

Formulary Coverage Is Not Patient Value: Reconciling Comparative Clinical Benefit, Treatment Burden, Patient Preferences, Budget Impact, and Real-World Access in Pharmacotherapy Allocation

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ABSTRACT

Formulary coverage is commonly treated as a practical endpoint of pharmacotherapy allocation, yet coverage alone does not establish comparative clinical benefit, acceptable treatment burden, preference concordance, affordability, or feasible treatment use. This analysis develops an evidence-bounded framework for distinguishing these domains and reconciling them without reducing patient value to a single coverage or economic signal. A targeted conceptual health-policy analysis was conducted across value assessment, health technology assessment, patient-preference methods, treatment-burden measurement, formulary policy, affordability, and real-world medication access. Evidence was used to define constructs, identify level-of-analysis boundaries, characterize discordant signals, and derive a proposed allocation architecture. Empirical findings were retained within their reported populations and policy contexts. The analysis separates five decision domains: comparative clinical benefit, treatment burden, patient preferences, budget impact, and real-world access. Coverage is positioned as an administrative state that can enable treatment but cannot independently establish patient value. The proposed architecture treats discordance among domains as information requiring explanation rather than as error requiring forced convergence. It also distinguishes payer affordability from patient affordability and nominal coverage from treatment feasibility. Patient-centered pharmacotherapy allocation requires reconciliation across clinical, patient, economic, and access evidence. The proposed architecture is not a validated score or policy rule; its usefulness depends on transparent domain-specific evidence, explicit uncertainty, local health-system context, and prospective evaluation of whether allocation decisions improve access without obscuring clinical appropriateness or patient heterogeneity.

Keywords: Formulary, Patient value, Pharmacotherapy allocation, Treatment burden, Patient preferences, Affordability

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Introduction

Pharmacotherapy allocation often compresses several distinct questions into the administrative binary of covered versus not covered. Health-economic work has long argued that value can include elements beyond conventional health gain and cost alone [1]. Cost-effectiveness and affordability are also analytically separable: an intervention may appear efficient relative to alternatives while still creating material budget pressure for a payer [2]. These distinctions matter because formulary status is a decision output produced under clinical, economic, statutory, and organizational constraints; it is not itself a patient outcome or a direct measure of treatment benefit. A coverage decision can therefore be administratively coherent while remaining incomplete as an account of what a particular patient is likely to gain, endure, prefer, afford, and actually receive.

Recent policy evidence reinforces this separation. In Medicare drug coverage for heart-failure therapies, publication of guideline recommendations did not mechanically remove formulary barriers, illustrating that clinical recommendations and coverage policy can move differently [3]. Coverage of drugs receiving accelerated approval likewise varies across products and time, showing that regulatory authorization and formulary inclusion do not resolve uncertainty about comparative patient benefit [4]. The practical implication is not that coverage lacks value. Coverage can be necessary for treatment access. The problem is treating it as sufficient evidence that a therapy delivers value to the patient expected to receive it.

This article therefore analyzes patient value as a reconciliation problem across comparative clinical benefit, treatment burden, patient preferences, budget impact, and real-world access. The central contribution is a proposed pharmacotherapy allocation value architecture that preserves these domains as analytically distinct while allowing explicit adjudication when their signals agree or conflict. The architecture is intended to clarify reasoning, not to supply universal weights, causal effects, implementation thresholds, or a validated score. It also keeps patient-, regimen-, payer-, and health-system-level evidence separate so that a favorable signal at one level is not silently transferred to another. This multilevel discipline is especially important when payer-level affordability is favorable but patient-level affordability or administrative feasibility is not.

Materials and Methods

This study used an original conceptual and health-policy analysis rather than an empirical effectiveness design. The analytic procedure began by decomposing the allocation problem into constructs that could be supported and bounded independently: comparative clinical benefit, treatment burden, patient preferences, payer budget impact, patient-level affordability, administrative access, and treatment feasibility. This decomposition was necessary because patient-preference integration in health technology assessment involves conceptual, procedural, methodological, and practical challenges that are not resolved by merely adding a preference label to an existing value framework [5].

