

The essential guide to launching a new therapy in a competitive market

Everything you need to know about utilizing patient support programs to launch your product in a competitive marketplace.

Entering a competitive marketplace with a new therapy comes with mighty challenges. But manufacturers have proven, time and time again, that they can be successful. To outperform legacy products and deliver value from day one, find a partner that understands your therapeutic area and the patients your therapy serves.

Every step matters

From initial concept and planning to program launch and management, there's so much that goes into the launch of a product and its corresponding patient support program. Manufacturers should have a comprehensive understanding of the program launch process from end to end. This ensures a smooth launch, and helps to manage any hurdles that may arise.

Established, competitive products come with experience and more data than most manufacturers know what to do with. So how do you differentiate your product from the pack when the competition has a head start?

A well-designed patient support solution—one that supports access, adherence, and faster speed to therapy—can help you stand out from the crowd, starting on launch day.

How to use this guide

This guide offers manufacturers of therapies in a competitive marketplace an inside look at the components proven to ensure a successful patient support program. You'll glean actionable insights from Lash Group's 30+ years in the patient services industry and the collective expertise of leaders from our Launch Center of Excellence, as well as our operations, analytics, and clinical teams.

We've included four key sections:



Spotlight on: **Launch Center of Excellence**

The categories covered in this guide come from the playbook of Lash Group's Launch Center of Excellence (LCOE), a business group dedicated to the successful launch of patient support solutions.

“ Our proven approach and standardized toolkit help us deliver high-quality implementations every time. The Launch Center of Excellence leverages a phased methodology: assess, design, implement, and operate, which is based on project management and client delivery fundamentals and is constantly refined to represent Lash Group and industry best practices. ”

– **Bill Smith, Senior Vice President of Business Excellence at Lash Group**

The LCOE framework helps ensure success when launching any new program. As you read through this guide, consider your own patient support launch through the lens of these four categories.



Assessment is a discovery process. Starting many months before launch, manufacturers—together with their patient support partners—align stakeholders, set goals, and envision their unique path to launch.

You'll put those thoughts to paper with an actionable blueprint in the design phase. But for now, allow the team time and space to contemplate this key question: what do we hope to achieve?

That one query can trigger many more. A patient support solutions provider can help you explore which goals are most important during this critical period of program planning. In particular, a few components of the assessment process stand out, especially for therapies launching into a crowded market with well-defined coverage profiles and other factors.

Set your launch up for success by giving each of these areas the time and attention it deserves.

Pinpoint patient needs

Partner with organizations aligned to your disease state for insights to help you better understand patient needs. In addition, research competing products that have already established their market foothold. Where are they missing the mark in patient experience? What barriers to access and adherence still exist? How can manufacturers promote better outcomes?

In addition to standard clinical factors, various non-clinical factors may also play a vital role in the patient experience and should be considered during the assess phase. Consider analyzing the social determinants of health, including factors like patient environment, income, and social status, as well as geography and health literacy. It is crucial for manufacturers to consider these factors to ensure all patients are able to gain access to the treatments they need.

That's how patient support programs can stand apart from the rest: start with the services that don't otherwise exist and consider known patient barriers to care to inspire a program that addresses unmet needs. An adaptable patient support program can always scale with more services offered after launch, but for now, focus on a fundamental need and deliver on it.

Best practices to identify opportunities:

- Note existing barriers that impact access, speed to therapy, and adherence
- Review payer coverage profiles and what hurdles they generate
- Consider eligibility requirements for copay and patient assistance programs
- Identify unmet needs and touchpoints in the patient experience
- Clarify and designate the essential program elements first; record a short list of add-ons for later

Anticipate the volume

Making informed projections can help predict the efforts necessary for successful market entry and meeting demand. When evaluating vendors, ensure that your patient support provider:

- Develops detailed, intensive staffing models to accurately determine the number of staff needed for each program
- Has the resources to scale, as launch volume may fluctuate
- Demonstrates the knowledge and experience to use volume projections to inform hub activity planning
- Understands and hires qualified people to support the patient experience

Comprehensive market research and clinical analytics can help you anticipate volumes. Above all, keep patient support providers in the loop.

Partners need to understand anticipated volume, not just on launch day but throughout the entire lifecycle of the product.

