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MEDICARE PART D IN 2026: WHAT PRESCRIBERS NEED TO KNOW

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TODAY'S DISCUSSION WILL FOCUS ON:

What has changed in Medicare for 2026 — and what is coming in 2027, 2028 and beyond

How Part D and Medicare Advantage plans are responding to their changing financial liability

Real-world implications of MFP effectuation and associated dispensing challenges

Utilization management: prior authorization, step therapy, and what it costs your practice

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

CMS' draft guidance on effectuating the Part B Maximum Fair Price through the Medicare Transaction Facilitator

WHY THIS MATTERS TO YOUR PRACTICE

Medicare payment rules and plan financial incentives increasingly determine whether your patient receives the therapy you recommend

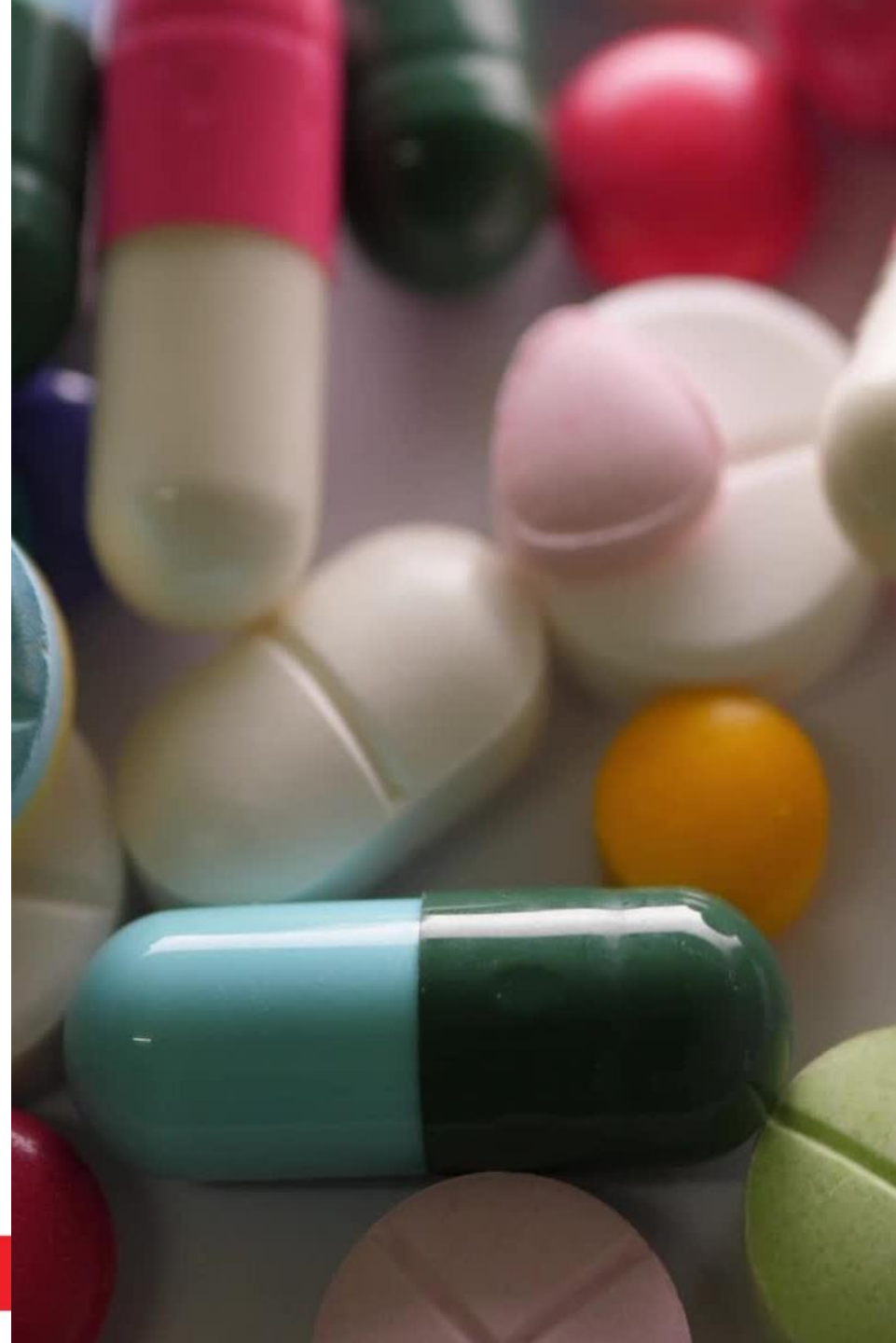
Plans delay, deny, and redirect care through administrative requirements that land as work inside the practice

