Volume 1

MMIT
a norstella company

The Essentials of Market Access

How to Build a Strong Commercialization Strategy for Your Pharmacy Benefit Therapy

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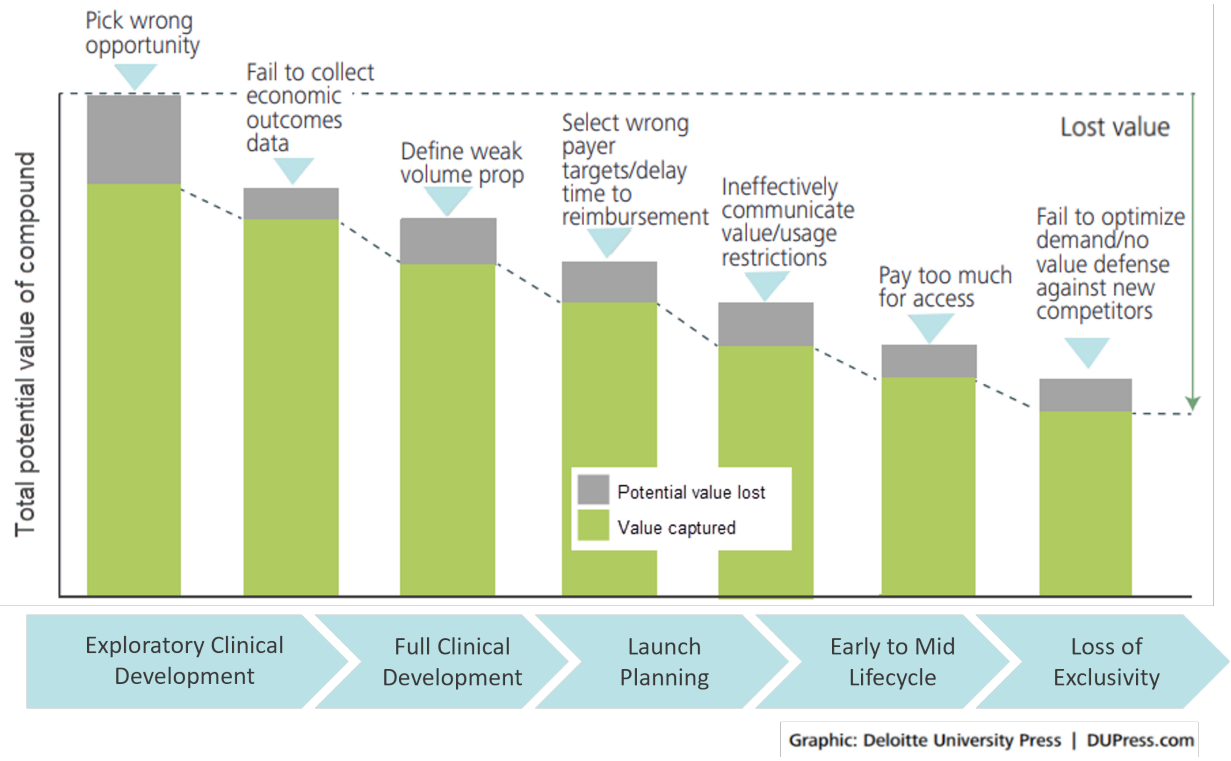
Introduction

The average cost of bringing a pharmaceutical asset to market is $2 billion, yet more than a third of all U.S. product launches fail to meet expectations. For many pharma companies, planning for commercialization only begins in earnest when a drug has been submitted for FDA approval—which is too late.

When companies get a late start on commercialization, they risk launching their product without firmly establishing their coverage, distribution, or reimbursement strategies, which can lead to suboptimal sales. In recent years, the FDA has also begun to reject applications if the manufacturer hasn't yet established a valid manufacturing and distribution strategy. Resubmitting on the FDA's timeline can cost millions in forecasted revenue.

