

THE ONCOLOGY ECOSYSTEM EQUILIBRIUM



REPLACING FAIL-FIRST POLICIES WITH SHARED ACCOUNTABILITY FOR TIMELY CANCER CARE

ABSTRACT

Step therapy and related utilization-management tools were developed with the pretense of protecting patients from low-value treatment and helping purchasers manage rapidly growing oncology expenditures. They have become clinically hazardous, however, when cost-first sequences override tumor biology, biomarkers, comorbidities, prior intolerance or the urgency of treatment. The evidence is strongest for process harm: new prior-authorization requirements have delayed or discontinued oral anticancer refills; initial denials are frequently reversed; oncology teams spend substantial unreimbursed time obtaining care that is ultimately approved; and patients report anxiety, financial toxicity, lost time, and erosion of trust. Evidence directly proving that payer or pharmacy benefit manager (PBM) step edits cause progression or death is sparse, and cancer-specific time sensitivity is heterogeneous. This article proposes “an oncology ecosystem equilibrium”: manufacturers, payers, PBMs, practices, employers, policymakers and patient advocates accept measurable duties that preserve evidence-based stewardship without substituting administrative algorithms for individualized care. Success should be judged not by drug spending alone, but by time to treatment, denial and reversal rates, clinical concordance, burden, total cost, patient experience, outcomes and equity.

Keywords: oncology; step therapy; fail first; prior authorization; pharmacy benefit managers; access; utilization management; administrative burden.

EVIDENCE-REVIEW APPROACH

This perspective is supported by a structured narrative review informed by PRISMA reporting principles, without representing a registered systematic review.¹ PubMed/MEDLINE and the Cochrane Library were searched from inception through July 2026, using combinations of oncology, cancer, step therapy, fail first, prior authorization, utilization management, treatment delay, administrative burden, limited distribution, PBM, rebate, and disease-specific terms. Searches were supplemented by cited-reference review and authoritative Centers for Medicare & Medicaid Services (CMS) and Federal Trade Commission materials. Peer-reviewed systematic reviews, comparative studies, and large observational cohorts were prioritized; regulatory sources were used for current policy.

By **Lucio N. Gordan, MD, & Jay Seemann**

Cancer-attributable medical care and oral drug costs were estimated at \$183 billion in 2015 and projected to reach \$246 billion by 2030 based on population growth alone.² Stewardship is therefore necessary. Yet oncology is unusually resistant to rigid sequencing: two regimens that look interchangeable at a population level may diverge for one patient because of histology, molecular subtype, organ function, drug interactions, prior exposure, toxicity, adherence or goals of care.

Chronic lymphocytic leukemia (CLL), the most common form of adult leukemia, illustrates this challenge. Even therapies within the same treatment class may have clinically meaningful differences for an individual patient. Age, comorbidities, concomitant medications, patient preferences and disease-specific risk factors can all inform treatment selection. A formulary



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Jay Seemann

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preference should therefore preserve the treating clinician's ability to account for these factors rather than assume that a preferred sequence is appropriate for every patient.

Commercial management has expanded accordingly. In an analysis of 5,419 policies from 18 large health plans, utilization management, excluding prescriber requirements, appeared in 14.5% of oncology policies in 2017 and 22.9% in 2024; step therapy rose from 4.3% to 16.5%.

Three-quarters of step therapy policies required a biosimilar or generic before a branded product, an often-reasonable form of clinically aligned competition.³

The problem is not every edit. It is a step edit that treats price preference as clinical equivalence, lags a rapidly changing evidence base or lacks a fast exception when the preferred step is contraindicated, predictably ineffective, previously failed or unsafe to delay. That includes step edits requiring a patient to demonstrate failure or intolerance to one therapy before accessing another selected by the treating oncologist based on patient-specific clinical factors.