These barriers concentrate on high-cost cancer therapies, and beginning in 2028 they extend into provider-administered Part B drugs

MFP “effectuation” will place increasing pressures on practices that administer Part B drugs and directly impacts the economics of Medically Integrated Pharmacies (MIPs) and In-Office Dispensing (IOD)

WHAT'S CHANGED IN 2026?

- Part D redesign is fully in effect: a \$2,100 annual out-of-pocket cap improves patient affordability.
- The Medicare Prescription Payment Plan lets beneficiaries avoid front-loading high OOP costs through a monthly payment plan.
- The first 10 negotiated drugs, including ibrutinib, now carry a Maximum Fair Price in Part D, effectuated through the Medicare Transaction Facilitator.
- Plans that change formularies or coverage criteria mid-year must provide written notice and provide appeal rights.
- Standalone Part D plan exits are moving patients to MA, where Part B utilization management and encounter-data timing matter more.
- CMS issued draft guidance on how the Maximum Fair Price will be effectuated for Part B drugs starting in 2028.

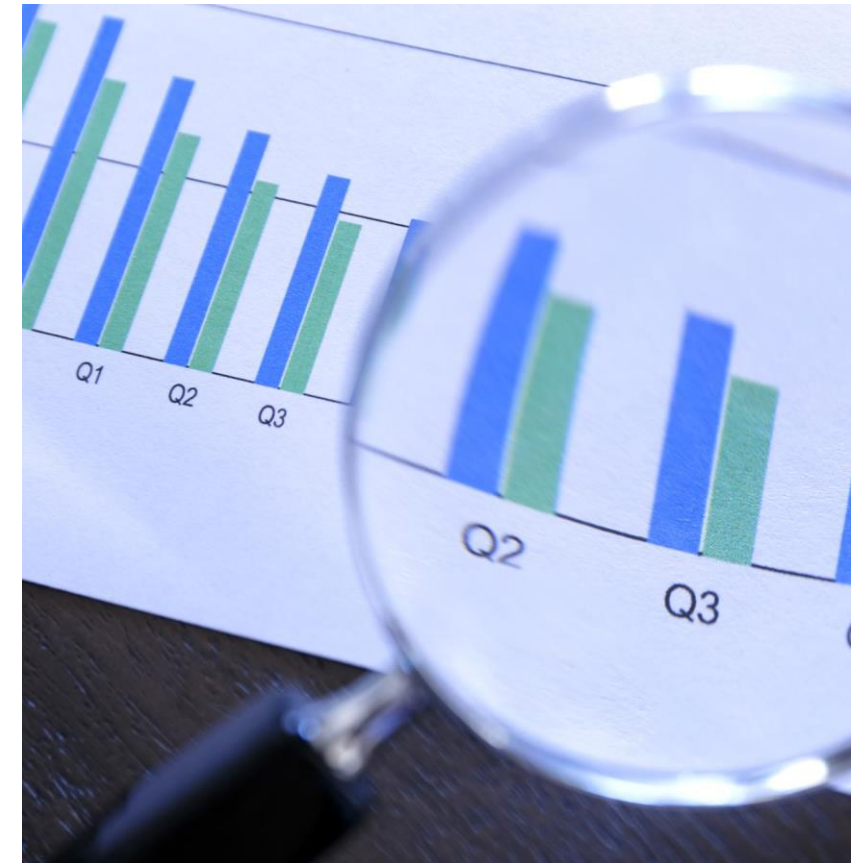


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PAYERS ARE ADAPTING — PRACTICES (AND PATIENTS) ABSORB THE CONSEQUENCES

- **Market Consolidation and Plan Exits:** Standalone prescription drug plans are down roughly 22% (from 464 to 360) as carriers exit unprofitable regions and concentrate on Medicare Advantage, shifting more of your patients into MA.
- **Cost-Sharing Shifts:** Higher deductibles (\$615 in 2026, up from \$590 in 2025) and a move from copays to coinsurance on high-cost drugs raise abandonment risk and financial-navigation workload for your staff.
- **Intensified Utilization Management:** Prior authorization, step therapy, and restricted formularies are the primary tools to manage specialty drug exposure — each one lands as administrative work inside the practice.
- **MFP Effectuation:** The first several months of MFP effectuation have given a glimpse into the potential challenges providers, especially oncology practices with in-office dispensing, might face with payment delays and increased administrative burden.