For a successful launch, manufacturers need to start market access planning **12-18 months prior to FDA approval.** Ideally, your commercial and market access teams should be fully functional by then, as many decisions must be made in the early phases of the drug development life cycle.



In this e-book, we'll unpack the complexities of market access to ensure your team is prepared for a successful launch. There are many ways market access can go wrong, from poor product differentiation to misunderstood provider preferences. But with solid foundational knowledge and a data-driven game plan, your team can anticipate and solve these challenges in advance—and get your drug into the hands of the patients who need it.

Understanding the Players

A Primer on Who Makes Access Decisions, and How

Section 1

What exactly is market access?

Market access is synonymous with patient access, which means ensuring that patients have the right access to the right therapy at the right price and the right time. The role of your market access team is not only to secure appropriate payer coverage for your products, but also to lay the groundwork for each drug's pricing, contracting, reimbursement and fulfillment strategies.

The cornerstone of a strong market access strategy is the process of defining and communicating your product's clinical and economic value to payers, providers and patients, as each is involved in the decision to initiate therapy. Market access is a critical function of a drug's development and go-to-market strategy, as it sets the stage for a successful product launch.

Why is the benefit structure important?

Most therapies on the market are oral, self-administered drugs, which are managed under the pharmacy benefit. Members can go to a retail or specialty pharmacy and fill their prescription on their own, without requiring a doctor. Each of these drugs has its own National Drug Code (NDC) on the package, which serves as an FDA identifier. Currently, there are approximately 90,000 active NDCs on the market.

All drugs that require administration by a doctor or other medical professional inside a medical facility are managed by the medical benefit, which covers the care a member receives in person. As these drugs are typically given as part of a medical procedure, they are associated with CPT codes or J-codes (for services like surgeries and tests) as well as HCPCS billing codes (for medical devices and supplies).

This ebook addresses market access concerns for pharmacy benefit therapies. To improve access to medical benefit therapies, see our companion ebook, The Essentials of Market Access: How to Build a Strong Commercialization Strategy for Your Medical Benefit Therapy.

How do formularies work?

Most Americans are members of at least one of the nation's estimated 7,500 health plans, whether it be a commercial plan or a government-regulated plan like Medicare or Medicaid. Each health plan utilizes a formulary, or a list that specifies which drugs are covered and whether utilization management restrictions are in effect for a particular drug.

Most formularies separate drugs into tiers—such as generics, preferred brands, non-preferred brands and specialty drugs—which are associated with different levels of cost-sharing for the patient. The amount of a patient's co-pay is specific to each health plan, and often differs for each plan using the same formulary.

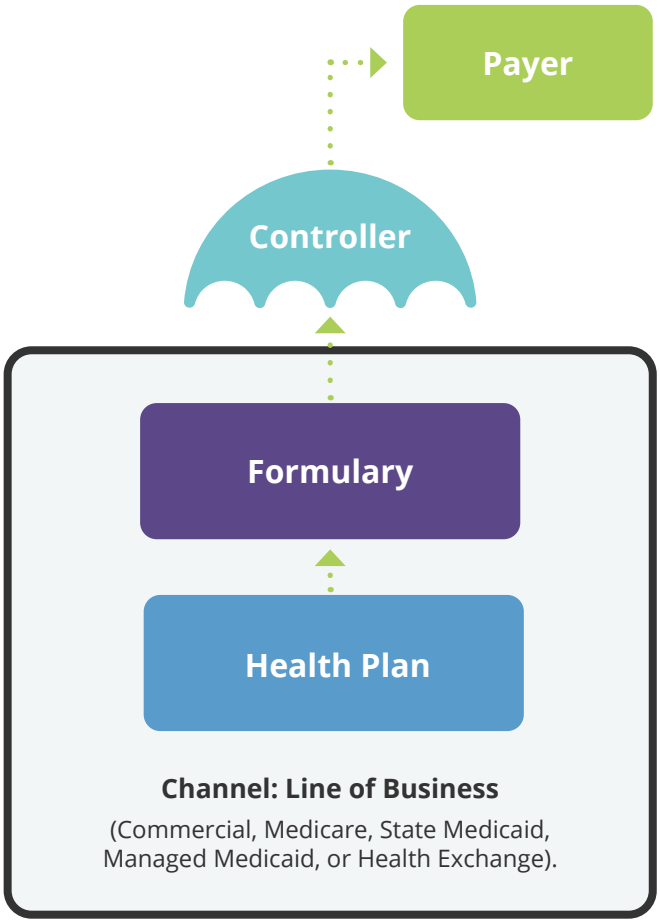
Pharma companies can learn which drugs are covered in each payer's published formulary documentation, which explains the tiers, edits, and codes used by each formulary. This document or database lists each drug's tier placement, as well as the presence or absence of utilization restrictions. **Although every health plan has a different benefit structure, first-tier drugs are associated with the lowest copayment, and copayment amounts increase with each tier.**

