

WHITE PAPER - AUGUST 2025

The Direct-to-Patient Channel in Pharma: A Practical Guide to Protect GTN, Expand Access, and Improve Patient Experience

INTRODUCTION

On July 31, 2025, the White House escalated U.S. drug pricing pressure by sending letters to 17 pharmaceutical CEOs demanding concrete steps to align U.S. prices with “most favored nation” (MFN) levels. At the same time, affordability pressure is rising from the bottom up. Patient out-of-pocket spending reached \$98 billion in 2024, up nearly 25% in five years, as overall net medicine spending grew 11.4% to \$487 billion. The broader message is clear: traditional gross-to-net models are under strain, and the industry is expected to find alternatives.

While ambiguity still clouds how or if MFN pricing will be achieved, the tone has shifted and the urgency to act is unmistakable. Alongside the MFN directive, President Trump’s letter explicitly called for companies to pursue direct-to-patient (DTP) business models. DTP will not resolve every challenge in today’s pharma model, but it is becoming an essential part of the toolkit. When implemented thoughtfully, it can provide patients with more predictable costs and give manufacturers greater control over their channels.

The market has already begun to move. Eli Lilly’s LillyDirect (launched January 2024) offers end-to-end digital access and home delivery for select medicines. Novo Nordisk’s NovoCare Pharmacy provides DTP shipping of Wegovy at \$499/month for cashpay patients (with Ozempic to follow shortly at the same price). And the BMS/Pfizer alliance will begin DTP sales of Eliquis on September 8, 2025, at >40% below list for eligible cashpay patients. These programs reflect a broader shift toward manufacturer-enabled DTP experiences that reclaim value from intermediaries while meeting patients where they are.

This white paper outlines key considerations for DTP models. It highlights how the channel has evolved, the opportunities and risks it presents, and practical steps to begin evaluating, piloting, and scaling without compromising gross-to-net performance.

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A BRIEF HISTORY OF PHARMA'S DIRECT-TO-PATIENT EVOLUTION

Pharma's journey to DTP sales tells a compelling story of innovation borne from necessity. In the early 2000s, patients with complex conditions such as multiple sclerosis needed more than just medication: they needed personalized care and detailed guidance beyond what the health care system provided. Manufacturers responded by creating patient-centered support programs featuring home delivery and adherence coaching, fundamentally improving patient experiences.

In the late 2010s, healthcare's digital evolution reshaped patient expectations around the prescription journey. Telehealth startups successfully introduced cash-pay models in obesity care, demonstrating that a critical mass of patients valued transparency, convenience, and simplicity enough to bypass traditional insurance channels entirely.

With the advent of ultra-rare and gene therapies, such as Novartis' Zolgensma and Spark Therapeutics' Luxturna, pharma prioritized end-to-end direct engagement with patients throughout their journeys as well. Innovators introduced concierge-style programs that integrated patient finding, travel and market access logistics, personalized patient care, and financial coordination, transforming an otherwise complex and fragmented process into a tangible approach to treatment.

Today, however, the pharmaceutical industry faces a new challenge: increasing patient affordability. Scrutiny from the White House, Congress, and CMS has sharply increased amid growing frustration over drug costs, while patients themselves face record-breaking out-of-pocket costs.

In response, major players like Eli Lilly (LillyDirect), Novo Nordisk (NovoCare), and Pfizer (Eliquis 360 Support this coming September) are increasingly adopting DTP models to provide end-to-end improvements in the patient experience across a broader portfolio of products. Leveraging digital platforms, flexible payment options, and comprehensive patient support services, these initiatives improve affordability, enhance patient engagement, and maintain pricing transparency, while insulating against rebate-driven list price inflation and meeting the call to action from the current administration.

This strategic shift among leading manufacturers toward DTP highlights that traditional distribution models need to evolve to meet today's market pressures and patient expectations.