That distinction answers the central question. Utilization management begins to practice medicine when it dictates an individual treatment choice despite patient-specific evidence, without timely review by a clinically relevant specialist or a meaningful exception pathway. Consensus work on step therapy similarly emphasizes evidence, flexibility, transparency and continuity, not unrestricted prescribing and not inflexible “fail first.”⁴

TIME MATTERS — BUT NOT IN THE SAME WAY FOR EVERY CANCER

A landmark meta-analysis of 34 studies and 1,272,681 patients evaluated 17 curative treatment indications. Each four-week increase in treatment interval was associated with significantly higher mortality in 13 indications; surgery estimates included hazard ratios (HRs)

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of 1.06 for colectomy (95% confidence interval [CI], 1.01–1.12) and 1.08 for breast surgery (95% CI, 1.03–1.13), while systemic-therapy estimates ranged from 1.01 to 1.28.⁵ These findings support minimizing avoidable treatment delays, but they do not isolate the effect of payer-related delays or establish a uniform 10% increase in mortality for every four-week delay across cancers and treatments.⁵

Disease context prevents overstatement. In 24,843 patients with stage I–III breast cancer, starting adjuvant chemotherapy at 91 days or later versus within 30 days after surgery was associated with worse overall survival (adjusted HR, 1.34; 95% CI, 1.15–1.57); the triple-negative subgroup estimate was 1.53 (95% CI, 1.17–2.00).⁶

By contrast, lung-cancer time-to-treatment studies are distorted by the “waiting-time paradox,” in which the sickest patients start fastest yet fare worst. A systematic review found this inverse pattern in six of eight advanced non–small cell lung cancer studies.⁷

In diffuse large B-cell lymphoma, prospective cohorts likewise show that short diagnosis-to-treatment intervals mark aggressive disease and trial-ineligi-

ble urgency rather than proving delay is protective.⁸

Acute leukemia further illustrates the need for clinical sorting. A meta-analysis of 13 acute myeloid leukemia studies (14,946 patients) found heterogeneous results: no included study linked delay to early death, while the pooled odds of complete remission fell modestly with each day (odds ratio, 0.974; 95% CI, 0.958–0.990).⁹ Selected stable patients may reasonably wait briefly for genomics that change therapy; suspected acute promyelocytic leukemia is different and requires immediate all-trans retinoic acid.

In a Swedish registry, 30 of 105 patients died within 30 days, at a median of four days, and 35% of those who died early never received all-trans retinoic acid.¹⁰

At the other extreme, randomized CLL12 data showed that early ibrutinib delayed progression in asymptomatic high-risk chronic lymphocytic leukemia (CLL) but did not improve overall survival; five-year survival was 93.3% with ibrutinib and 93.6% with placebo.¹¹ Observation remains appropriate until accepted treatment criteria are met.

Thus, a two- to four-week administrative delay can be dangerous in some settings, tolerable for essential diagnostic work in others and irrelevant when treatment is not yet indicated. The correct safeguard is urgency stratification by the treating oncology team — not a blanket clock and not a blanket reassurance. Payer utilization-management processes should reflect that clinical urgency and avoid creating unnecessary delays once the treating oncology team determines that treatment should begin.

THE ADMINISTRATIVE AND HUMAN TAX

The most direct oncology evidence concerns access processes. A 2026 survey of 75 oncology clinicians and administrators found that community respondents estimated 29% of physician-administered drug requests were denied initially; 60% cited an unmet step edit among common reasons. Nearly 60% reported typical delays of one to two weeks and 20%

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reported three to four weeks. Medical exceptions took up to one hour for 57% and up to two hours for 17%; 52% reported sometimes foregoing an exception because the patient could not wait.¹²

More rigorous quasi-experimental evidence comes from 25,136 established Medicare users of 11 oral anticancer drugs. After a new prior-authorization policy, adjusted discontinuation within 120 days was 5.8% versus 1.4% without a policy change (odds ratio, 7.1; 95% CI, 6.0–8.5), and the first refill was delayed by an additional 9.7 days (95% CI, 8.2–11.2).¹³ The study addressed refills, not new starts, and most controls already faced prior authorization. Nevertheless, it shows that a new administrative gate can interrupt established cancer therapy.

Denials also generate work even when care is ultimately authorized. At one academic radiation center, 206 initially denied cases included 127 (61.7%) later approved unchanged and 56 (27.2%) approved after payer-requested modification; 72 delivered cases (34.9%) were delayed, with a median delay of five days (range, 1–49).¹⁴ Time-driven costing at another academic radiation practice estimated 51–95 minutes and \$28–\$101 per authorization event, nearly \$492,000 annually; 94% of departmental cost related to treatments were ultimately approved.¹⁵

These single-center estimates should not be generalized to all oncology, but they reveal the opportunity cost: physician, nurse, pharmacist, navigator, financial counselor, and authorization-specialist time displaced from patient care.