A new drug's placement on a high tier can mean lower utilization and reduced revenue for its manufacturer. Physicians are reluctant to prescribe drugs that they believe might create a cost burden for their patients; if the patient can't afford the co-pay, they may abandon treatment and fail to get better.

Who makes formulary and coverage decisions?

While patients might assume that payers are responsible for determining which drugs their health plans cover, that's not necessarily the case. At MMIT, we label the entity that controls the formulary decision as the **controller**. The controller may be a payer, a pharmacy benefits manager (PBM), a managed care organization (MCO), or a government entity.

For example, for a managed Medicaid plan with a state-mandated formulary, the state itself is the controller. In addition to deciding which drugs to cover and which drugs will require utilization management restrictions, a controller is also responsible for reviewing any formulary exceptions or appeals.



What is the timeline for formulary decisions?

The decision that a controller makes to cover or exclude a drug, and even to impose access restrictions, is always a strategic one. Contrary to popular belief, controllers do not necessarily review a drug as soon as it is approved by the FDA. Their timelines vary depending on several factors.

After the FDA accepts a manufacturer's application for approval, the company may begin outreach to payers and PBMs to discuss the new therapy. Each **pharmacy and therapeutics (P&T) committee** will meet several times to evaluate the drug's clinical use and efficacy, the applicability of regulatory mandates, and whether the drug provides sufficient benefits or clinical differentiation to justify its cost.

Once the drug is FDA approved, each controller's P&T committee will meet—typically within the first 90 days—to determine whether to place the drug on formulary, with or without access restrictions.

What is utilization management?

Utilization management refers to the policies and restrictions health plans use to evaluate the necessity of medical treatments. Health plans rely on these policies to reduce unnecessary services and ensure patients receive clinically appropriate and cost-effective care.

If a health plan has imposed utilization restrictions on a certain medication, a pharmacy will be unable to dispense it at the point of sale unless those restrictions have been met. For example, a **quantity limit** restricts the amount of a particular medication that can be dispensed within a given time frame. This restriction is usually aligned with the directions on the drug's label; a drug that is given twice daily might have a quantity limit of 60 tablets within 30 days.

Payers can also impose **step therapy restrictions**, sometimes called "fail first" requirements, to ensure that patients try a generic or less expensive drug before a more expensive one. If only one step is mandated, issuing a prescription for the higher-cost medication will not necessarily require step therapy. When a patient tries to fill the prescription, the pharmacy's adjudication platform will automatically review past claims to determine if the patient has already tried the first-step therapy and is compliant with their plan's coverage rules.

Prior authorization (PA) restrictions are commonly used for expensive medications, drugs that have dangerous side effects, or drugs that a payer considers to be overused. To prescribe these drugs, the provider must first complete a PA request and receive advance approval from the payer.

While PA may be appropriate for certain drugs, this restriction can act as a powerful deterrent to providers. Despite recent legislation supporting electronic PA standardization, the PA process is still complex, time-consuming and highly manual. Providers are often unsure if they are including the right documentation with the request, which contributes to denials and unnecessary care delays. As a result, the presence of a PA restriction can lead providers to prescribe a different medication altogether.

