

Prelaunch Product Evaluations: When Label-Based Assumptions Don't Tell the Whole Story

When a pharmaceutical asset was being assessed for valuation, the due diligence team faced a question: how much would patients use this therapy in the real world?

In a therapeutic area where provider logistics, dose increases, interruptions, and symptom-driven modifications were common, standard label dosing rarely reflected actual utilization accurately. This gap between clinical trial assumptions and real-world behavior can lead to uncertainty around prescription volumes, revenue potential, cost to payer, and patient lifetime value.



Challenges

Product labels are built on clinical trial assumptions, controlled conditions designed to demonstrate efficacy, not capture everyday patient behavior. For business development teams evaluating pharmaceutical assets, this distinction carries real financial consequences.

Key evidence gaps included:

- **No established framework** for translating label-based dosing into real-world prescription volume and revenue estimates
- **Dose modifications, treatment interruptions, and early discontinuations** were prevalent but not reflected in standard financial models
- **Persistence rates** varied significantly across patient cohorts, creating uncertainty in patient lifetime value calculations
- **Label-based forecasts** did not account for the front-loaded induction period followed by meaningful patient drop-off, a pattern that materially compresses realized annual utilization

Solutions

Precision AQ implemented several solutions to help bridge the gap between label-based assumptions and observed patient behavior, including:

- **Real-world dispensing analysis** across treated patient cohorts to quantify dosing frequency and dose strength utilization
- **Comparison modeling** of label-based versus observed dosing behavior, including front-loaded induction and maintenance phase dynamics
- **Persistence curve modeling** across multiple cohorts
- **Patient-level wholesale acquisition cost (WAC) modeling** to translate utilization insights into annual revenue estimates
- **New-to-brand (NTB) growth analysis** to inform long-term volume trajectory

Results

The analysis revealed material differences between label-based projections and real-world dispensing economics.

Critical findings included:

- **Front-loaded utilization skews early economics.** The on-label model predicted a blended induction pattern of seven doses in month one, tapering to two doses per month through maintenance – a pattern confirmed in real-world data but accompanied by significant early attrition.
- **Persistence compressed realized revenue.** With approximately 50% of patients discontinuing within three to four months, and long-term persistence at only 15–25% at 12 months, the annual WAC per patient was substantially lower than label-only assumptions suggested.
- **NTB growth provided a counterbalance.** Continuous new patient enrollment — growing through 2024 and into 2025 — offset attrition and sustained prescription volume at the portfolio level.
- **Dosing variability created a WAC range.** Differences in dose strength utilization (X mg vs. 1.5X mg) and frequency drove a meaningful range in monthly WAC per patient, requiring scenario-based modeling rather than a single-point estimate.

Precision AQ's analysis gave the client a more accurate view of actual dosing and utilization patterns, helping to quantify the true revenue potential and value of both the pharmaceutical product and the therapeutic area. Understanding these patterns further improved confidence in acquisition valuation, enabling investors to make informed decisions about growth potential.

Work with Precision AQ to Turn Data into Decisions

When label assumptions meet real-world complexity, the gap between projected and realized value can be significant. At Precision AQ, our **access consulting** and **market access** teams develop data-grounded evaluations across the full product lifecycle, from prelaunch opportunity assessments and product valuations to real-world utilization modeling and forecasting. **Connect with our team** to explore how we can help you build the commercial clarity your next decision demands.



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