DIRECT-TO-PATIENT: PROMISE AND PITFALLS

As more manufacturers explore/expand DTP models, it is critical to understand the opportunities and risks DTP presents.

Selected Opportunities:

- **Patient/Margin Economics:** Cash-pay models help reclaim margins ceded to intermediaries (who may increase time to fill without adding value to patients) while offering patients clearer, and often lower, OOP costs. Even when a drug is on a preferred tier, patients are often exposed to high deductibles, coinsurance, accumulators/maximizers, and high OOP maximums which can drive their effective OOP beyond what they would pay at a flat net price.
- **Patient Engagement:** Manufacturer control over DTP can reduce friction in patient and prescription journeys. By removing intermediaries, DTP can enable patients to more clearly identify the brand behind their treatment (including manufacturer support/services) while reducing manufacturer uncertainty around pharmacy fulfillment (HCP call-backs for brands, generic substitution).
- **Real-time Data:** DTP platforms not only provide immediate dispensing data – they enable manufacturers to develop marketing and patient services strategies around a self-contained data set (DTP and product-specific website traffic, patient support program engagement, adherence tracking insights). DTP also offers a rare window into real-world willingness-to-pay, data that is often clouded by a mix of manufacturer and third-party discount cards and hub interactions in retrospective claims.

Selected Risks:

- **Pricing Challenges:** If not carefully structured around a comprehensive set of uninsured and underinsured patient use cases, cash-pay programs in DTP can trigger unfavorable “Best Price” implications within Medicaid and 340B channels.
- **Payer Backlash:** Payers may view DTP as channel leakage and respond with additional formulary exclusions and restrictions, reducing patient choice within traditional channels while prioritizing competitors that do not pursue DTP (and creating a “whack-a-mole” dynamic for regulators).
- **Channel Disruption:** DTP may disrupt relationships with specialty pharmacies, wholesalers, and large provider networks – many of whom offer ancillary patient support services that manufacturers must absorb. To prepare accordingly, manufacturers pursuing DTP may need to anticipate its final form – will the market remain fragmented, or consolidate into an Amazon-like clearinghouse? Will first movers and large players influence the landscape in their favor (e.g., Amazon-like sponsored or premium brands), driving manufacturers to contract for formulary position by another name?

MAKING DTP WORK FOR YOUR PATIENTS AND BRAND

Introducing a DTP channel is a significant strategic decision and must begin with key questions for your brand (e.g., “what are we solving for in the moments that matter to our patients?” and “how does DTP solve for it?”).

Begin by identifying the strategic need for DTP solutions:

- **Pricing:** DTP can offer a lower and more transparent price for patients than their cash price (varies by pharmacy) or their effective OOP cost otherwise.
- **Access:** DTP can bring access to patients ineligible for assistance programs, exploited by alternative funding programs, or facing frustrating coverage restrictions.
- **Fulfillment:** DTP can create a fast and clear path from script to fill for patients without coverage or awaiting access (e.g., bridge supply during complex/rare disease PAs).
- **Persistence:** DTP can complement high-touch patient support services to maximize new starts and persistence on therapy.
- **Benchmarking:** End-to-end data from DTP and patient support can enable price optimization for patient willingness to pay in high-value scenarios (e.g., on-demand therapy).

After identifying the strategic need, clarify whether/how to pursue DTP for your brand:

- **Validate Product-Channel Fit:** Market size and DTP demand, patient OOP and brand margin economics, drug administration support, clinical monitoring burden, digital engagement readiness, and contracting and policy requirements should each be evaluated (not exhaustive). Conduct a multi-factor feasibility assessment before pursuing DTP.
- **Anticipate Product-Model Fit:** Brand-owned, marketplace, or hub-anchored DTP models work best in different scenarios (e.g., hub-anchored for multiple brands integrated along a patient journey). Identify potential synergies before committing to a specific model.
- **Lead with Clarity for Patients:** Keep the program simple, trustworthy, and brand-centric. Make website navigation, purchasing, fulfillment, and patient support fast and reliable to establish a positive digital relationship with patients. Keep the brand visible throughout the digital relationship so it feels connected to the services provided.
- **Set Clear Guardrails:** Design your program to mitigate Best Price/340B implications and relationships with channel partners. Be clear that cash purchases may not count toward insurance benefits. Bring Compliance/Legal teams in early to prepare.
- **Measure and Course Correct:** Track website traffic and conversion to script, time to first dose ± persistence, brand volume/margin (DTP + non-DTP channels), and compliance. Expand efforts when signals are positive; iterate when they are not.