Prior Authorization Restriction

Quantity Limit

Step Therapy Requirements

How are specialty drugs managed?

While in theory the medical benefit covers all provider-administered drugs, it does not always work that way in practice. For example, many specialty drugs are managed across both the medical and pharmacy benefit structures. The practice of **cost-splitting**—in which the cost of the drug is processed under the pharmacy benefit, while the cost of physician administration is processed under the medical benefit—is especially common with Medicare and Medicaid plans.

Cost-splitting also makes it easier for payers and PBMs to receive drug rebates. If a manufacturer has a rebate agreement with a payer, the payer may be able to easily pull medical benefit claims for the administration of a particular drug and submit them to the manufacturer for rebate. However, many payers find it easier to process claims for pharmacy benefit rebates, and so choose to separate member benefits at the health plan level.

Understanding the governance of your product is crucial for improving market access. Many denied claims are rejected because a physician's office verified the member's benefits under the pharmacy benefit, but the drug is in fact managed under the medical benefit. When physicians must resubmit or appeal prior authorizations due to an administrative denial, the resulting delay hampers patients' treatment plans and manufacturers' go-to-market goals.

Why are new-to-market blocks deployed?

More and more controllers are now instituting new-to-market blocks, which block access to new drugs for up to 180 days, on at least a subset of newly launched drugs in therapeutic areas with other available treatment options.

These blocks function largely as a risk mitigation strategy. If the payer allows a drug to be covered for a patient immediately after launch but later the P&T committee decides not to cover the drug, the payer is then obligated to allow any patients on the drug to continue treatment or accept the risk of switching medications. This creates a burden for the payer, especially for high-cost specialty medications.

Many controllers also use new-to-market blocks to allow for the collection of additional real-world evidence of efficacy and success. They might also track which payers are covering the drug and determine how patients are using it before making a coverage decision. This wait-and-see period is quite common for drugs that have been fast-tracked by the FDA, which do not yet have long-term efficacy data. (See Payer Coverage of Fast-Tracked Therapies: A Cautionary Tale for more details.)

Weighing the Case for Formulary Exceptions

How to Determine When Your Drug Is in the Sweet Spot

Section 2

Payers and PBMs often place a mandatory six-month block on new therapies to allow for review by the P&T committee as final coverage is determined. While circumventing these initial coverage blocks is a critical consideration during a drug's launch period, it's important for your market access team to understand how the exception process functions for a drug throughout its life cycle.

In many cases, manufacturers might achieve greater market access when they succeed in persuading payers/PBMs to cover their drug or lift utilization restrictions. In other cases, the bulk of a manufacturer's patients may access their drug exclusively via exceptions, which may be perfectly fine. Determining which scenario works best for your drug will be a crucial part of your job as your team prepares for commercialization.

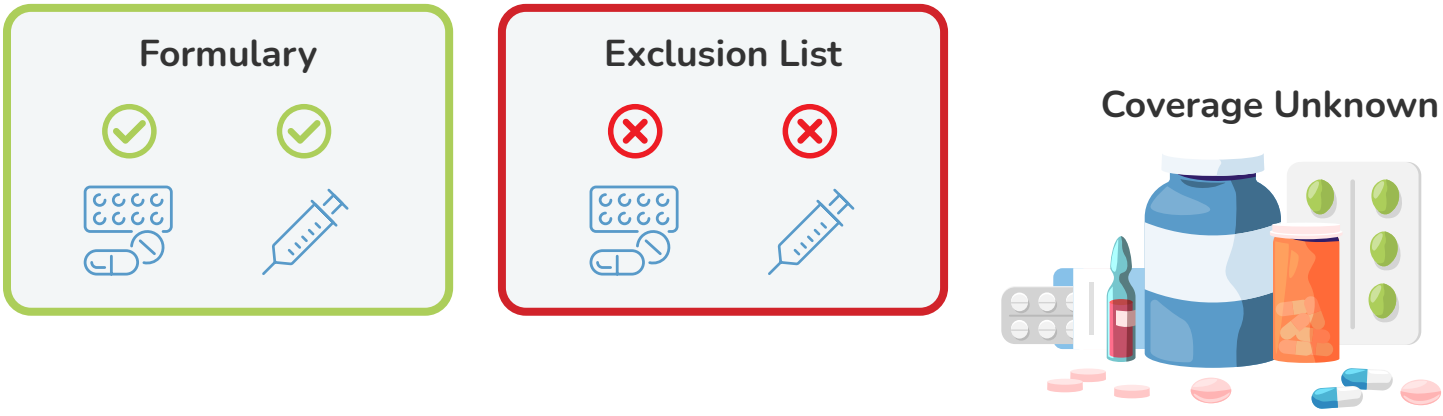
What's the difference between formulary exceptions and exclusions?