Evidence was then examined for the level at which each claim operates, the decision stage it informs, and the limits on transfer. Qualitative evidence from Canadian, Belgian, and German health technology assessment representatives indicates that patient preferences are used differently across institutional contexts and may support rather than mechanically determine decisions [6]. Accordingly, this analysis does not assign fixed preference weights or assume that a preference elicited in one jurisdiction or disease state is transportable to another. Patient-centered real-world evidence guidance further supports deliberate inclusion of patient-experience information in study design and interpretation [7]; here, that principle is used to distinguish patient-relevant feasibility from administrative availability. Evidence was not converted into a common strength score. Instead, each source was used only at the level supported by its design: conceptual sources for definitions or decision logic, observational studies for bounded associations or policy patterns, and patient-centered studies for reported burden or preference constructs.

The synthesis proceeded in three steps. First, evidence-supported distinctions were identified within each domain. Second, cross-domain tensions were examined for level mismatch, uncertainty, temporal instability, and plausible alternative explanations. Third, those distinctions were organized into a proposed allocation architecture and a set of discordance states. The resulting framework is explicitly nonquantitative: no composite score, numerical threshold, or dominance rule is inferred. Empirical findings are used only for the claims their designs support, while new cross-domain relationships are presented as proposed synthesis requiring prospective, pragmatic, and cross-system evaluation. Hard cases were retained rather than resolved by assumption: evidence could be clinically favorable but access-constrained, economically attractive but burdensome, patient-preferred but comparatively uncertain, or formally covered yet practically unusable.

Results and Discussion

The analysis produced a value structure in which formal coverage is separated from the conditions required for therapeutic value to be realized. Multistakeholder work in US value assessment shows that decision makers may regard additional value elements as relevant beyond conventional cost-per-QALY inputs [8]. This supports a multidimensional decision space, but it does not establish which elements should dominate in every

pharmacotherapy allocation. The present analysis therefore treats the domains as noninterchangeable inputs rather than ingredients of a universal additive score.

A second result is the separation of patient needs, treatment burden, and preferences. Needs assessment and preference elicitation answer related but different questions and should not be collapsed into one patient-centered variable [9]. In the resulting logic, burden describes what treatment asks of a patient, whereas preference describes how the patient values competing attributes or outcomes; neither is assumed to be equivalent to adherence. Likewise, patient-informed value elements can broaden cost-effectiveness analysis in a disease-specific setting, but their availability and importance are context dependent [10]. These findings support a structure in which patient experience modifies interpretation of value without replacing comparative clinical evidence.

Third, the analysis identifies discordance as a substantive decision state. A covered therapy can have uncertain added benefit; a clinically attractive therapy can create burdens that matter differently across patients; a payer-favorable option can remain unaffordable or administratively difficult to obtain. Agreement across domains can strengthen confidence in allocation, but disagreement should expose the source of conflict rather than be erased through an implicit hierarchy. The proposed architecture therefore asks whether signals converge, conflict, or remain unresolved, and at which level. That distinction sets the basis for the domain-specific results below.

Comparative clinical benefit and the limits of coverage status

Comparative clinical benefit should be assessed before coverage status is interpreted as evidence of value. Comparative-effectiveness judgments can differ across assessment systems because comparator selection, methods, and evaluative conventions differ; a qualitative comparison of ICER and the German Federal Joint Committee illustrates that added-benefit conclusions are not mechanically interchangeable across institutions [11]. For allocation, this means that “covered” should not erase the evidentiary question of benefit relative to the relevant alternative for the intended population.

Uncertainty is also temporal. Assessment of medicines for spinal muscular atrophy, cystic fibrosis, and hypercholesterolemia showed variation across health technology assessment bodies in the handling of long-term relative-effectiveness uncertainty, including use of reassessment or managed-entry approaches in some contexts [12]. Coverage can therefore coexist with unresolved evidence maturity. Conversely, strong clinical evidence does not guarantee unrestricted availability: Medicaid programs have varied in access to cardioprotective medications for type 2 diabetes [13]. These findings support treating comparative benefit, uncertainty, and coverage as connected but non-equivalent states. The policy task is consequently not to privilege benefit over coverage in every case, but to make explicit when restrictions reflect evidentiary uncertainty, budget constraints, or administrative design rather than silently converting those considerations into a claim of low clinical value.