Patients experience that burden as uncertainty. In a convenience survey of 178 patients who encountered prior authorization, 69% reported a delay; among those delayed, 73% waited at least two weeks and 33% at least one month. Twenty-two percent did not receive the originally recommended care because of prior-authorization delays or denials. Twenty percent reported that they and/

or their caregivers spent at least 11 hours addressing prior-authorization issues. Mean self-reported authorization-related anxiety was 74.7, compared with usual anxiety of 37.5, on a 0–100 scale ($P < .001$).¹⁶ The sample was predominantly younger, non-Hispanic white, female, and privately insured, limiting the generalizability of these estimates.

Taken together, these barriers can create a cascade of “hidden burdens” for patients and care teams: additional care navigation, repeated documentation, coverage uncertainty, treatment-plan changes and erosion of trust at a moment when patients most need clarity and stability. When a coverage decision changes the treatment plan a patient and oncologist have already discussed, it can also undermine shared decision-making and the patient-clinician relationship.

A counterpoint is equally important: at a well-resourced academic center, 1,024 new oral anticancer prescriptions reached patients in a median of nine days with authorization activity and 10 days without it ($P = .124$), suggesting that integrated access teams can absorb some friction at a cost — to practice capacity.¹⁷

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An equilibrium does not mean equal power or diluted accountability. It means that every actor is responsible for keeping the patient at the center while balancing access, value and sustainability (see **Figure 1** on next page):

▲ **Manufacturers and distribution:** Manufacturers should compete on clinical value and responsible net price, avoid contract terms that reward exclusion rather than parity, and make coverage-support information interoperable with the care team. Commercial arrangements should support competition without creating incentives for formulary preference to become mandatory treatment sequencing when clinically meaningful differences exist for an individual patient.

Limited distribution networks may be justified by Risk Evaluation and Mitigation Strategies, handling, pharmacovigilance or specialized support.

They should be no narrower than those functions require.

In a single-center study of 409 oral-oncologic prescriptions, median access was six days for limited-distribution drugs versus three days for nonlimited drugs; an embedded pharmacist reduced but did not erase the gap.¹⁸ Qualified medically integrated pharmacies should therefore have a transparent path into networks, with measurable service, safety and data standards.

▲ **Payers and PBMs:** Appropriate management verifies diagnosis, indication, dose, biomarker and evidence; discourages demonstrably low-value variation; and supports biosimilar competition. Excessive management imposes cost-first sequencing without patient-specific exceptions, repeats documentation already available, changes criteria without continuity protection or uses reviewers without relevant oncology expertise.

PBMs can negotiate lower net prices and premiums, but their formulary, network and rebate roles create potential conflicts. Three PBMs processed 79% of prescription claims and six processed 96% in a 2023 review.¹⁹

Rebate evidence is mixed: a study of 444 branded drugs linked larger rebates to higher out-of-pocket spending through higher list prices, but the association disappeared after adjustment for list price,²⁰ while a 2026 analysis found rebate size was not independently associated with coverage restrictions. Highly competitive classes, however, had greater odds of restriction (adjusted odds ratio, 2.09; 95% CI, 1.21–3.63).²¹

