CLL SOCIETY

Smart Patients Get Smart Care™

MEDICARE PART D IN 2026: WHAT PATIENTS NEED TO KNOW

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SPEAKERS

Saira Sultan
JD
(SPEAKER)

President & CEO
Connect 4 Strategies
Director of Government Affairs & Public Policy
CLL Society

Kay Scanlan
JD
(SPEAKER)

Principal
Consilium Strategies

Perla Salazar
(WELCOME)

Program Coordinator
CLL Society

TODAY'S DISCUSSION WILL FOCUS ON:

What has changed in Medicare for 2026?

How Part D plans and sponsors appear to be responding to changes in their financial liability due to Part D benefit redesign

What is utilization management?

Step therapy for BTK inhibitors and National Comprehensive Cancer Network (NCCN) revised CLL guidelines

What to do if you are told your plan "denied" coverage for your CLL treatment

WHY THIS MATTERS

Medicare rules and changes in financial responsibilities/incentives can directly affect whether you receive the treatment your doctor recommends

Plans may delay, deny, or restrict access through administrative requirements

These barriers most often affect high-cost cancer therapies like BTK inhibitors

Understanding how the system works helps you respond quickly and effectively

KEY TERMS IN PLAIN LANGUAGE

Formulary – The list of prescription drugs your plan agrees to cover

MA or Medicare Advantage – an optional alternative to traditional Medicare that relies on insurers to cover beneficiary medical costs

Prior Authorization (PA) – Your plan must approve a drug before it will pay for it

Step Therapy – You must try a plan-preferred drug first, and have it "fail" or be unable to tolerate it before another is covered

Copay vs. Coinsurance – A copay is a fixed dollar amount; coinsurance is a percentage of the drug's price, often higher for specialty drugs

KEY TERMS IN PLAIN LANGUAGE (CONT'D)

Organization Determination – A plan's formal coverage decision; getting one triggers your right to appeal

Expedited Exception – A fast-tracked request to cover a drug the plan normally wouldn't; urgent decisions come within 24–72 hours

Medicare Prescription Payment Plan (MPPP) – Lets you spread your out-of-pocket drug costs across the year instead of paying all at once

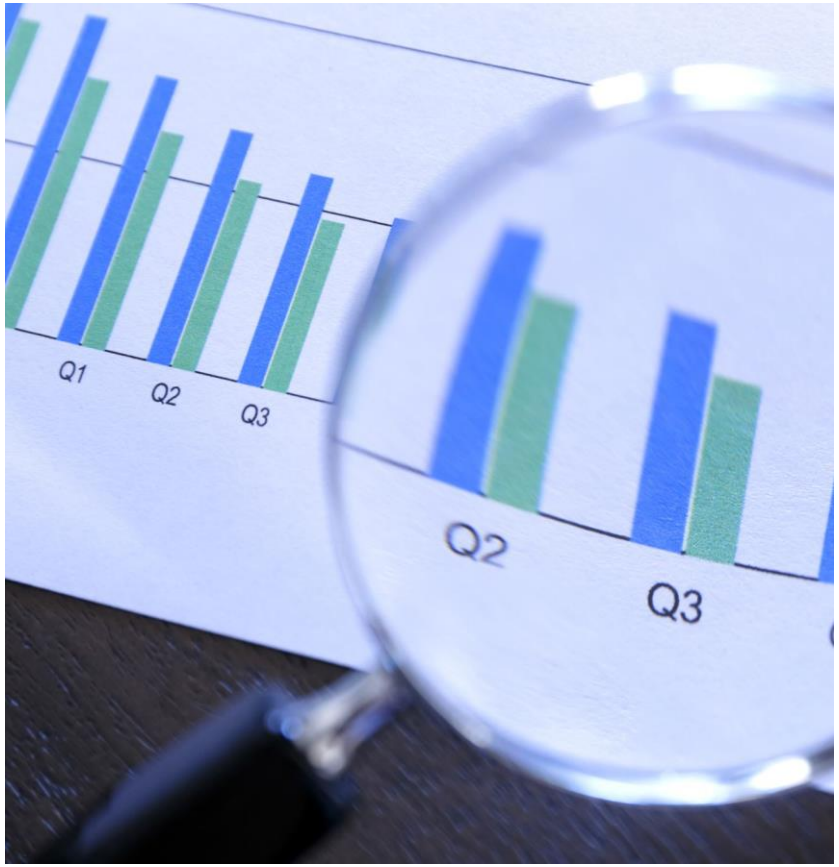
Protected Class – Categories of drugs, including cancer treatments, that Part D plans must cover broadly

WHAT'S CHANGED IN 2026?