Table 1 registers the clinically important ways in which formulary status can diverge from comparative benefit without assigning a numerical value score.

Table 1. Coverage status can conceal different comparative-benefit states

Formulary option	Coverage status	Comparative benefit dimension	Evidence uncertainty	Patient-relevant limitation	Allocation implication
Clinically advantaged option	Covered or restricted	Added benefit supported for a defined population	Residual long-term uncertainty possible	Access may still be conditional	Preserve benefit evidence; inspect restrictions
Clinically advantaged option	Not readily available	Benefit may exceed available alternatives	Evidence may be mature or evolving	Eligible patients may not obtain treatment	Do not infer low value from noncoverage
Covered option with uncertain advantage	Covered	Added benefit unclear or comparator-sensitive	Material	Exposure to burden without established added benefit	Coverage should not substitute for reassessment
Context-dependent option	Covered	Benefit varies by population or comparator	Population transfer uncertain	Average assessment may miss subgroup fit	Match evidence to intended patient group

Note: Rows synthesize evidence-supported distinctions described in the text. Allocation implications are proposed analytical interpretations, not validated decision rules.

Treatment burden and patient preferences in value assessment

Clinical benefit is experienced through a regimen, not in isolation from the work required to receive and sustain treatment. The Patient Experience with Treatment and Self-management measure demonstrates that treatment

burden is multidimensional and can be assessed from the patient perspective [14]. Burden therefore should not be treated as a synonym for adverse effects, adherence, or low preference; it includes the practical work imposed by treatment and self-management.

Preferences add a different layer. In older adults with multiple chronic conditions, patient-priorities-aligned care has been operationalized in clinical practice, supporting the feasibility of eliciting patient goals while also underscoring that findings remain population and implementation specific [15]. Time burden is likewise visible across patients, caregivers, and clinicians in cancer care, where treatment can impose substantial logistical demands beyond clinical outcomes [16]. The magnitude of such burden cannot be generalized automatically to other diseases, but the construct is transferable: clinically similar options can differ meaningfully in what they require from patients and families. Preference-sensitive allocation may therefore legitimately rank two clinically acceptable options differently for different patients. That heterogeneity is not noise to be averaged away; it is part of the patient-level feasibility question, provided that preference is elicited transparently and does not substitute for evidence of comparative benefit.

Table 2 distinguishes burden from preference-sensitive trade-offs so that allocation does not average away heterogeneity that may be decisive for individual feasibility.

Table 2. Patient value changes when treatment workload and preferences are kept visible

Burden or preference dimension	Patient experience	Likely heterogeneity	Measurement approach	Allocation relevance	Risk of averaging
Self-management workload	Ongoing tasks, coordination, regimen work	High with multimorbidity	Patient-reported treatment-burden measure	Tests whether benefits are practically sustainable	Mean burden can hide high-workload patients
Time and logistics	Travel, visits, waiting, caregiver time	High by care intensity	Time-use data or qualitative assessment	Distinguishes equal efficacy with unequal workload	Resource averages may miss lived disruption
Goal concordance	Fit with what the patient prioritizes	Intrinsically individual	Explicit priority elicitation	Identifies preference-sensitive choices	Population preference may override individual goals
Caregiver dependence	Reliance on unpaid or informal support	Family and context dependent	Patient-caregiver reporting	Reveals feasibility beyond the patient alone	Patient-only measures can understate burden

Note: Measurement approaches reflect evidence-supported constructs; allocation relevance and averaging risks are proposed uses of those constructs.

