (attach physician's supporting statement, if applicable)

Prescriber

FORMULARY and TIERING EXCEPTION requests cannot be processed without a prescriber's supporting statement. PRIOR AUTHORIZATION requests may require supporting information.

☒ REQUEST FOR EXPEDITED REVIEW: By checking this box and signing below, I certify that applying the 72-hour standard review timeframe may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

F756 requires medications to be available in a timely manner (interpreted as the next dose or day). CMS states "as a matter of general practice, LTC facility residents must receive their medications as ordered without delay" .

https://www.cms.gov/files/document/modelcoveragedeterminationrequestformpdf

CMS. State Operations Manual. Appendix PP. Guidance to Surveyors for Long Term Care Facilities. Rev 211 02-03-23

Supporting Information

- Diagnosis and Medical Information
  - Medication, Strength, Route of Administration of requested drug
  - Date Started (check if *new start*)
  - Expected Length of Therapy
  - Patient Height/Weight
  - Drug Allergies
  - Diagnosis – list all diagnoses treated with requested drug w/ICD-10 codes
    - If the condition being treated is a symptom, provide the diagnosis causing the symptoms (if known)
  - Other RELAVENT DIAGNOSES
  - DRUG HISTORY
    - Drug name, dose, total daily dose
    - Dates of drug trial
    - Describe Failure or Intolerance
  - Current drug regimen for the condition requiring the requested drug

It is valuable to list ALL diagnoses present in a NF resident as multiple-comorbidities documents resident frailty and may trigger a more thoughtful medical review.

Nursing staff can provide this information from the NF resident's chart. LTC pharmacy may also have this history.

Rationale For Request

- ❑ Alternate drug(s) contraindicated or previously tried, but with adverse outcome
- ❑ Patient is stable on current drug(s); high risk of significant adverse clinical outcome with medication change
  - Explain anticipated significant adverse clinical outcome and why it is expected (e.g., falls, hospitalization, undue pain or suffering, significant limitation of functional status)
- ❑ Medical need for different dosage form and/or higher dosage
- ❑ Request for formulary tier exception
- ❑ Other (explain below)
- ❑Required Explanation

Ms/Mr [name] is a frail, [age], nursing home patient with [#] comorbidities who requires [drug] to treat [condition]. S/he has previously tried alternate medications listed in the Drug History and [is unable to tolerate] or [failed to achieve an acceptable response]. [Drug] is necessary due to [reasons] and its use is supported by [clinical practice standard]. A delay in receiving [drug] is expected to worsen her condition] and may result in significant harm or require the need to hospitalize Ms/Mr [name].

Beneficiaries Residing in Nursing Facilities Have Special Benefits

Transitional Supply

- Plans must provide a 90-day transitional supply (up to 98-days) for all non-formulary or prior authorization drugs when a beneficiary changes from a plan covering that drug to a plan restricting access.

- Anytime within the first 90 days of participation in a new Part D plan
- Provides up to 98 days of covered medication before PA required

Emergency Supply

- Plans must provide up to a 31-day supply of a non-formulary or prior authorization drug while coverage authorization is sought

- Resident can start medication prior to coverage determination
- LTCP is guaranteed payment
- Provides up to 31 days to process prior authorization
- Can be in addition to the transition supply

Ongoing Enrollment

- Residents can change their Part D plan upon admission or discharge and anytime while residing in the nursing care center

- Allows the resident to always select a Part D plan that better covers the medications they need

1. CMS. Part D Manual Chapter 6.v.011. September 2016.
2. Medicare.gov. Special circumstances (Special Enrollment Periods) _ Medicare. https://www.medicare.gov/basics/get-started-with-medicare/get-more-coverage/joining-a-plan/special-enrollment-periods. Accessed September 16, 2024.
3. CMS Part D Manual. Chapter 3. PDP Enrollment and Disenrollment Guidance. June 2017.

Transitional Supply

Purpose

To promote continuity of care and avoid interruptions in ongoing drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated.

Benefits

1. New enrollees into prescription drug plans
2. Enrollees who switch from one plan to another after the start of the contract year
3. Current enrollees affected by negative formulary changes across contract years
4. Enrollees residing in LTC facilities

Ensures Access to

1. Part D drugs that are not on a sponsor's formulary
2. Drugs previously approved for coverage under an exception once the exception expires
3. Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a plan's utilization management requirements

Time Frame

- Within the first 90 days of enrollment in a new prescription drug plan

Amount Covered

- Nursing Facility Beneficiary: 90-day supply (up to 98-day supply depending on dispensing system)
- All Other Beneficiaries: 30-day supply (may be less if the prescription is for a lesser day's supply)

CMS. Medicare Prescription Drug Benefit Manual. Chapter 6 – Part D Drugs and Formulary Requirements. Rev. 18, 01-15-16.