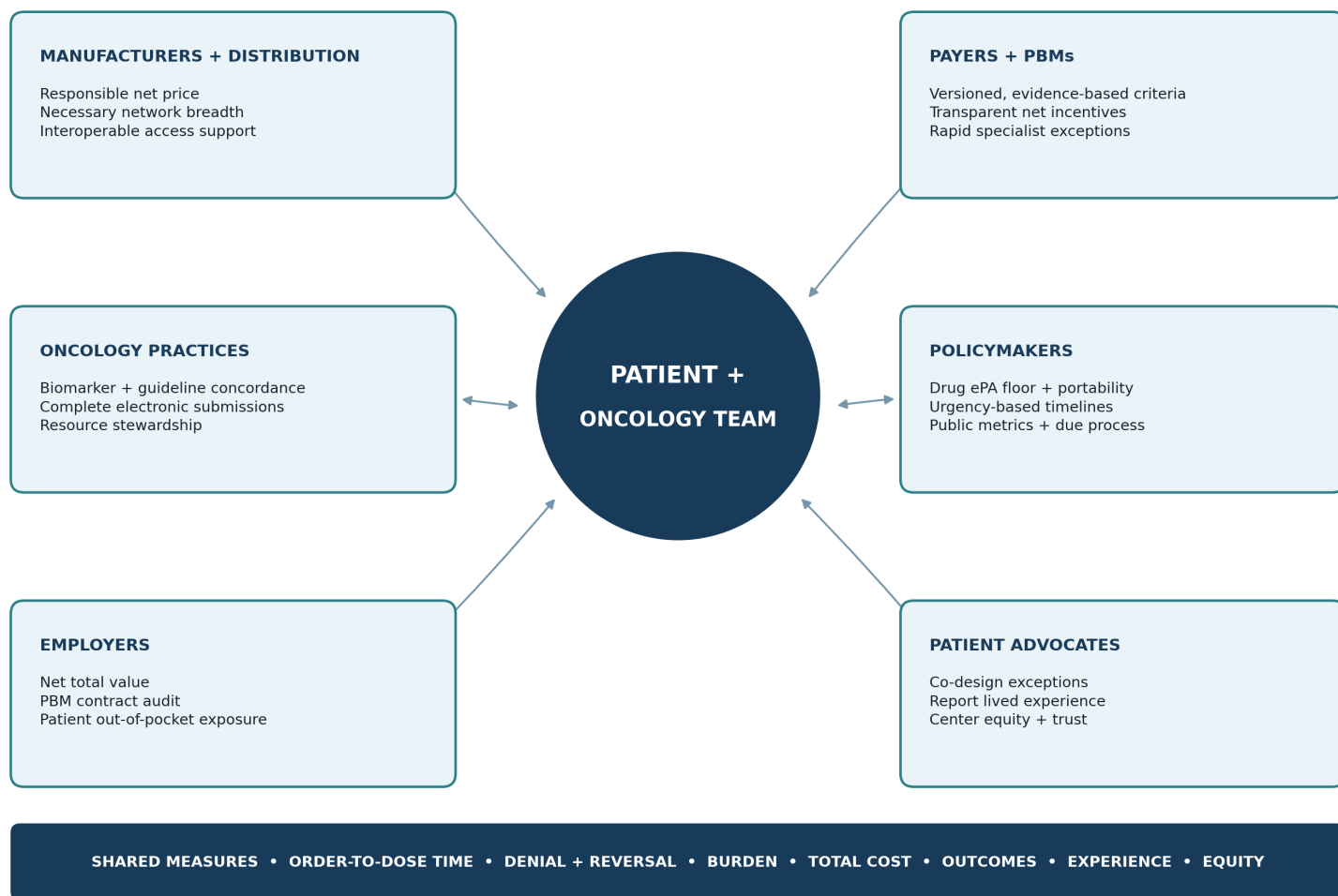
Transparency and contract-specific evidence are warranted; the evidence does not support claiming that rebates alone cause oncology denials.

▲ **Practices, employers, policymakers and advocates:** Oncology practices owe complete, guideline- and biomarker-concordant documentation, prudent use of therapeutically equivalent lower-cost options, and participation in outcomes-based care.

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FIGURE 1: THE ONCOLOGY ECOSYSTEM EQUILIBRIUM

EQUILIBRIUM MEANS RECIPROCAL, MEASURABLE ACCOUNTABILITY



Each stakeholder carries a distinct duty, but accountability is shared through common measures of timely, evidence-based, affordable and equitable care.

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Employers should audit PBM guarantees and compare net total medical-plus-pharmacy cost, patient out-of-pocket exposure, access and outcomes — not gross rebates or acquisition cost alone.

Patient advocates should help design exceptions and report lived experience.

Policymakers should create a national floor for rapid drug authorization, portable approvals, specialty-matched review, transparent criteria and gold-carding that does not disadvantage low-volume or rare-cancer practices.

A legal nuance matters. Antineoplastics

— not oncology services as a whole—are one of six Medicare Part D protected classes. Plans generally must cover all or substantially all such drugs yet may apply prior authorization or step therapy to new starts. The protection does not govern most infused Part B drugs or commercial coverage.²²

That distinction makes meaningful CMS oversight especially important: protected-class coverage should not be undermined in practice by utilization-management requirements that impose clinically inappropriate sequencing or restrict access without meaningful patient-specific exceptions. CMS should closely scrutinize Part D formulary and utilization-management policies to

ensure they reflect nationally recognized, evidence-based treatment guidelines and remain consistent with the access protections the protected-class framework is intended to provide.

