



Playbook

Support Drug Commercialization with Market Access Intelligence

Best Practices to Maximize Success During Critical Pre-Launch Stages

Months before the first scripts are written, and long before revenue actuals are compared to sales forecasts, a launch brand's market access future has largely been determined. So why aren't pharma teams shifting market access strategies to earlier phases of drug development? The influence of payers and PBMs is often poorly understood across a pharmaceutical organization.

Market analyst IMG Health notes that market access is now central to drug commercialization and, as a function, is crucial to achieve market leadership.ⁱ Pharma teams can no longer afford to wait until they receive their PDUFA date to derive market access strategies from external analogues, past launches or internal benchmarks.

“For upwards of 85 percent of pharmaceutical launches, a drug’s market access trajectory is set in the first six months, making market access modeling prior to launch critical.”ⁱⁱⁱ

**McKinsey
2014**

Planning for Payer and PBM Impacts on Market Access

Twenty-four months before commercial launch, pharma teams need to model evidence requirements that payers may use to determine market access. Phase II and Phase III launch teams need to examine how emerging commercial models impact launch planning and understand what steps can be taken to prepare earlier by leveraging market access intelligence.ⁱⁱ

Considering the market shift toward specialty drugs and the focus on treatment of chronic and rare diseases, pressure to find a balance between budget management and patient access has never been greater. The confluence of regulatory, economic and financial pressures on both pharmaceutical and payer strategic planning requires that pharma manufacturers take a more sophisticated approach to developing market access assumptions – even as early as Phase II – to remain competitive.

The Growing Importance of Market Forecasting During Pre-Launch Stages

IMS Health finds that an increasing number of launch brands fall short of expectations because of market access obstacles.^{iv} Examining whether market access assumptions are applied too late in the planning cycle, IMS Health surveyed market access leaders from 22 US and EU pharma companies. The focus of the study centered on Phase II vs. Phase III launch planning.

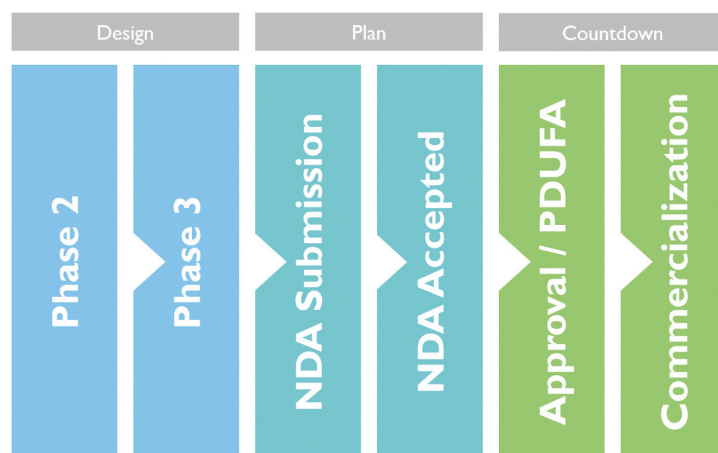


Figure 1: Drug development timeline. Market Access impacts forecasting up to twenty-four months before commercial launch.

Pharma Leaders Now Rank Market Access Equally, If Not More Important in Phase II Compared to Phase III

A 2015 survey of pharma leaders, most aligned to global market access and pricing, ranked market access considerations equally important to launch planning in Phase II as in Phase III.

Primary Challenges of Early Stage Forecasting

Shifting market access modeling to earlier pre-launch stages is not without challenges. Savvy pharma teams will need to employ change management best practices and consult with market access leaders and third-party partners to fully reap the benefits of this earlier planning model. Key challenges include:

- **Resource Constraints – Time and Budget**
- **Continuity of Organizational Resources**
- **Availability of Accurate Access Intelligence**

More than 50 percent of IMS Health survey respondents believe their current approach to forecasting falls short and doesn't adequately reflect pricing and market access risk.^v Despite the acknowledged benefits of leveraging market access intelligence in earlier stage planning, most pharma teams are challenged to develop accurate and appropriate market access assumptions.

“Companies willing to make the necessary investments and commitment to early stage market access development stand to gain a tremendous advantage.”