THE DTP PLAYBOOK

To bridge strategy and execution, we outline three steps to evaluate, pilot, and scale DTP.

#1: Draw Up the Play (evaluate readiness)

- **Clarify the Goal & Guardrails:** State which patients/geographies to serve, how to measure success, and what is out of scope
- **Check Feasibility:** Confirm therapy (e.g., storage, monitoring), regulatory (e.g., REMS) needs and digital/operations readiness
- **Size the Basics:** Outline price options, unit costs, expected volume, and GTN impact. Flag policy and channel risks (e.g., Best Price, specialty pharmacy relationships)
- **Make an Initial Call:** Decide to proceed, learn more, or pause — based on evidence, not just enthusiasm

Triangle Insights Group's Role: We deliver a summary brief and structured scorecard, model GTN/channel impact, and recommend practical guardrails

#2: Test the Formation (pilot & learn)

- **Choose a Delivery Model:** Select a brand-owned site, marketplace, or hub anchored approach. Assign clear owners and decision rights. Set service levels in plain language
- **Design the Patient Experience:** Sequence the patient/product journey as discovery, verification/prescription, purchase, delivery, onboarding, and refills. Set KPIs for service targets
- **Make Compliance & Safety the Default:** Cover consent and identity, adverse event and product complaint capture, pharmacovigilance, state-by-state rules, and data retention
- **Measure What Matters:** Track reach, conversion, time to first shipment, early persistence signals, and support contacts

Triangle Insights Group's Role: We support DTP strategy development and craft the playbook

Valeris' Role: We architect the pilot, select partners, stand up reporting, rehearse safety/data flows, and run weekly test-and-learn reviews

#3: Drive to the End Zone (scale with proof)

- **Set Decision Thresholds:** Require minimum incremental starts, acceptable customer acquisition cost, 90day persistence at target, and positive contribution margin after GTN
- **Maintain Channel Health:** Set clear pricing guardrails, partner terms, and a proactive communications plan to maintain channel confidence
- **Ready Operations:** Greenlight scale only after operations pass readiness gates for planning, supply/cold chain, people, and support
- **Manage Change:** Provide field playbooks and training, update digital properties and collateral, and continue MLR supervision

Valeris' Role: We coordinate the go/hold decision, codify SOPs, map near-and long-term expansion, and guide the transition.

CONCLUSION

Direct-to-patient is no longer theoretical. It is already reshaping patient journeys in select categories and is now explicitly contemplated by federal policy. The July 31 letters signal that manufacturers must deliver transparent affordability while reducing reliance on opaque rebate structures or face potential regulatory action.

DTP will not be the primary solution for every product or organization. But when applied thoughtfully, it can expand access, accelerate time to therapy, strengthen patient connection, and reclaim value otherwise ceded to intermediaries. Success requires careful attention to pricing guardrails, Best Price and 340B considerations, data flows, and pharmacovigilance from the start.

With the reconciliation and MFN policy developments still evolving, the policy environment will remain fluid. In this context, a disciplined test-and-learn approach — evaluate, pilot, scale — offers a practical path forward.

Our recommendation: put DTP on your brand's agenda. Use a framework like our playbook above to de-risk the path, protect gross-to-net, and demonstrate value early. Triangle Insights Group can help you determine if, when, and how DTP makes sense for your brand, and Valeris can help you build, operate, and scale a pilot with compliance at its core.