MOVING TOWARD BETTER SOLUTIONS

First, create clinical safe harbors. A complete request should receive real-time approval when it is an on-label or compendium-supported regimen with the required biomarker and no plan-specific clinical ambiguity.

An automatic safe harbor for National Comprehensive Cancer Network Category 1 recommendations is a defensible

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reform proposal, not current universal law. Exceptions should be granted when the preferred drug is contraindicated, expected to be ineffective from tumor biology, previously failed or not tolerated under any plan, incompatible with comorbidity or concomitant treatment, inconsistent with documented patient-specific clinical factors, or likely to create irreversible harm through delay. Stable therapy and prior-step history should follow the patient across plan changes.

Second, build a rapid oncology pathway: structured electronic fields for histology, stage, risk factors, biomarkers, prior therapy, organ function, and contraindications; a specific denial reason; one-click submission of supporting evidence; urgent review within 24 hours and standard review within 72 hours; and relevant-specialist human review before an adverse decision is sustained.

Gold-carding should be regimen- or service-specific, automatic when transparent approval thresholds and adequate case volume are met and protected by notice and appeal before rescission.

Third, make reform accountable. A 2025 nonrandomized quality-improvement study of 6,551 radiation cases associated clinically integrated authorization software with a decline in denial from 7.6% to 2.6% and median authorization time from 4.2 to 2.8 business days (both $P < .001$).²³ Its historical controls, single system and vendor involvement limit causal certainty, but the result shows what measurable workflow redesign can target.

Current federal rules leave a drug gap. CMS's 2024 final rule requires many public-program payers to decide expedited non-drug requests within 72 hours and standard requests within seven calendar days, give specific denial reasons, and report metrics — but explicitly excludes drugs.²⁴

In April 2026, CMS proposed expanding electronic prior authorization for medical-benefit drugs, generally beginning October 1, 2027. For

Qualified Health Plan entities on the federally facilitated exchange, the proposal would require the authorizations within 72 hours for standard decisions and 24 hours for expedited requests.²⁵ As of September 13, 2026, that proposal was not final. Oncology should not wait for fragmented implementation to establish a clinically appropriate standard.

MEASURE SUCCESS BEYOND DRUG SPEND

Every oncology utilization-management program should publish a small, auditable scorecard:

- ▲ Median and 90th-percentile time from treatment order to first dose;
- ▲ Real-time approval and incomplete-request rates; initial denial, appeal, peer-to-peer and post-appeal approval rates;
- ▲ Treatment substitution, abandonment, and interruption;
- ▲ Physician and staff minutes;
- ▲ Patient out-of-pocket costs and total medical-plus-pharmacy costs;
- ▲ Emergency visits and hospitalizations;
- ▲ Guideline and biomarker concordance; and
- ▲ Toxicity, patient-reported experience and relevant clinical outcomes.

Results should be stratified by cancer type, urgency, race and ethnicity, rurality, language, disability, and insurance product. Reporting both the “complete request” clock and the order-to-decision clock prevents missing-document requests from hiding delay.

The equilibrium test is simple: did the policy help the right patient receive the right evidence-based treatment at the right time, with less total waste? A lower pharmacy line item is not success if it produces avoidable appeals, care fragmentation, treatment interruption, higher patient expense or inequitable access.

CONCLUSION

Cancer is not a trial-and-error disease, but neither is every utilization-management tool inherently inappropriate. The boundary is clinical substitutability, individualized evidence, and time.

Fail-first policies like step therapy cross that boundary when they require predictable failure or harm before the treating team can use the indicated therapy.

A durable response is shared accountability: responsible manufacturer contracting and distribution; transparent, specialist-informed payer and PBM rules; rigorous practice stewardship; employer purchasing based on net total value; patient participation; and enforceable policy floors.

When those duties are measured together, the oncology ecosystem can contain waste without making the patient absorb the cost of containment.

▲ **Lucio N. Gordan**, MD, is President and Managing Physician, Florida Cancer Specialists & Research Institute in Gainesville, Florida. **Jay Seemann** is Vice President, Market Access & Value: US & Shared Services (Ex China), BeOne Medicines, Raleigh-Durham, North Carolina.

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