**IMS Health
P&MA Outlook
2015**

Phase II and Phase III Team Continuity Challenges

Ranked with budget availability challenges and resource shortages is the organizational issue of multi-phase team continuity. Half of all pharma teams surveyed noted that a different team takes over responsibility for forecasting as a product progresses from Phase II to Phase III. Insights gained during early phase analysis may be lost during team transition. Compounding the continuity problem, market analogues critical to planning aren't considered by Phase II forecasting and planning teams – most market access analogues are reviewed only by Phase III forecasting teams months after Phase II planning is complete. A failure to rapidly and accurately synchronize and transfer knowledge among team resources across development and planning stages can severely handicap an otherwise well-planned launch.

Access to Accurate P&MA Data Challenges

Beyond timing, budget and resource transition issues, the roadblock for nearly 8 out of 10 pharma companies is the development of accurate pricing and market access data. Acquiring and applying quality P&MA input for the clinical profile, competitive environment, and evolution of the market access landscape threatens to sidetrack or derail product launch. The impact of poor P&MA data modeling is traced back to decisions made 24 months before launch and is felt months after market introduction.

Best Practices: Improving Market Access Planning During Each Pre-Launch Stage

Given the importance of gathering and leveraging accurate P&MA intelligence early in the planning timeline, MMIT developed the following best practices guide. This guide organizes complex pre-launch activities into a set of high-level steps to help launch teams at each phase of planning. A collection of playbooks for each critical pre-launch phase provides in-depth analysis.

Pre-Launch through Market Introduction P&MA Checklist

Market intelligence needs shift throughout development and planning stages; one size doesn't fit all. This framework is modeled on drug launches for all sizes of organizations and across dozens of disease areas. From the simple to the complex, and from emerging to big pharma, this framework will guide and inform priority launch decisions and will clarify the role of market access intelligence during each stage of launch.

Teams will be well positioned to:

- Understand and plan for payer/PBM impacts on market access
- Leverage enrollment data to map field sales territory and decide how to organize their sales teams
- Develop a communication plan of simplifying market access coverage at launch so HCPs can easily understand how to write for a new brand

Three Stages of Pricing and Market Access Planning for Drug Launch



Design

Design: Phase II P&MA Planning, 24+ Months Before Commercial Drug Launch

In this clinically-focused phase, market access data can impact strategic decisions including Phase II to Phase III advancement, resource allocation, and clinical study design. Payer evidence requirements planning will positively shape launch decisions.

Key market access need: Educational information with a focus on analytics is central to gaining a clearer understanding of the competitive landscape. Market intelligence at this stage helps product planners better understand the payer/PBM “climate” and adapt global access strategies with precision. Trial planning can become more strategic, and product differentiation can become more closely linked to the evidence base. At this phase, payer-specific planning, and market intelligence specific to the competitive landscape are essential in successfully navigating the transition from Phase II to Phase III strategies.

Clinical Trials and the Impact of Market Access Intelligence

Pharma manufacturers must ensure that knowledge of the competitive landscape and payer/PBM requirements are considered during clinical trial design at this early pre-launch planning phase. While knowledge of clinical trial design and scientific medicine rests with the medical and statistical staff in pharmaceutical companies, market access teams need insights early in the process to ensure that payer needs are evaluated in early- and late-stage development.^{vi}

Planning Challenge: Limited visibility to the complexities of payers/PBMs. Which entities have the largest presence across the country?



Impact of Poor Planning: Defining a launch strategy without accurate data can lead to false market assumptions and misinformed decisions.



MMIT Best Practice: Leverage a trusted third-party market access source for managing payer/PBM hierarchy. Allocate lives based on formulary control with no redundant counting.

Planning Challenge: Team building and territory mapping. How many FTE resources are needed to efficiently call on payers and PBMs? How many representatives in the field do I need to educate HCPs or specialists on our brand?



Impact of Poor Planning: A large, skilled team without the right tools may lead to inefficiencies that negatively impact development of a robust launch plan.



MMIT Best Practice: Leverage robust software solutions allowing more time to be invested in high-value strategies and less on collecting and normalizing payer data.

Planning Challenge: Planning team is unfamiliar with launching into a specialty class in which both pharmacy and medical benefits are relevant.



Impact of Poor Planning: Limited insight into management strategies of both benefits can lead to misinformed decisions during early planning.