- New Part D benefit redesign lowered 2025 annual out-of-pocket cost for prescription drugs to $2000; 2026 cap is $2100
- Medicare Prescription Payment Plan allows costs to be spread across the year and individuals remaining in the same plan are automatically re-enrolled
- When plans change their formularies or coverage criteria, they must provide written notice to beneficiaries. Beneficiaries have the right to appeal the change
- Centers for Medicare and Medicaid Services (CMS) proposed a more relaxed "special enrollment period" for Medicare Advantage (MA) enrollees but declined to finalize the change
- Drug pricing models (GLOBE, GUARD) are still proposed and not currently active

PART D PLANS ARE ADAPTING TO CHANGING FINANCIAL LANDSCAPE

- **Market Consolidation and Plan Closures**: The number of standalone prescription drug plans (PDPs) is decreasing by 22% (from 464 to 360) as carriers abandon unprofitable regions to focus on Medicare Advantage (MA-PD) plans.
- **Increased Deductibles and Cost-Sharing**: Some plans are raising deductibles to the allowable maximum ($615 in 2026, up from $590 in 2025) and shifting from copays to coinsurance for high-cost drugs to control exposure to expensive treatments.
- **Increased Utilization Management**: Plans are aggressively implementing utilization management tools such as prior authorization, step therapy, and restricted formularies to limit usage of high-cost specialty drugs.



POLL QUESTION

PLANS MAY USE MORE AGGRESSIVE TACTICS TO STEER PATIENTS TOWARD (OR AWAY FROM) CERTAIN DRUGS

Tiering Disparities: Plans may place negotiated drugs and other drugs with less favorable financial factors on less favorable tiers

Initial Claim Denials: Recent studies show that over 70% of specialty claims in chronic conditions face initial denials, often requiring 2–3 appeals before approval

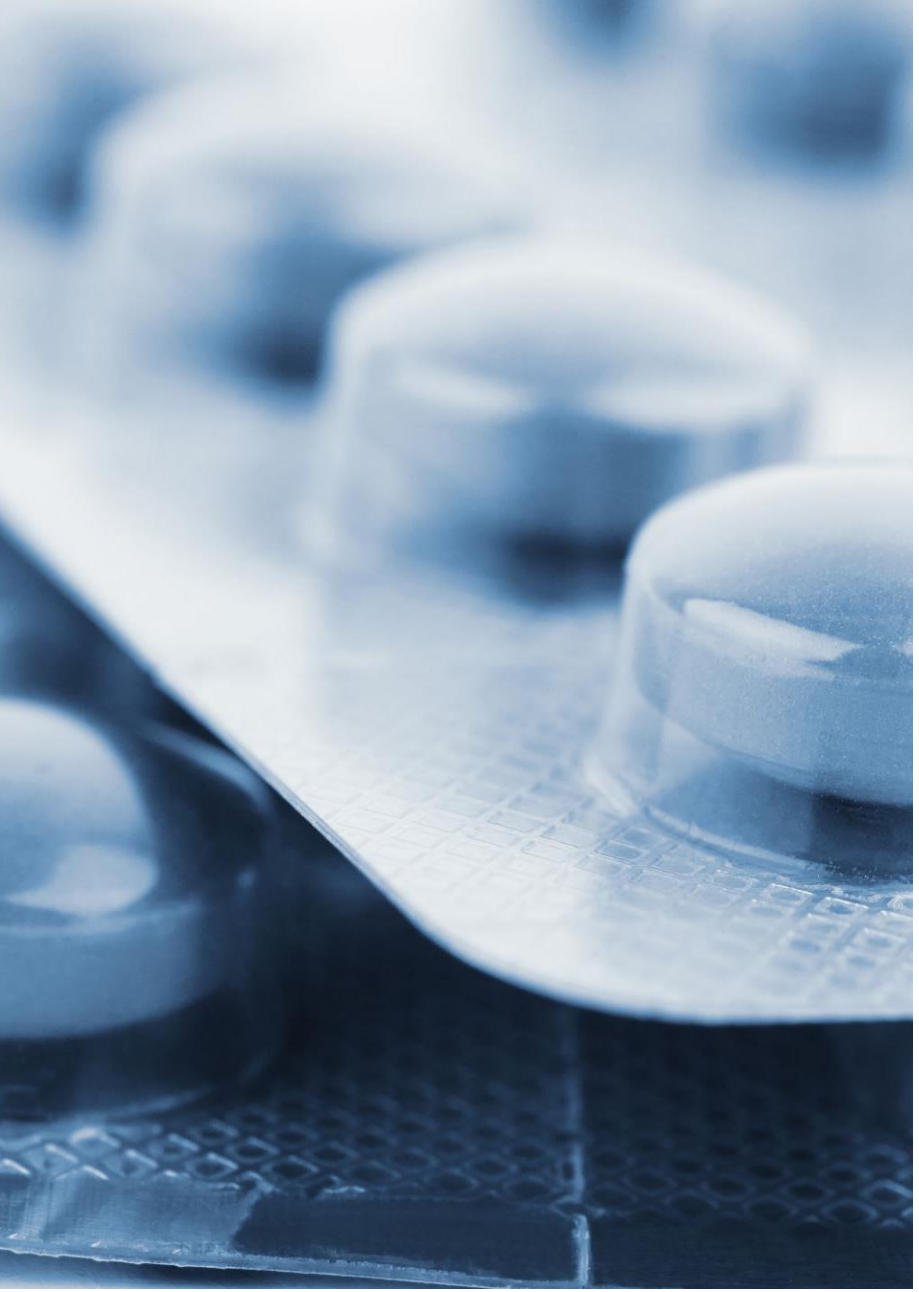
Prior Authorization (PA) Gaps: Even for patients stable on a drug, new PA requirements can trigger at the start of the year, potentially causing a 5–10-day treatment gap