Best practices for projecting patient volumes:

- Conduct market research
- Invest in a competitive analysis
- Recalculate projections based on real-time market conditions
- Collaborate with an experienced patient support partner
- Align all stakeholders across brand, market access, clinical, operational, distribution, and other areas

Plot out the variables

Competitive or not, any therapy has a lot at stake during launch. But those stakes are especially high for products that involve a wide web of vendors, processes, investments, infrastructures, and countless stakeholders.

For such complex programs, just one unexpected event can invite disarray. Between regulatory surprises and evolving market conditions, curveballs tend to come at the most inopportune times.

Understanding those change agents can help save hassle and headache later on. Complete adaptability may not always be possible, but knowing the potential obstacles and determining a contingency plan can limit the disruptions these curveballs have on your launch strategy.

Best practices to stay prepared:

- Assess if your program needs to implement a risk evaluation and mitigation strategy (REMS) based on your product profile and potential FDA requirements
- Develop risk mitigation strategies with your patient support partner to help manage any plan deviations
- Ask all stakeholders for input into potential mid-stream changes
- Create a robust response strategy with realistic, scenario-based potential actions



Who are your decision makers?

Every major therapy launch requires multiple stakeholders, but too many voices can add noise to the process and hold progress back. Preempt those problems by appointing decision makers and making sure everyone knows their unique role(s) and responsibilities. Even better, share that roster with your patient support partner. If they know who the leaders are ahead of time, they'll be more prepared to manage expectations.



The assessment phase imagines the destination, while the design phase charts your route to get there.

This phase transforms the insights and decisions gleaned from assessment into a codifiable plan. It's when stakeholders map their vision for the program ecosystem, requirements, and process flow. While this process may be initially scheduled to take place over two to three weeks, changes or modifications may impact timelines.

It's also important for manufacturers to be mindful of identifying strategies that can help differentiate the patient experience from established products in the market.

“ The more rigor we put in the design, the more opportunity we have for a smooth launch process. ”

– Tom Richards, Director,
Lash Group Launch Center of Excellence

Match deliverables with requirements

Apply the learnings from the assess phase to develop a list of achievable deliverables for launch—from physician awareness to platform specifications. For example, competitive therapies may warrant more extensive touchpoints imbued into the patient experience hub that vary by patient population, from digital solutions to paper communications. As you flesh out the deliverable list, however, don't forget to note the requirements of each one. This may include staffing needs, technical bandwidth/infrastructure requirements, and more.

What to do:

- Create a clinician awareness strategy with patient engagement
- Define and document standard operating procedures
- Evaluate technology needs to support digital experiences
- Establish a staffing plan that's right-sized for the anticipated volume and scope of defined services
- Identify and develop plans for any known factors that could impact launch
- Train patient support program and field team members

Explore additional patient-centric support

Research that helps ensure a good product launch should also encompass different areas of patient-centric support – with the goal to hire the right support teams with direct disease state experience.

What to do:

- Review the research and scope out resources and interventions that align with evidence-based need
- Strategize hiring and training plans for nurses and other clinical support staff with an eye for specific experience
- Create a contingency plan in the event of regulatory or other hurdles



Look to automate

Look for a partner that provides extensive tools and technology options to speed access to therapy—for example, technology solutions like electronic benefit verification (eBV)—especially those that include both medical and pharmacy benefits. Additionally, new technology components (like a digital assistant who interacts with payers) can preserve benefit counselors' time to handle highly complex cases or connect with patients and providers.



Implement

Implementation takes the planning from the design phase to build, configure, and test all of the necessary systems before program launch. Given the complexities of patient services, this phase will require abundant testing and training, shepherded forward by a disciplined project management team.

Project management

Project management is essential during all phases of a successful launch, particularly for implementation. Effective approaches use tools and methods deeply entrenched in risk-mitigating project management to increase the ability to deliver on time, on budget, and on schedule. With practical project management tools and personnel, there's a lesser risk of backlogs, delays, and burnout.

While successful partners will have their own project management teams, manufacturers can also greatly benefit from internal stakeholders who have that expertise as well. Even better, find a patient support partner who can guide your team on project management fundamentals so that all stakeholders are ready from the outset.