Recent MMIT data reveals that approximately 75% of all formularies are still considered open. In theory, this means that any drug that is not listed on a payer or PBM's formulary can still be prescribed—if, of course, providers are willing to take on the administrative burden of requesting an exception.

It's important to remember that a payer's formulary is essentially an advertisement of coverage. There are some drugs that a payer will cover, but which are not listed publicly on the formulary. For example, a payer may recognize that it needs to provide patients with access to an expensive gene therapy. If the payer advertises that fact by placing it on the formulary, patients in need of that therapy may switch plans to obtain coverage—and then the payer is obligated to pay for an expensive treatment for several new patients.

Most payers and PBMs also publish a **formulary exclusion list**, which specifies drugs that they will not cover. Changes and additions to these lists are common, and patients are often asked to switch medications mid-treatment. However, even the existence of a drug on a formulary exclusion list does not mean that the payer/PBM will not cover it if the treatment is judged medically necessary.

For drugs on the pharmacy benefit, formulary exceptions are usually driven at the point of sale by the pharmacist. If a drug is explicitly excluded from the formulary, the pharmacist will be alerted during claims processing that the drug is not covered. If the drug isn't listed on the formulary but isn't explicitly excluded, it may simply be processed at the point of sale without error. In this case, there is usually a tier placement default for non-formulary drugs, generally at the highest patient co-pay tier.



When are the pharmacists likely to request an exception?

If the pharmacy claims system rejects the claim, the pharmacist can choose to make a call to the processing hub that manages claims assistance to request a one-time exception. These exceptions are typically granted. Each hub will likely have a variety of thresholds that trigger a review, such as a cost threshold or multiple-prescriptions threshold. The exception request may then be routed to the on-staff medical director for review and approval or denial.

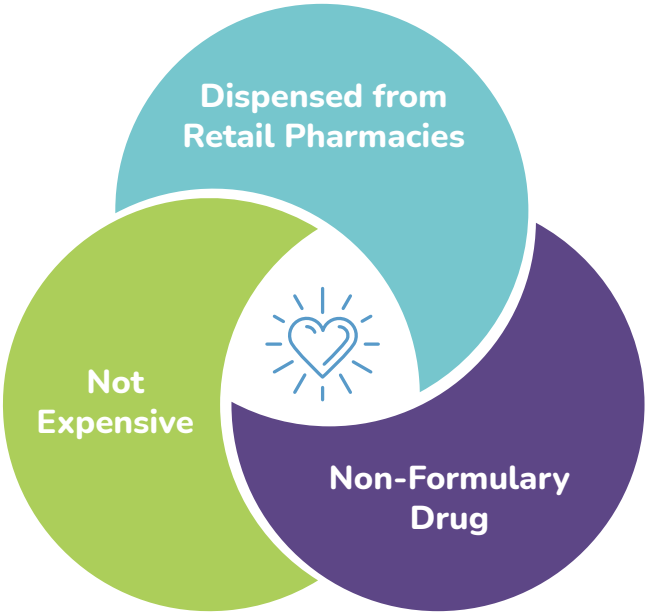
Pharmacists are incentivized to request exceptions in many ways, most notably regarding their inventory. For example, if a pharmacist is handed a prescription for a non-formulary drug and has that drug in stock, they are more likely to go to the trouble of requesting an exception, as they want to sell their inventory. But if the pharmacist has a generic or reference drug available instead, they are more likely to call the doctor to request a different prescription.