PLANS ARE MORE AGGRESSIVE IN STEERING PATIENTS TOWARD (OR AWAY FROM) CERTAIN DRUGS

Tiering Disparities: Plans may place negotiated drugs and other agents with less favorable net economics on less favorable tiers.

Initial Claim Denials: Recent studies show over 70% of specialty claims in chronic conditions face initial denials, often requiring 2-3 appeals before approval — PBM arrangements may include a “per click” fixed charge, mitigating revenue lost from rebates.

Prior Authorization & Treatment Gaps: Expect 75-100% of specialty drugs to require PA. Even for patients stable on therapy, new PA requirements can trigger at the start of the plan year, causing 5-10 day treatment gaps.

CLL IS INITIAL “BATTLE GROUND” FOR FIGHTING IRA-RELATED DENIALS, STEP THERAPY

The Challenge: Why the Denial Happens

- **Net Cost, Not Clinical Equivalence:** Plans prefer whichever covalent BTK inhibitor carries the better net price — a negotiated MFP or a larger rebate — regardless of patient-level fit
- **Automated Step Edits:** Claims are often rejected by rule engines before any clinical review occurs, so the first denial is rarely a clinical judgment

The Tool: The National Comprehensive Cancer Network (NCCN) Updated CLL Clinical Guidelines

- **Standard of Care:** NCCN states that choice of covalent BTK inhibitors (ibrutinib, acalabrutinib, zanubrutinib) is made by the clinician based on patient-specific factors, and specifies that the ***BTKi's are not interchangeable***
- **Why It Matters:** That removes the therapeutic-equivalence premise a step edit depends on, and gives the cleanest basis for appeal

GENERAL PRIOR AUTHORIZATION DEFENSE

The Core Objective

- Shift the practice from a *reactive* appeals workflow (waiting for a denial) to a *proactive* submission workflow that pre-empts automated PBM algorithms
- **The Standard Universal Protocol: The Guidelines-First Attachment**
- **Do not submit a clean script alone** — always attach a standardized, one-page clinical justification to the initial Electronic Prior Authorization (ePA) portal upload
 - **Explicitly quote NCCN language** including any language regarding **non-interchangeability** and **clinician autonomy** for that specific drug class

The Patient Comorbidity Filter

- Train your Medically Integrated Pharmacy (MIP), financial navigators, or other professionals to cross-reference the Electronic Health Record (EHR) *before* hitting submit
- Hard-code checkboxes into your internal PA templates for universal high-risk factors:
 - Cardiotoxicity / arrhythmia risk (e.g., BTKis, CDK4/6s)
 - Hepatic or renal impairment restrictions
 - Concomitant drug-drug interactions (CYP3A4 inhibitors/inducers)



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WHEN A THERAPY IS DENIED OR STALLED

STEP 1: Capture the Denial Precisely

- Get the exact reject or denial reason: *"prior authorization required," "step therapy," "non-formulary," and "not medically necessary" each require a different response*
- Confirm what kind of decision it is — a coverage determination, an organization determination, or an automated claim edit — because that sets your timeline and appeal rights

STEP 2: Stabilize the Patient

- **Bridge the gap:** Use *manufacturer bridge and free-drug programs* so therapy is not interrupted while the appeal is pending
- **Assign ownership:** Name one person — navigator, pharmacy technician, or PA coordinator — accountable for the case until it closes

STEP 3: Escalate on the Clock

- **Request expedited review:** Urgent Part D determinations generally must issue within 24 to 72 hours; expedited Medicare Advantage organization determinations run on a 72-hour standard.
- **Put the guideline argument in writing:** Attach the NCCN citation and the patient-specific rationale at every level — redetermination, reconsideration, and independent review.