Emergency Supply

Purpose

- To ensure nursing facility residents receive their medications as ordered without delay

Benefits

- Enrollees residing in a nursing facility

Ensures Access to

- Restricted drugs, including non-formulary drugs and drugs with a prior authorization or step-therapy requirement

Time Frame

- Anytime during the plan year, or
- After the 90-day transition supply if a new Part D plan enrollee is already taking the drug

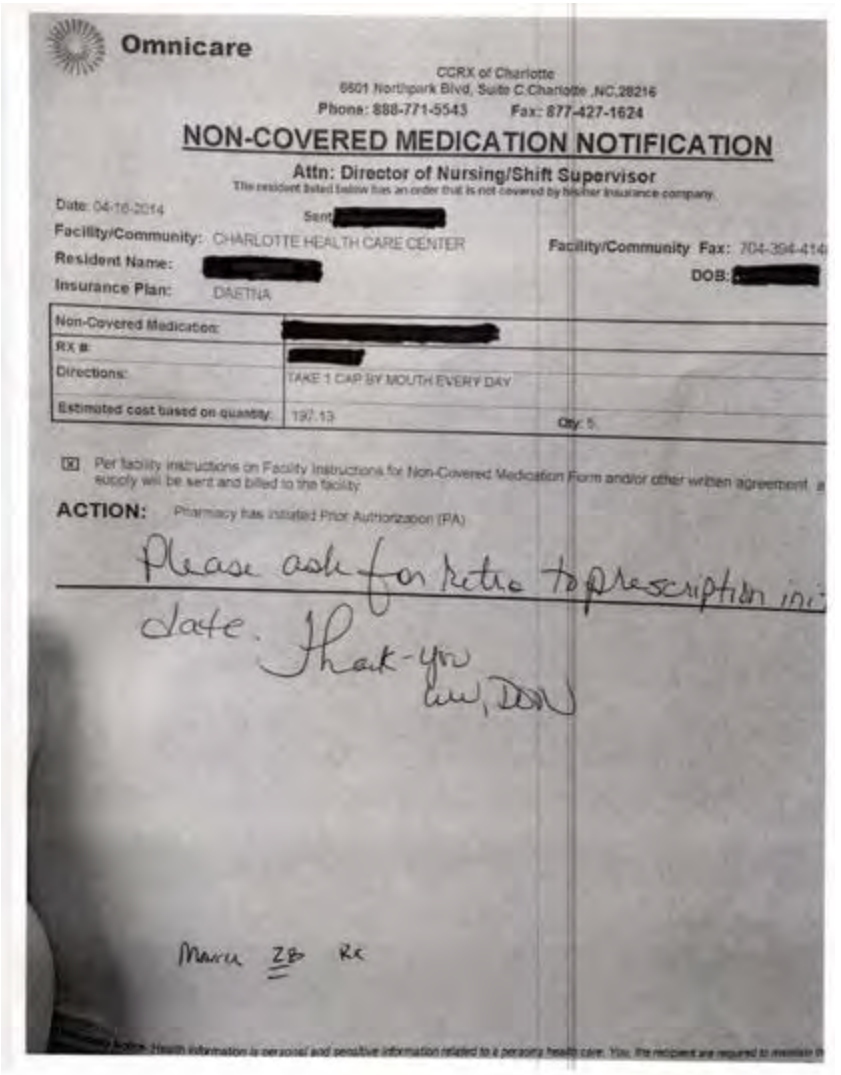
Amount Covered

- 31-day supply (may be less if the prescription is for a lesser day's supply)
- A Part D plan does not have to provide more than a one-time 31-day emergency fill of a particular drug per LTC stay