WHAT IS UTILIZATION MANAGEMENT?

Utilization management refers to processes insurers use to control access to treatments

Common tools include prior authorization, step therapy, and quantity limits

They can create delays or barriers even when treatment is medically appropriate



2026 UTILIZATION MANAGEMENT TRENDS

- **Increased Prior Authorization (PA)**: The use of PAs for brand-name drugs is rising, with 75-100% of specialty drugs likely to be subject to PA
- **Expansion of Step Therapy**: Plans are increasingly requiring patients to try lower-cost alternatives (like generics or “preferred” drugs in the same class) before covering non-preferred medications
- **New "Negotiated Drug" Controls**: Plans must cover all 10 drugs (e.g., ibrutinib) selected for the first round of Medicare price negotiation. Plans are applying new UM strategies like **step therapy** or changing tier placements to manage the impact of replacing rebates (savings go to plan) with CMS-negotiated prices

WHO DECIDES YOUR TREATMENT?

You and Your Doctor

- Evaluates your condition
- Understands your previous treatments, if any
- Considers side effects
- Considers your preferences and lifestyle
- Knows your medical history, including co-conditions
- Selects treatment

Your Insurance

- May decide which treatment is best for all patients with your condition based on financial factors
- Applies step therapy
- For high-cost treatments, may ask for “proof” that you need the prescribed medication (prior authorization)
- May prefer lower-cost drug
- Network and out-of-network pharmacies (where you get your treatment)

POLL QUESTION

STEP THERAPY IS A PROBLEM IN CLL

- Step therapy requires patients to try one drug before accessing another
- It is the clearest “case” of your insurer, not your clinician, making treatment decisions
- In CLL, treatment decisions are highly individualized and patient-specific
- BTK inhibitors differ in side effects, tolerability, and effectiveness
- Forcing patients to ‘fail first’ can lead to unnecessary risk and delay optimal care
- NCCN Guidelines on BTK inhibitors for CLL state that treatment decisions should be made by the treating clinician based on patient-specific factors and that the BTK inhibitors **are not interchangeable**
    - **This makes step therapy for BTK inhibitors not just “a problem” but against explicit CMS instructions that plans cannot have coverage criteria that conflict with NCCN guidelines**

FIGHTING "STEP THERAPY" DENIALS FOR BTK INHIBITORS

The Challenge: Why the Denial Happens

- **Cost Control:** Many Part D plans prefer ibrutinib, zanubrutinib or acalabrutinib over the others because they may have lower negotiated prices (Maximum Fair Price or MFP) or higher rebates for the plan
- **"Step Edit" Requirement:** The plan's computer system may automatically reject a claim, requiring you to try and "fail" a different BTK inhibitor first

The Tool: The NCCN Updated CLL Clinical Guidelines

- **Standard of Care:** The NCCN Guidelines now explicitly state that covalent BTK inhibitors (ibrutinib, zanubrutinib, acalabrutinib) are not interchangeable
- **Why It Matters:** This clinical distinction means a plan cannot legally or medically claim that one is an equivalent of or an exact substitute for the other

FIGHTING "STEP THERAPY" DENIALS FOR BTK INHIBITORS (CONT'D)

The Action Plan: How to Appeal

- **Immediate Appeal** (The "Clinical Exception"):
  - Have your doctor file an **Expedited Clinical Exception Request**
  - **The Key Language:** Ensure the appeal includes the phrase: *"Per NCCN Guidelines, these BTK inhibitors are not interchangeable; switching based on cost violates the standard of care for CLL treatment."*
  - Standard of Care: Clinician and patient choose based on patient-specific factors. The NCCN Guidelines now explicitly state that covalent BTK inhibitors (ibrutinib, zanubrutinib, acalabrutinib) are not interchangeable