Budget impact without patient-level accessibility

Budget impact addresses consequences for the payer, whereas patient accessibility concerns whether a person can obtain and continue treatment under actual benefit design. These levels can move in opposite directions. Among Medicaid patients, procedural prescription denials were associated with subsequent acute-care utilization and spending, although the observational design does not establish that denials caused those outcomes [17]. The finding nevertheless illustrates why a utilization-control mechanism cannot be evaluated solely by its immediate pharmacy-budget effect.

Patient affordability is a separate constraint. A national survey of US adults aged 65 years or older documented cost-related medication nonadherence and demand for medication-cost information, demonstrating that coverage can coexist with affordability problems at the patient level [18]. More recent policy evidence after the Inflation Reduction Act found reduced cost-related medication nonadherence among Medicare beneficiaries relative to a comparison group, consistent with the proposition that changing patient cost exposure can alter affordability-related medication use [19]. That result does not imply that administrative, geographic, supply, or treatment-burden barriers disappear when cost sharing falls. Budget impact can thus be favorable from a system perspective while the patient still encounters an unaffordable copayment, a denial, or another barrier to treatment initiation. Conversely, lowering patient cost exposure can improve one access pathway while increasing payer expenditure. The architecture therefore prohibits treating either budget impact or affordability as a proxy for the other.

Table 3 makes the transmission problem explicit: a mechanism that protects a budget can still create or leave unresolved barriers between formal coverage and treatment use.

Table 3. Budget protection can transmit access burdens to patients rather than eliminate them

Allocation or access mechanism	Budget effect	Administrative requirement	Out-of-pocket or friction pathway	Who may be excluded	Mitigation lever
Procedural prescription denial	May limit immediate drug spending	Resubmission or alternative pathway	Delay and navigation burden	Patients unable to complete extra steps	Simplify or target review
High patient cost exposure	Shifts spending away from payer	None necessarily	Affordability barrier	Cost-sensitive patients	Lower patient cost sharing
Cost-sharing reduction	Raises payer share	Usually unchanged	Financial friction decreases	Nonfinancially constrained patients may remain	Pair with access-process reform
Budget control with out access monitoring	Protects aggregate expenditure	Depends on benefit design	Hidden abandonment or delayed use possible	Patients facing multiple barriers	Track fills, delays, and continuation

Note: Budget effects are directional conceptual descriptions, not quantified estimates. Mitigation levers are proposed policy options requiring context-specific evaluation.

Real-world access, administrative friction, and treatment feasibility

Formal coverage becomes patient value only if the treatment remains obtainable under actual benefit design. In Medicare Part D, prior authorization for oral anticancer drugs was associated with delayed or discontinued prescription fills, illustrating that administrative approval can intervene between coverage and treatment receipt [20]. The consequence of an access requirement cannot therefore be inferred from its formulary label alone. Administrative friction is also health-system dependent. Prior-authorization requirements vary across Medicare Advantage insurers, indicating that access difficulty can arise from plan design rather than from an intrinsic property of the medicine [21]. Coverage may additionally coexist with utilization restrictions and substantial out-of-pocket exposure, as demonstrated for SGLT2 inhibitors and GLP-1 receptor agonists in Medicare Part D [22]. These findings support a distinction between nominal coverage and real-world treatment feasibility. The latter requires a workable sequence of authorization, dispensing, affordability, initiation, and continuation. Failure at any one boundary can prevent clinical benefit from being realized, although treatment noninitiation or discontinuation may also reflect preference, adverse effects, response, or other clinical circumstances.

Figure 1 depicts these access boundaries and deliberately separates evidence-supported access barriers from the proposed monitoring and reassessment logic.