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FIGHTING "STEP THERAPY" DENIALS FOR BTK INHIBITORS

- Don't wait for the PBM to issue a denial for zanubrutinib or acalabrutinib. Use the internal Medically Integrated Pharmacy (MIP) to submit the defense upfront.
- **The Tactic:** Create a standardized, single-page "BTKi Choice Justification Form" for the practice's EHR that includes language that: **"Per the current NCCN Guidelines for B-Cell Lymphomas (CLL/SLL), BTK inhibitors are explicitly designated as not interchangeable. The guidelines mandate that the choice of agent be determined by the treating clinician based on patient-specific factors. For this patient, [insert prescribed agent], is the appropriate treatment due to [insert patient factor]."**
- If/When a PBM's automated system issues a denial anyway, the practice should immediately bypass the standard electronic appeals queue and demand an immediate peer-to-peer **with a board-certified oncologist.**

FIXED-DURATION BTKi + VENETOCLAX: A DIFFERENT COVERAGE PROBLEM

Time-limited BTK inhibitor plus venetoclax regimens are now a standard option — and they create coverage complexity that indefinite monotherapy does not.

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

PROTECTING ACCESS TO A COMBINATION REGIMEN

- **Multi-Agent Regimen Front-Loading**
 - For oral/infused combination therapies, secure PAs for **all components and all subsequent cycles** upfront before Cycle 1, Day 1.
 - Submit the manufacturer's exact dose-escalation schedule immediately to prevent automated "quantity limit" rejections in subsequent weeks.
- **The Zero-Tolerance Escalation Trigger**
 - If an automated denial is issued, bypass the standard portal appeals track entirely.
 - Demand an immediate **Expedited Peer-to-Peer Review** with a board-certified oncologist and force written clinical accountability for overriding guideline-directed care.



MEDICALLY-INTEGRATED PHARMACIES HAVE AN EDGE NAVIGATING PBM HURDLES

The Multi-Disciplinary Defense Playbook

- To keep Medically Integrated Pharmacies (MIP) and In-Office Dispensing (IOD) feasible, practices must use their clinical proximity to rapidly overturn denials
- **Pre-emptive Toxicity Mapping:** Acalabrutinib and zanubrutinib are routinely preferred over ibrutinib due to vastly lower rates of atrial fibrillation, hypertension, and bleeding risks.
 - *The Pivot:* The internal pharmacy team should review the patient's electronic health record (EHR) *before* the script is submitted. Document any history of cardiovascular issues or concomitant anticoagulant use directly in the initial submission to bypass the standard step therapy prompt.
- **The Next-Gen Mutation Argument:** If a patient progresses or possesses specific mutations (like *BTK C481S*), older generation BTK inhibitors will not work. MIP clinical pharmacists are uniquely positioned to submit specific genomic sequencing results instantly with the prescription, proving that forcing a patient onto a negotiated alternative is non-viable.

NAVIGATING THE 2027 CALQUENCE MFP SHOCKWAVE (FOR MEDICALLY INTEGRATED PHARMACIES, IN- OFFICE STOCKING)

- **The Timeline Challenge:** On January 1, 2027, acalabrutinib officially enters Maximum Fair Price (MFP) effectuation, causing a sharp drop in reimbursement rates and requiring dispensing entities to manage refund reconciliation process
- **Avoiding the Inventory Trap:** Dispensing entities may acquire acalabrutinib above the MFP and depend on subsequent refund. Delays, mismatches, or rejected refund claims can create significant cash-flow and reconciliation risk.
- **The Execution Blueprint**
 - Implement a **7-to-14-day Just-In-Time (JIT) stocking protocol** for acalabrutinib starting in October 2026
 - Automate electronic wholesaler chargeback software to instantly claim the manufacturer-wholesale rebate variance once the drug is dispensed



NEW 2026 APPEALS PROTECTIONS

- **Protection Against Mid-Year Cuts:** A plan that stops or reduces coverage for a drug during the plan year must treat the change as an **organization determination**, with formal notice and immediate appeal rights
- **Faster Dispute Resolution:** Expedited review is available where delay would jeopardize the patient; urgent Part D decisions generally must issue within **24 to 72 hours**
- **Support for Continuity:** It is harder for a plan to move a patient already stabilized on a specific agent — a clarification that helps, though it is not an absolute guarantee

COMING IN 2028: THE MAXIMUM FAIR PRICE REACHES PART B DRUGS

Part B drugs become subject to negotiated Maximum Fair Prices beginning in 2028 – including provider-administered oncology therapies

CMS proposes to effectuate the discount by extending the Medicare Transaction Facilitator built for Part D, rather than redesigning Part B reimbursement around provider cash flow