MMIT Best Practice: Leverage distinct covered enrollment data for pharmacy and medical benefits to appropriately plan payer targeting and messaging.

Plan

Plan: Phase III Early P&MA Planning, 12-24 Months Before Commercial Drug Launch

This is the education and resource focus phase of pre-launch planning. Communication between Phase II and Phase III teams is critical. As Phase II ends, focus shifts to NDA/BLA and submission with PDUFA data. Regulatory process creation and new team formation are critical at this planning stage.

Key market access need: A thorough understanding of recent therapeutic class trends and an analysis of what to expect from payers/PBMs at launch is essential. Strategic validation and hypothesis validation are key steps at this stage of planning. Market access intelligence at this stage of planning will inform creative payer messaging and positioning.

Planning Challenge: Payer/PBM's response to an upcoming launch is uncertain.



Impact of Poor Planning: Forecasting surprises at launch due to inaccurate information can lead to poor brand performance in first 6-12 months.



MMIT Best Practice: Find a partner that has expertise supporting launch brands, especially one who has a deep understanding and expertise in your therapeutic category. Market access partners must deliver full transparency to payer/PBM new-to-market policies and must provide workflow tools that will empower account managers.

Planning Challenge: Align multi-phase and matrixed resources to define and execute a successful launch strategy.



Impact of Poor Planning: Misaligned payer sales resources, field account managers and HCP detailing resources could overrun resource budgets or underperform against targets.



MMIT Best Practice: Engage with a partner that actively supports dozens of pharma manufacturers and has extensive market access experience. Market access planning partners must have comprehensive market intelligence data comprised of thousands of active employer plans to help field teams target specific populations, geographies, and demographics.

Planning Challenge: Lack of experience launching into a dual-benefit class.



Impact of Poor Planning: Ignoring a market sector that may have market opportunity will negatively impact launch performance goals.



MMIT Best Practice: Retain a market access intelligence partner that has a demonstrated record of accomplishment supporting transparency across pharmacy and medical benefit.

Countdown: Phase III Late P&MA Planning, 0-12 Months Before Commercial Drug Launch

This is the “tactical focus” phase of pre-launch planning. At this point a more granular understanding of P&MA is needed at account and geographic levels supporting contracting and promotional planning foundation work. Earlier Phase II assumptions are validated and tuned as launch Day 1 approaches.

Key market access need: Thorough understanding and model validation of payer/PBM-level data for contracting and promotional solutions that inform and support physician marketing. At this stage, market communication and field confidence must engage the provider community.

Planning Challenge: Define sales team territory coverage to optimize launch success.



Impact of Poor Planning: Unproductive field team activities can result in reduced prescription performance.



MMIT Best Practice: Leverage market access intelligence that provides zip code-level insights. Detailed P&MA data powers field team planning for coverage and restrictions expected at launch. With superior data modeling and web-based tools, even last-minute payer access changes can be easily communicated to field teams.

Planning Challenge: Field team messaging development. Training reps to answer “How is your drug covered?”



Impact of Poor Planning: Coverage communication breakdown can lead to a lack of field/rep confidence to answer market access questions.



MMIT Best Practice: Lack of coverage information is the primary reason prescribers fail to write for a brand. Engage with a market access partner that will simplify market access communication with technologically-advanced, real-time promotional solutions.

Planning Challenge: Complex, dual-benefit coverage in a therapeutic class presents complex challenges. In addition to traditional market access data, teams need access to real-time policy and restriction details.



Impact of Poor Planning: Failure to understand specific competitive advantages and disadvantages in certain geographies across pharmacy, medical and restrictions, could result in poor HCP uptake performance.



MMIT Best Practice: Select a market access partner that has expertise managing the launch of brands with complex benefit and coverage details. Teams with comprehensive pharmacy, medical and restriction databases and transparency will smooth launch communication and maintain ongoing accuracy of brand competitive positioning.

Overcoming a Changing Market in Early Stage Forecasting

Changing market conditions have allowed payers to place increased demands on pharma manufacturers to demonstrate the product effectiveness and to justify reimbursement. Market analysts note if the pharma industry's principal challenge in the early 2000's was redefining the R&D model to address declining productivity, the next decade could very well be termed "the rise of the payer."^{vii} The increased emphasis on evidence-based medicine poses a new challenge to manufacturers requiring a greater and earlier focus on the payer attitudes and strategies when planning commercial drug launch.