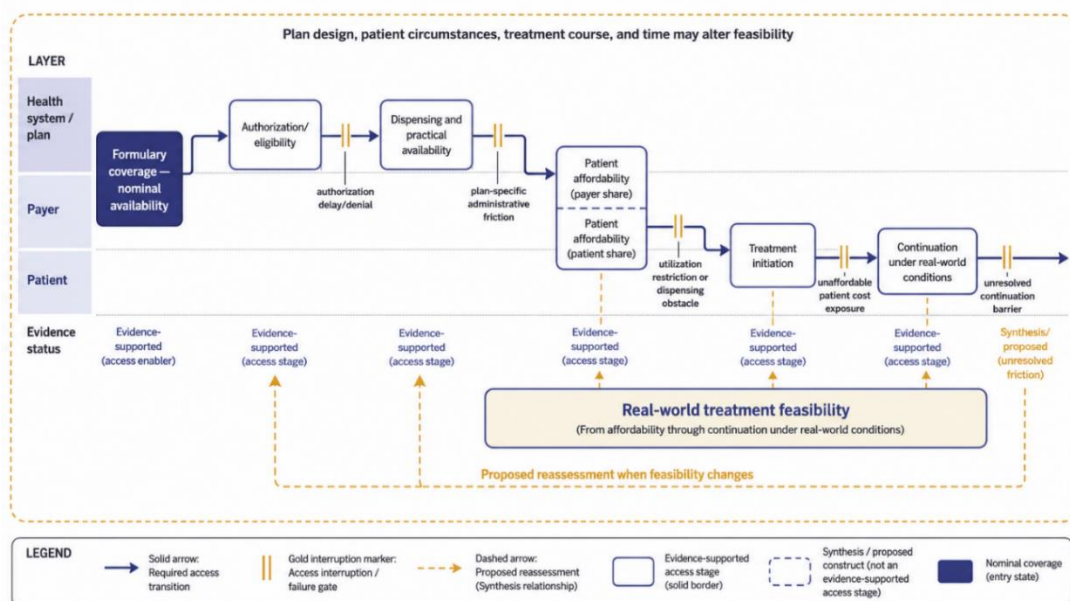


Figure 1. Nominal coverage can break before pharmacotherapy becomes feasible treatment

The proposed pharmacotherapy allocation value architecture

The preceding evidence suggests that allocation decisions operate across domains that cannot be substituted for one another. Disease-specific work has already proposed an access-focused, patient-centric formulary framework, demonstrating the feasibility of making access explicit in formulary reasoning without validating a universal model [23]. Multistakeholder consensus work similarly supports incorporating patient-relevant inputs throughout value and health technology assessment processes [24]. Broader value-assessment scholarship also cautions that conventional cost-effectiveness analysis may omit recognized value elements while emphasizing that additional elements require methodological discipline [25].

The architecture proposed here therefore does not sum clinical benefit, burden, preferences, budget impact, and access into a composite score. Instead, each domain produces a separately interpretable signal at its appropriate level. Allocation proceeds to a reconciliation boundary, where concordance strengthens the case for a decision and discordance requires explanation. Evidence uncertainty, patient heterogeneity, jurisdiction, and time remain visible rather than being absorbed into a weight. A therapy may consequently be clinically attractive yet access-infeasible, economically manageable yet poorly aligned with patient priorities, or formally covered while evidence remains uncertain. **Figure 2** represents this proposed multilevel adjudication logic.

