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Forecasting Through an Uncertain Access Environment – Building Credible, Defensible Assumptions in a Volatile Policy Era

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WHITE PAPER

Introduction

Pharmaceutical forecasting has always required navigating uncertainty, but today's access environment introduces a level of volatility that fundamentally changes how assumptions must be built, stress-tested, and communicated. Emerging legislation, shifts in payer behavior, and new commercial models—spanning the IRA, O3B Act proposals, MFN frameworks, direct-to-consumer discounting, and cash-pay channels—are just a few of the many factors reshaping how products are priced, reimbursed, and adopted.

Forecasts that once relied on historical analogs or stable policy norms now require explicit scenario planning and meaningful policy fluency. Triangle Insights Group (TIG) uses an approach grounded in continuous tracking of legislation and payer policy, disciplined methods for translating those signals into forecast inputs, and proprietary data from Policy Reporter that connects historical policy patterns to emerging access dynamics. The result is a forward-looking and defensible forecast that anticipates and quantifies variability rather than reacting to it.

The Access Environment Has Entered a New Phase of Volatility

Several structural shifts are now directly influencing pricing, coverage, UM, and uptake:

Channel/distribution shifts

Channel control (white bagging, brown bagging, site-of-care mandates) along with mandates for direct-to-patient models, particularly in categories with high out-of-pocket burden (e.g., dermatology, obesity, migraine) directly impact gross-to-net. These models, along with alternative purchasing models (e.g., Walmart, Amazon, Cost Plus), introduce uncertainty in channel mix, patient behavior, and payer response—requiring scenarios that explore where net revenue may erode or accelerate.

IRA: Structured uncertainty and evolving negotiation thresholds

While IRA timelines are known, the drivers of final negotiation outcomes remain fluid. Forecasters must consider therapeutic-area dynamics, competitive density, indicative analog discount trends, and early CMS interpretation signals. Rather than treating IRA as a fixed assumption, TIG builds bounded scenarios informed by past negotiation patterns and category-specific precedent.

Tariffs and MFN pricing proposals

Tariffs on APIs, evolving trade policies, and periodic reintroduction of MFN models influence list price strategy, global reference pricing, and gross-to-net erosion. We track these shifts as they emerge and translate them into probability-weighted pricing paths.

Evolving payer behavior

Shifts in 340B expansion, Medicaid/ACA coverage, and payer consolidation and integration affect both time-to-access and the intensity of UM. These behaviors must be understood within their policy context and tested for how they shape RWE needs, coverage quality, step edits, and adherence.

TIG's Methodology: Translating Policy Signals into Forecast Inputs

TIG pairs real-time policy monitoring—powered by our proprietary Policy Reporter database—with structured forecasting methods that convert evolving legislation, payer actions, and access signals into measurable assumptions. This ensures the forecast reflects the access reality a product will face, not a hypothetical landscape.

Using Policy Reporter, we anchor assumptions in how payers and regulators are behaving today. Active legislation, benefit design changes, Medicaid dynamics, and channel steering trends are translated into quantitative inputs that shape the forecast's core assumptions.

TIG focuses on four access levers most likely to influence performance:

1. Coverage & Restrictions: Anticipated formulary placement, PA criteria, step edits, and how these evolve with shifting policy pressure.
2. Channel Utilization: Movement between medical and pharmacy benefit, cash-pay and DTC dynamics, and how Medicaid policy influences site-of-care and access points.
3. Patient Affordability: Cost-sharing rules, accumulator/maximizer activity, and state affordability programs that influence adherence and persistence.
4. Rebate & Discount Pressure: Policy-driven contracting constraints, evolving payer demands, and the net pricing environment.

We model baseline and alternative scenarios—such as tightening Medicaid rules, increased channel steering, or affordability mandates—to show how different policy trajectories shift uptake, adherence, and net revenue. This produces a forecast that is analytically rigorous and grounded in real-time policy intelligence.

Forecasting in a Policy-Volatile Era

Today's access environment demands forecasts that are flexible, transparent about uncertainty, and built with deep policy fluency. TIG combines:

- Real-time policy and payer monitoring
- Proprietary Policy Reporter analytics
- Disciplined, scenario-based modeling
- Cross-functional forecasting expertise

to help clients build forecasts that are credible, adaptable, and resilient—even as the access environment changes faster than traditional forecasting cycles can keep up.

Case Example: Using Payer Management Archetyping to Strengthen Forecast Assumptions

A top-20 pharmaceutical company sought to understand how a novel, new-to-market asset would be managed in a highly competitive therapy area—an essential input for building their launch forecast.

TIG collaborated with the client to identify analog products with parallel pricing strategies, evidence profiles, and competitive pressures. Using Payer Management Archetyping (PMA) and Policy Reporter data, we evaluated for each analog:

- Formulary restrictions across payers, channels, and integrated MCO/PBMs
- Approved vs. rejected claims and how these differed by archetype
- Evolution of payer restrictiveness as markets matured
- Unexpected disconnects between high restrictiveness and low claims rejection (and vice-versa)

The analysis revealed surprising variance across specific payers and channel-integrated entities—variance that would have materially altered early uptake assumptions had it not been identified.

By integrating PMA findings into the forecasting workstream, the client was able to:

- Re-segment accounts based on actual behavior rather than broad payer categories
- Adjust access and GTN assumptions for high-risk archetypes
- Refine early uptake curves to reflect likely UM intensity
- Align pricing, value, and PIE strategies ahead of launch

The result was a far more defensible forecast, with access assumptions grounded in historical behavior rather than generic expectations.