LTC Pharmacy Must Bill Part D Plan for Transitional Supply or Emergency Supply

What you can do …

- Instruct LTC Pharmacy to bill the Part D plan *before* sending a prior authorization request or a "non-covered medication" form.
- Instruct LTC Pharmacy to notify facility of "non-covered medication" status *only after* receiving confirmation from the Part D plan.
- Work with facility to amend the pharmacy agreement to require billing Part D plan for transitional supply or emergency supply.
- Require medication coverage communication from the LTC pharmacy to be resident-centric.
  - Replace "Non-Covered Medication Notification" with "Medication Coverage Concern"
  - Remove check-box stating 3-day supply will be sent and billed to facility
  - Add
    - ❑ Transitional supply sent. Coverage will end on _(date) . Please submit for coverage exception to the resident's Part D plan prior to this date.
    - ❑ Emergency supply sent. Coverage will end on _(date) . Please submit for coverage exception to the resident's Part D plan prior to this date.
    - ❑ Plan has denied the request for coverage exception. Please consider changing to __(drug)__, which is a formulary alternative covered by the plan. If medication is continued without Part D plan coverage, the cost will be __($ amount)_ and will be billed to the __ resident / __ facility.



Omnicare

CCRX of Charlotte
6601 Northpark Blvd, Suite C Charlotte ,NC,28216
Phone: 888-771-5543 Fax: 877-427-1624

NON-COVERED MEDICATION NOTIFICATION

Attn: Director of Nursing/Shift Supervisor

The resident listed below has an order that is not covered by his/her insurance company.

Date: 04-16-2014 Sent: [redacted]

Facility/Community: CHARLOTTE HEALTH CARE CENTER Facility/Community Fax: 704-394-414

Resident Name: [redacted] DOB: [redacted]

Insurance Plan: DAETNA

Non-Covered Medication:	[redacted]
RX #:	[redacted]
Directions:	TAKE 1 CAP BY MOUTH EVERY DAY
Estimated cost based on quantity:	197.13 Qty: 5

☒ Per facility instructions on Facility Instructions for Non-Covered Medication Form and/or other written agreement a supply will be sent and billed to the facility

ACTION: Pharmacy has initiated Prior Authorization (PA)

Please ask for retro to prescription in date. Thank-you Lm, DON

Maria ZB RC

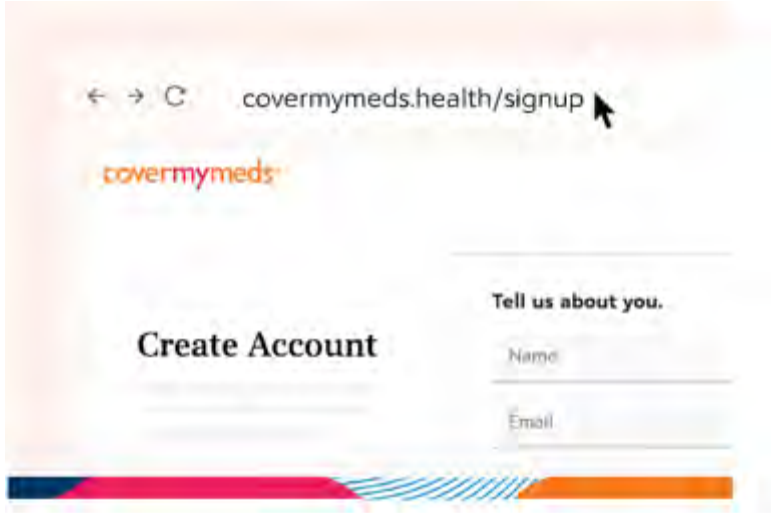
Writing a Compelling Coverage Request

Ms/Mr [name] is a frail, [age], nursing home patient with [comorbidities] who requires [drug] to treat [condition]. S/he has previously tried alternate medications listed in the Drug History and [is unable to tolerate] or [failed to achieve an acceptable response]. [Drug] is necessary due to [reasons] and its use is supported by [clinical practice standard]. A delay in receiving [drug] is expected to worsen her condition] and may result in significant harm or require the need to hospitalize Ms/Mr [name].

- Use the resident's name
- State their age
- Mention/describe their frailty (if appropriate)
- State that they are a nursing home resident
- List all comorbidities
- List other medications tried for condition (if appropriate) and primary concern with each drug
- State reason for requested drug
- State clinical practice standard (be as specific as you can)

Who Can Assist With a Request for a Coverage Exception

- Nursing facility DON / staff can
  - Provide demographic information
  - Provide current diagnoses list
  - Provide historical information on drugs tried and resident's failure to respond or intolerance
- LTC Pharmacy can
  - Initiate coverage exception request in CoverMyMeds
  - Provide historical information on drugs tried
- Office staff can
  - Complete coverage exception request for your signature/e-sig
  - Monitor for response from Part D plan
  - Notify LTC Pharmacy and nursing facility of response