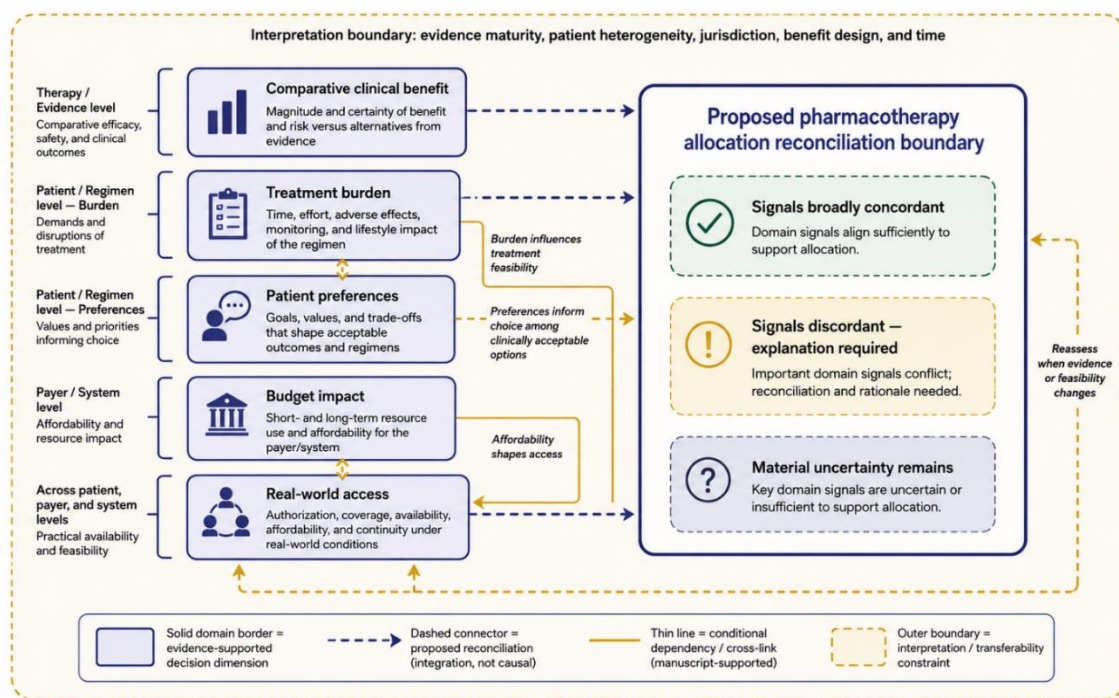


Figure 2. Formulary inclusion and patient value separate when allocation signals do not converge

Allocation trade-offs and discordant value signals

Discordance is expected when allocation signals originate at different levels. Preference-based value assessments can vary across individuals and equity frames, cautioning against treating an aggregate preference weight as universally representative [26]. Health-system signals can likewise diverge: Medicaid coverage and reimbursement of antiobesity medications vary across states even within the same therapeutic class [27]. At patient level, time, administrative, and financial burdens may also intersect rather than operate independently [28].

The proposed architecture therefore treats discordance as a state requiring adjudication, not as a calculation error. Clinical benefit remains necessary to characterize therapeutic value, but it need not automatically dominate preference-sensitive burden when clinically acceptable alternatives exist. Similarly, a favorable payer budget signal cannot erase severe patient-level access friction, while generous access does not compensate for unresolved comparative-benefit uncertainty. Distributional concerns are also distinct: a policy may improve aggregate efficiency while concentrating administrative or financial burdens in particular groups.

Table 4 converts these tensions into qualitative allocation cases. The cases are proposed analytical archetypes, not observed patient groups or validated decision categories.

Table 4. Discordant allocation cases requiring multi-perspective adjudication

Clinical benefit	Treatment burden/preference	Budget impact	Real-world access	Distributional concern	Decision rationale	Unresolved uncertainty
Strong	High burden or poor fit for some patients	Acceptable	Feasible	Burden concentrated in subgroups	Preserve option; enable preference-sensitive alternatives	Which patients experience unacceptable burden?
Strong	Acceptable	Unfavorable	Restricted	Access may favor better-resourced patients	Do not equate budget pressure with low clinical value	Can access be improved without unacceptable system cost?
Uncertain	Strong patient preference	Acceptable	Feasible	Preference may differ across groups	Retain evidence uncertainty; avoid preference replacing benefit assessment	Does later evidence change comparative benefit?
Strong	Acceptable	Favorable	Administratively difficult	Procedural barriers may selectively exclude	Address feasibility before declaring patient value realized	Which access mechanism drives nonuse?

Note: All rows are proposed adjudication cases. They illustrate noncompensatory reasoning and do not constitute a validated hierarchy, score, or allocation algorithm.

This analysis reframes formulary coverage as one condition within pharmacotherapy allocation rather than as an endpoint equivalent to patient value. That position is consistent with broader value theory, which recognizes value elements beyond conventional outcomes, but the present contribution is narrower and operational: coverage, comparative benefit, treatment burden, patient preferences, payer budget impact, and real-world access should remain visible long enough for discordance to be examined rather than hidden inside one metric [25].