Technical alignment

Your patient support provider should work closely with IT collaborators to configure systems so that they launch on time and in scope and can sustain the necessary support afterward. To ensure the appropriate testing and implementation of all components, your partner should offer a readiness simulation before go-live. This last-stretch process helps align staffing, training, credentialing, standard operating procedures, other vendor services, and protocols before program launch.

Hiring and training

Manufacturers need a partner with access to a vast talent network of many skillsets and consistency in training across geographies. This approach ensures that patients receive the intended experience, no matter who or where they are.



Focus on what you can control

When common FDA hurdles mean delays in launch plans, those variables often fall outside of your control. Manufacturers can best prepare their programs by focusing on what they can control: system readiness, staff preparedness, training, distribution plans, and more. You can maintain momentum during implementation by acting on contingency plans, responding promptly to regulatory and other requests, and ensuring the operability of all other systems before launch day.



Operate

Congrats! You've launched your product. Now what?

With the launch of your therapy, program enrollments may begin immediately—giving you insights to use and adjust in the market, in real time. Work with your patient support provider to set up routine communications including program performance reviews. Together, you can utilize the data to designate growth benchmarks and indicate how well the program is operating—diligently watching for trends, opportunities, and potential changes.

Check in with staff

Regularly check in with field and other teams to ensure the program is meeting projections, both operationally and in terms of patient experience. Plan to make adjustments to staff sizes as needed.

Monitor market demand

Your patient support provider should help monitor system readiness and staffing—prioritizing the upgrades that can make the most meaningful impact on all stakeholders. Ensure your chosen patient support partner has a team that can monitor and respond to technical and staffing issues in the weeks after your program goes live.

Measure success

Success is measured quantitatively and qualitatively. Not only will you want to keep track of platform and program KPIs—such as volume, conversion rate, distribution, speed to therapy, and market share—but measurement should also account for the more intangible indicators of success, such as patient and provider experience. Regular feedback from field teams, as well as patient and provider surveys, are good ways to monitor and act on these insights.

The next step: Find the right patient support partner

Your therapy deserves a patient support provider that can meet the demands of a competitive market. As you evaluate your options, consider these essential attributes:

Experience where it counts

Entering a competitive market requires a partner adept in not only the clinical aspects of your product, but also in the nuances, complexities, and skillsets in patient services. Ensure your selected partner can pair insights with action to ensure the hub sees traction and engagement from the get-go.

Fluency in digital and data

Support programs for therapies in competitive markets will have no shortage of data and analytics to help inform implementation, from outside organization research and legacy competitors to your own product's in-market performance post-launch. Experienced partners know how to use that data actionably.

Reach and resources

Manufacturers expecting fierce competition need a partner that has extensive reach across multiple areas of the pharmaceutical supply chain. By selecting a partner with a breadth of experience, you can ensure that you're getting the best expertise in the industry.

Get your therapy launch-ready

The launch of a competing therapy is both exciting and challenging. By following a phased approach from assessment and design to implementation and operation, manufacturers can ensure their patient support program positions their therapy to improve outcomes for patients while standing apart from rival products. Working with a consultative, skilled, and experienced partner can bring that approach to life.



Questions to ask:

How can you help us leverage our differentiators in a way that will make the most impact in this competitive market?

Can you share examples of therapies that you have launched in competitive markets?

How do you best-fit technology solutions to competitive product launches?

How do you see the patient services landscape evolving?

How will you make sure our patient services hub can meet the demand?

What competitive analysis can you offer to inform our launch strategy?

What information will you need from me to help make our partnership successful?



Learn more

Lash Group pioneered the patient services industry. Three decades later, we continue to innovate with purpose, putting the patient at the center of everything we do. And we continue to lead the patient support industry in finding new ways to drive access to innovative therapies.

Find out what's possible when you launch a program with Lash Group.

To learn more, visit lashgroup.com.

As part of AmerisourceBergen's integrated suite of product life cycle solutions, Lash Group's patient support program design and delivery is just one way we help manufacturers unlock product potential and move health forward. AmerisourceBergen is the only partner with the combination of proven solutions, diverse perspectives, and unmatched scale to get therapies to the smallest, or largest, patient populations.