PX3AXS®
transforming access

The Myths and Truths of Payer Coverage

As payer management continues to intensify, achieving access at launch is no longer solely about securing medical policy or formulary inclusion. For rare disease and oncology treatments, the real challenge lies in the *quality of coverage*. Addressing this challenge requires a fundamental shift in how manufacturers engage payers before and after launch.

Yet many access strategies remain anchored to outdated assumptions. Persistent myths continue to shape payer engagement models, often overlooking the impact of quality of coverage and, ultimately, patient access.

Payer Access Myths

Several myths continue to frame the current access model and must be dispelled before we can adopt the next-generation approach to ensure high-quality access for brands.

	PAYER COVERAGE MYTHS	vs	ACCESS TRUTHS
1	First-in-class therapies achieve better coverage than later entrants		First-in-class products frequently have lower-quality access due to a lack of payer and provider understanding
2	Higher-priced products have lower payer coverage		Products with higher prices and a strong value proposition have better access than lower-priced treatments with a weak value proposition
3	Rare treatments always receive coverage due to disease severity and a lack of treatment alternatives		Rare treatments often have poor coverage due to limited understanding of the disease, surrogate end points, and treatment value
4	Oncology treatments are covered because payers are required to provide access, since they are incorporated into guidelines		While oncology treatments are covered, the quality of coverage varies and often requires significant criteria to be met based on clinical trial structure driven by the payer perception of value
5	Products with accelerated approval receive quicker payer review and coverage		Payers have standard review timelines regardless of expedited FDA review processes
6	Data required by the FDA is sufficient for payer coverage decisions		Trial data requirements by the FDA alone can be insufficient, leading to poor payer coverage, particularly if the trial design is limited in duration and lacks end points that are critical for value assessment

Myth 1: First-in-Class Advantage

The assumption that first-in-class therapies benefit from superior access due to a lack of alternatives is increasingly untrue. In practice, first-in-class products often face **lower-quality coverage** at launch, driven by payer uncertainty and limited understanding of value. For example, initially, treatments approved for spinal muscular atrophy (SMA) struggled to obtain quality coverage across all patient subtypes while follow-on products rapidly achieved coverage across appropriate subtypes based on the educational groundwork of previous treatments.

Myth 2: Products With Higher Prices Obtain Lower Coverage

Price alone is not a reliable predictor of coverage quality. ICER analyses show that some of the highest-priced therapies launched since 2022, including LENMELDY™, ZYNTEGLO™, and BEQVEZ™, achieved rapid and high-quality outcomes, with over 80% of lives covered within 6 months.[1] These products demonstrate that a strong and clearly articulated value proposition, rather than price level, drives payer adoption. When clinical benefit, durability, and patient impact are well understood, payers are more willing to offer high-quality access. Achieving access requires improved integration of medical and commercial teams, alignment on how clinical trial data will impact and support the product launch, and the generation of additional post-launch data to support payer needs.

Myth 3: Rare Products Obtain Better Coverage

Payers often lack a clear understanding of rare disease incidence, outcomes, complex surrogate measures, and treatment value, creating unique challenges for rare-drug treatment access. Payer philosophies regarding the management of rare diseases range from open to highly skeptical of value, resulting in variable coverage access. These differences in payer approach can create distinct barriers based on the channel mix, as these conditions can often have a higher incidence in Medicaid and uninsured populations or require patients to transition coverage type based on the course of their disease.

Myth 4: Oncology Products Are Automatically Covered

While it is often assumed that oncology products are quickly covered due to mandates and rapidly included in guidelines, the reality is more nuanced. Even with guideline-driven categories, new products that fail to clearly articulate clinical value to payers and institutions often experience lower-quality access with significant prior authorization requirements that leverage clinical trial criteria to include restrictive use of inclusion and exclusion criteria to narrow use.

Myth 5: Expedited FDA Review Leads to Faster Payer Access

Regulatory speed does not translate into faster payer access. ICER data demonstrate that payer review timelines remain consistent regardless of whether the FDA approval pathway is expedited or accelerated.[1] Most products require approximately 6 months before coverage policies are finalized. In some cases, accelerated approvals face even greater scrutiny, as payers express concerns about data maturity and long-term durability—factors that can negatively affect coverage quality.

Myth 6: FDA-Required Trial Data Is Sufficient

Regulatory approval is based on safety and efficacy. Payer coverage decisions, however, evaluate a broader set of criteria: unmet need, durability of response, subpopulation analysis, cost-effectiveness, and comparative value versus existing therapies. Trial data alone—particularly when end points are not established and lack long-term outcomes—often results in restrictive coverage, as payers reassess value based on trial duration for initial response criteria.

Redefining Access Strategy

Collectively, these myths illustrate why traditional access strategies often fall short. In today's environment, success depends on proactively shaping payer understanding—through evidence, education, guideline alignment, and patient advocacy—to drive high-quality coverage. Dispelling these myths is a critical step toward transforming the access paradigm and establishing how we define high-quality access and the requirements to minimize hurdles for patients to access the treatments they need.

1. Agboola F, Lin GA, Lee W, Wright A, Phillips M, Lee M, et al. Launch Price and Access Report. Institute for Clinical and Economic Review (ICER). October 23, 2025. Accessed January 21, 2026. https://icer.org/wp-content/uploads/2025/10/ICER_2025_Launch-Price-and-Access-Final-Report_For-Publication.pdf

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