The distinction matters because apparently inconsistent decisions may reflect differences in comparator choice, evidence maturity, patient priorities, payer constraints, or administrative design. Comparative-effectiveness judgments themselves can vary across assessment systems [11]. Procedural prescription denials are associated with downstream utilization and spending in Medicaid, illustrating that a mechanism intended to control drug expenditure can coexist with consequences outside the pharmacy budget [17]. Preference heterogeneity further means that a population-average valuation need not represent every patient [26]. None of these observations proves that a particular formulary restriction is inappropriate. They instead show why the reason for a restriction should remain distinguishable from the treatment's clinical value.

The proposed architecture consequently uses reconciliation rather than aggregation. Concordance across domains can support a clearer allocation rationale; discordance triggers explanation, qualification, or reassessment. Access also remains temporally revisable. Authorization, affordability, insurance status, treatment burden, clinical response, or patient priorities can change after a formulary decision. The framework therefore should be interpreted as a reasoning architecture rather than a scoring instrument, implementation protocol, or claim of optimal policy.

Policy and research implications

Evaluation should test whether the proposed distinctions can be measured consistently and whether making them explicit improves decision transparency. Prior-authorization processing time, final approval, dispensing delay, and abandonment are observable operational outcomes that could test the access component without assuming that faster authorization necessarily equals better clinical value [29]. These measures should be paired with clinical appropriateness, patient-reported burden, affordability, and treatment continuation.

Longitudinal designs are particularly important because access can change with insurance status. Changes in buprenorphine dispensing during Medicaid unwinding demonstrate that medication use can shift during coverage transitions [30]. Future evaluations should therefore examine whether an allocation judged reasonable at one time remains feasible after benefit-design, insurance, or treatment-course changes.

Preference integration also requires prospective methodological discipline. Good-practice guidance emphasizes specifying the decision context, target population, purpose, method, analysis, and intended decision impact of preference studies [31]. Validation of the proposed architecture should therefore include pragmatic applications across therapeutic areas, external health systems, and heterogeneous patient groups; prespecified examination of

discordant cases; and comparison with existing formulary processes. Findings should be capable of refining or rejecting elements of the architecture rather than merely confirming it.

Limitations

The analysis integrates heterogeneous evidence types that differ in causal strength, measurement maturity, population, and institutional setting. Challenges in patient-preference integration remain substantial [5], while comparative-benefit conclusions can depend on assessment methods and comparators [11]. Long-term treatment effects may also remain uncertain at the time of allocation [12]. The resulting architecture therefore cannot convert heterogeneous evidence into a common evidentiary scale without additional assumptions.

Transferability is another constraint. Several access studies are US payer analyses, whereas treatment-burden evidence includes disease-specific settings such as cancer care [16]. Prior-authorization requirements also vary across insurers [21], and Medicaid coverage decisions differ across jurisdictions [27]. Consequently, the framework should not be interpreted as a universal formulary standard. It does not establish that access barriers cause poor outcomes in every setting, that patient preferences should override clinical evidence, or that every additional value element improves allocation. Its central constructs, measurement approach, decision consequences, and distributional effects require external and prospective testing.

Conclusion

Formulary coverage is an important administrative condition for pharmacotherapy use, but it is not equivalent to patient value. Patient-centered allocation requires separate consideration of comparative clinical benefit, treatment burden, patient preferences, payer budget impact, and the real-world feasibility of obtaining and continuing treatment.

The proposed architecture preserves those domains instead of collapsing them into an unvalidated score. Its central decision principle is reconciliation: agreement can strengthen an allocation rationale, whereas discordance should expose the underlying clinical, patient, economic, access, or evidentiary tension. Formal availability therefore should not be interpreted as realized therapeutic value, just as budget pressure should not be interpreted automatically as low clinical benefit.

This framework remains conceptual. Its applicability will depend on therapeutic area, patient heterogeneity, evidence maturity, benefit design, jurisdiction, and change over time. Prospective and pragmatic evaluation is needed to determine whether explicit reconciliation improves the transparency or usefulness of pharmacotherapy allocation and to identify circumstances in which the architecture should be modified or rejected.

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