What To Do When a Plan Says “No” … Appeal

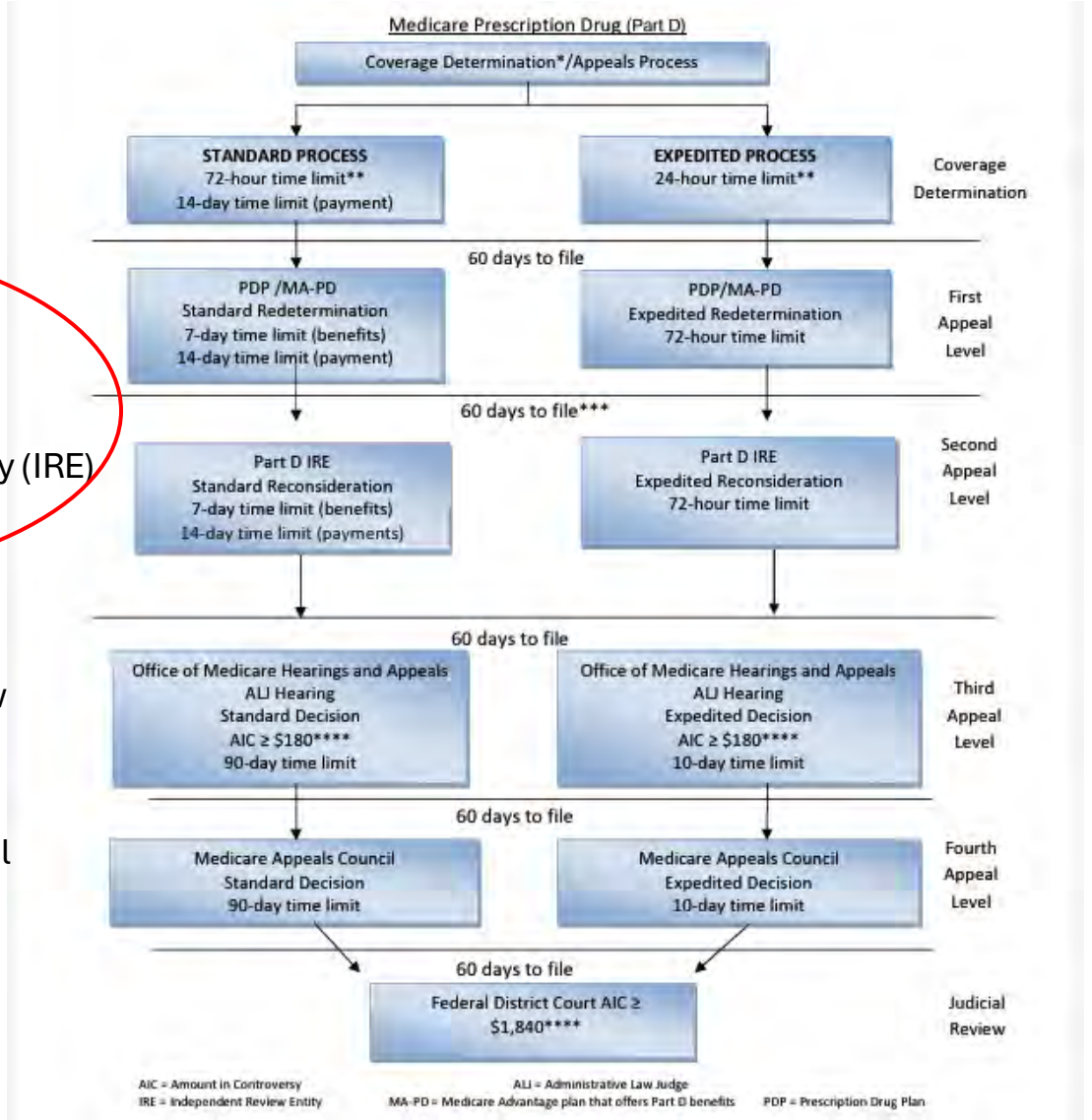
Level 1 – Part D Redetermination

Level 2 – Independent Review Entity (IRE) Reconsideration

Level 3 – OMHA Administrative Law Judge Hearing

Level 4 – Medicare Appeals Council

Level 5 – Federal District Court Judicial Review



One for the road...

One more for the road…

Dr. Glaucomflecken is the online persona of Dr. Will Flanary, a U.S.-based ophthalmologist, comedian and cancer survivor.