Transitioning P&MA intelligence to actionable insights as early as Phase II is crucial for pharma teams competing for market access. Pharma companies that successfully make this change will gain significantly more launch control and will reduce variability between pre-launch and post-launch forecasting models.

Prioritize Market Access Modeling Before Launch

The importance of achieving substantial market access before launch means that pharma teams must have the knowledge and skills to adapt to the needs and drivers of many different access stakeholders. Learning how to adapt launch plans to changing payer and PBM needs is critical for launch success.

Achieving brand success requires multi-dimensional planning and a thorough understanding of the market, key stakeholders and influencers. Market access is often determined well in advance of prescribing and revenue attainment, making it critical to understand how key access stakeholders, including payers, PBMs and providers, influence access.

Ten Ways to Achieve Optimal Pharma Market Access

Pharmaceutical executives responsible for brand management and patient access must develop effective and agile payer marketing strategies or risk product launch failure. These ten best practices, and associated playbook downloads, will help brand managers reach their market access goals.

- 1. Understand the market access landscape.**
For the target therapeutic class, understand payer and PBM customer groups who have significant market access influence.
- 2. Leverage therapeutic analogues.**
Understand the target therapeutic market and let historical analysis of relevant analogues guide forecasting models — especially if launching into a new class.
- 3. Analyze payer and PBM behavior.**
Get the new-to-market policies for every payer and PBM so that, until P&T determinations are made, patient and HCP experiences on launch “Day 1” are well understood.
- 4. Gather patient assistance program data.**
Consider what the data indicates regarding the merit of a rebating strategy versus patient assistance programs.
- 5. Take the guesswork out of forecasting.**
Use a reliable dataset for market uptake forecasting so realistic expectations are set internally.
- 6. Empower field teams with information.**
Remember that HCPs won’t prescribe a brand if it is a hassle. Empower field teams with intuitive tools to convey policies and restrictions simply.
- 7. Staff for success.**
Hire knowledgeable field teams where market access is strong and stakeholder attitudes are favorable toward the launch brand.
- 8. Keep your eye on the market.**
Continually monitor where each brand is being placed on formularies and what the coverage statuses are.
- 9. Leverage a credible third-party dataset.**
Monitor coverage status to ensure contracted status levels are consistently applied by payers.
- 10. Plan for a changing future.**
Anticipate the impact new market entrants will have on brand performance and take proactive steps to limit disruption from changing payer and PBM attitudes and policies.

Citations

ⁱ Benoff, Marc, P&MA, IMS Consulting Group, “Pricing and Market Access Outlook 2015/2016 Edition”. Last accessed March 2017. https://www.imshealth.com/files/web/Global/Services/P&MA_2015.pdf.

ⁱⁱ Ed Schoonveld, “Can Payers and Drug Industry Agree on Real Value,” PharmaExec.com, March 2105. Last referenced February 2017.

ⁱⁱⁱ Jamie Cattell, Fanny Cavalie and Giulia Chierchia, “Beyond the Storm - Launch Excellence in the New Normal”, McKinsey and Company, 2014.

^{iv} Benoff, pg 47.

^v Benoff, Pg 49.

^{vi} Wang and Richardson. Pg. 7.

^{vii} Lujing Wang and Ryan Richardson, “Planning for Change: Adapting to Shifts in the Global Market Access Landscape,” Campbell Alliance, Inventive Health.

About MMIT

MMIT is a product, solutions and advisory company that brings transparency to pharmacy and medical benefit information. MMIT partners with PBMs, payers and pharmaceutical manufacturers from P&T to point of care. We analyze market access trends and market readiness issues, while providing brand and market access solutions to navigate today’s rapidly changing healthcare market.



Our team of experts focuses on pharmaceuticals, business drivers, market intelligence and promotional behavior. Our products and services support brands approaching launch, commercialization efforts, pre-P&T market planning, launch strategy and readiness. We partner with hundreds of payers and manufacturers ensuring that our products continually capture and analyze formulary coverage and restriction criteria for more than 98% of all covered lives.