WHAT TO DO IF YOUR BTK INHIBITOR IS DENIED OR TOO EXPENSIVE

STEP 1: Don’t Walk Away (The "Pause" Phase)

- If you are asked to pay more than you expected but are (or are interested in) participating in the “payment program”, ask the pharmacist: *"Am I successfully enrolled in the Medicare Prescription Payment Plan (MPPP) for this fill?"*
- Ask for the "Reject Code": Ask the pharmacist for the specific insurance rejection code (e.g., "Prior Authorization Required" or "Step Therapy")

STEP 2: Immediate Troubleshooting

- **The 3-Day Emergency Supply:** Ask the pharmacist: *"Can you provide a 3-day emergency supply while we resolve this?"* (Many Part D plans allow this for "protected class" oncology drugs)
- **Call Your Oncology Team:** Do not wait. Tell the clinic’s specialty pharmacy coordinator or nurse navigator (or other office staff) immediately that there is a "dispensing delay."

WHAT TO DO IF YOUR BTK INHIBITOR IS DENIED OR TOO EXPENSIVE (CONT'D)

STEP 3: Escalation (The "Resolution" Phase)

- **Request an "Expedited Exception":** If the plan requires a different drug (Step Therapy), your doctor can file an Expedited Clinical Exception. The plan must respond within 24 hours.
- **Contact the Patient Navigator:** Reach out to the drug manufacturer's support program. They often have "bridge programs" to provide free drug if insurance paperwork is stalled.

POLL QUESTION

FIXED-DURATION BTKI + VENETOCLAX: A DIFFERENT TREATMENT PATH

Some patients are prescribed a time-limited combination of a BTK inhibitor plus venetoclax – taken for a set number of months, then stopped.

- **All-oral, fixed-duration:** Acalabrutinib + venetoclax was FDA-approved in February 2026 as the first all-oral, fixed-duration regimen for previously untreated CLL/SLL; ibrutinib + venetoclax is also used
- **A defined timeline:** Treatment runs roughly 12 to 14 months and then stops, offering a treatment-free period instead of indefinite daily therapy
- **Two drugs, two sets of rules:** Because the regimen pairs two high-cost specialty drugs, each can carry its own prior authorization, tier, and coverage criteria under Part D
- **Backed by guidelines:** NCCN lists these BTK inhibitor + venetoclax combinations as recommended options for CLL/SLL

PROTECTING YOUR ACCESS TO A FIXED-DURATION COMBO

- **Expect prior authorization on both drugs:** The plan may require separate approvals for the BTK inhibitor and for venetoclax, so start the paperwork before treatment begins
- **Watch the venetoclax ramp-up:** Venclexta starts low and steps up over a 5-week schedule; quantity limits at the pharmacy can flag these changing doses, so confirm each fill is approved
- **Mid-treatment switches are especially harmful:** The combo is a planned sequence, so a step-therapy demand to swap drugs partway through can disrupt the whole regimen. A mid-year coverage cut must now be treated as an organization determination with formal notice and appeal rights

PROTECTING YOUR ACCESS TO A FIXED-DURATION COMBO (CONT'D)

- **Use expedited appeals:** If either drug is denied, your doctor can file an expedited clinical exception; urgent Part D decisions generally come within 24 to 72 hours
- **Plan for the treatment-free phase:** Once the course ends, confirm with your team what follow-up monitoring is covered

NEW 2026 APPEALS PROTECTIONS

- **Protection Against Sudden Mid-Year Cuts**: If your plan attempts to stop or reduce coverage for your BTK inhibitor during the year they must now officially treat this as an "**organization determination**." This requires them to provide a formal notice and grants you immediate appeals rights
- **Faster Dispute Resolution**: Because oncology care is time-sensitive, the rule supports your ability to request expedited appeals. If a plan refuses to continue your current therapy, they generally must issue a decision within **24 to 72 hours** for urgent Part D cases
- **Support for "Grandfathering"**: While not an absolute guarantee, the clarification makes it harder for plans to abruptly switch you to a different drug (step therapy) if you are already stabilized on a specific BTK inhibitor

TAKEAWAYS

- Changes in Medicare drug payment rules will continue to push changes in Part D plan behaviors
  - Burdensome processes can overwhelm clinicians
  - A plan's "preferred" treatment may not be the best for you
- Understanding "the system" and how to work within it empowers patients and care partners as advocates

AUDIENCE Q&A

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