Draft guidance is open for comment now – and the questions CMS is asking are ones providers are best positioned to answer

HOW CMS PROPOSES THE PART B MFP WOULD WORK

1. The practice purchases the drug through the normal buy-and-bill process
2. The practice administers the drug to the patient
3. The Medicare claim is adjudicated — by the MAC in fee-for-service, or via encounter data in Medicare Advantage
4. CMS transmits the claim information to the manufacturer through the MTF
5. The manufacturer must send the refund through the MTF within 14 days of that transmission
6. The practice is **eventually given funds to approximate the MFP**

Note where the 14-day clock starts: at step 4 — not at step 1, which is when your money actually goes out the door



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WHERE CMS MOVED IN THE RIGHT DIRECTION

- CMS adopted a firm 14-day manufacturer payment deadline, recognizing that settlement timing — not just the existence of a refund — drives provider behavior
 - That is a meaningful improvement over an open-ended payment window
- CMS explicitly acknowledges that Medicare Advantage encounter-data timing is a problem
 - It asks for comment on improving MA encounter submission timelines
- The MA timing question is genuinely open — which makes it **the place where comments are most likely to change the outcome**

But . . . recognizing a problem and requesting comment is not the same as solving it

GAP 1: PROVIDERS STILL FINANCE THE DISCOUNT

- The practice purchases inventory at full acquisition cost
- The practice administers treatment before any discount exists
- The practice waits for the claim to be submitted and adjudicated
- The practice waits for CMS verification and transmission through the MTF
- Only at that point does the 14-day manufacturer payment window begin
- CMS shortened one segment of the timeline; it did not eliminate **the provider financing period**

For high-cost infused oncology drugs that gap is real working capital — and it scales with volume

GAP 2: CMS OPTIMIZED FOR ITS ADMINISTRATIVE EASE, NOT ACCESS

- CMS started from the question: “how do we administer manufacturer refunds?”
- The question that matters clinically is: how do we preserve patient access?
- The guidance is built around data flow, verification, audit trail, and payment processing
- What determines access is provider behavior, stocking decisions, and site-of-care viability
- The statutory objective is not merely that the MFP eventually reaches providers; it is that implementation **preserves beneficiary access**

That access standard is the right yardstick for evaluating the MTF, and should be the overarching theme of our comments



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GAPS 3 AND 4: THE CASH-FLOW CLOCK AND MEDICARE ADVANTAGE

- The guidance assumes a 14-day payment window is sufficient
- But the financing clock starts long before CMS transmits the claim to the manufacturer
- Acquisition, administration, claim submission, and CMS adjudication all sit outside those 14 days
- In Medicare Advantage, encounter-data submission adds a further and less predictable delay
- CMS acknowledges the MA timing issue but resolves it only by requesting comment
- If MA timing extends financing beyond fee-for-service, effectuation produces **different economics depending on payer mix**

Practices with heavy MA penetration would carry the longest float — and face the strongest disincentive to stock



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GAP 5: WHAT “KEEPING PROVIDERS WHOLE” MUST MEAN

- CMS defines “whole” narrowly: the provider eventually receives the manufacturer payment
- A workable definition is broader — providers should not have to finance negotiated discounts
- Providers should not lose the economics of ASP-based reimbursement
- Providers should not absorb new administrative costs created by the effectuation mechanism
 - Administrative burden changes provider behavior as surely as cash flow does
- The guidance still introduces **enrollment, data matching, dispute resolution, payment reconciliation, and MTF onboarding**

Those costs deserve considerably more attention than the draft gives them



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TAKEAWAYS

- Utilization management is now the primary lever payers use to control specialty drug cost — and it lands as clinical and administrative work inside your practice.
 - NCCN's position that covalent BTK inhibitors are not interchangeable remains your strongest tool against step edits
 - Beginning in 2028 the Maximum Fair Price reaches Part B, and CMS proposes to effectuate it through the Medicare Transaction Facilitator
- “Effectuation” through the transaction facilitator has created problems for providers dispensing specialty drugs. The delays and administrative burden are unreimbursed costs to oncology practices.
- This same effectuation mechanism is proposed as appropriate for Part B drugs. The open question is not whether the discount eventually arrives, but who finances it in the meantime — and whether patients can still get their treatment.



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AUDIENCE Q&A



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