Patient preference can also be a motivating factor. If a patient explicitly asks the pharmacist to call and get an exception, the pharmacist is likely to do so; of course, most patients aren't aware that they have this option. Often, the pharmacist will hand the prescription back to the patient and tell them to call or visit their doctor again for an alternative prescription.

What is the sweet spot for non-formulary drugs?

Although the formulary exception is technically a one-off, if a patient needs a refill of the drug within 120 days, that refill—along with all subsequent refills—is also likely to be covered. Once the exception is processed and the prescription is in the patient's claims history, most claims processing hubs will bypass the exclusion edit. The patient will be able to access the drug indefinitely.

This access trick poses a conundrum for manufacturers. If your non-formulary drug is in the sweet spot—meaning that it's an inexpensive drug, dispensed from retail pharmacies rather than specialty pharmacies—it may be preferable to stay where you are rather than attempting to get on a plan's formulary.



While this seems counterintuitive, negotiating with payers to gain formulary placement opens up the possibility that a payer might impose utilization management restrictions on your drug. Physicians might need to submit a prior authorization, subject to review by the plan's medical director, before the prescription is allowed. Worse yet, the drug might be saddled with step therapy restrictions, which specify that patients must first step through a competitor's drug before beginning treatment.

Both scenarios are typically much worse for your bottom line than the drug remaining unlisted or on an exclusion list. Essentially, if your drug has the potential to be in the sweet spot, your company will likely fare better by sending sales reps out to educate physicians about your drug's benefits and general availability, regardless of its lack of formulary placement.

Improving Your Drug's Formulary Position

How to Influence Coverage and Communicate Changes

Section 3

Securing an optimal formulary position ensures greater patient access to your therapy. The factors that drive formulary placement can vary significantly across therapeutic areas, ranging from the number of treatment options available to the cost of treating a given population.

While it may seem like placement and coverage decisions are out of manufacturers' control, steps can be taken to help secure a favorable position on formulary. As your drug's market access begins to improve, all changes should be immediately conveyed to prescribing providers.

1. Analyze the Preexisting Coverage Landscape

Understanding which payers might restrict your brand—and why—is key to improving market access. Prior to launch, your team will need to keep a close eye on the coverage landscape, as this information will help you better understand your brand's access advantages and disadvantages.

Your market access team should track the new-to-market policies for every payer and PBM, making sure to identify controllers with significant influence. Also note which payers cover your brand's competitors. How have they covered competitor products in the past, and what are they basing their coverage decisions on? This information can help you identify payers that are likely to restrict access to your brand and build an effective strategy for early targeting.

2. Use Historic Analogues for Better Predictions

Before launch, use historic analogues to predict payer responses to your drug and guide your forecasting. Typically, a launch analog analysis tracks coverage for a previously released drug throughout the first year of approval, within all payer segments. Select an analog that mimics your therapy's market entry scenario and is comparable to your drug in at least one factor, such as the disease area or competitive landscape. Real-world payer preference and behavior data can also augment your analog analysis.

Ideal Historic Analog

Choose a drug that is similar to yours in at least three categories:

- **Drug type: Branded, generic, biosimilar**
- **Benefit type**
- **Line of therapy**
- **Therapeutic area**
- **Testing requirements**
- **Category dynamics**
- **Payer segment mix**
- **Price range**

Your team can also interact with P&T committee members to get a better understanding of how controllers are analyzing the cost and efficacy of competitive products. By observing P&T meeting simulations or reviewing clinical dossiers of your therapeutic area, your team can better anticipate and mitigate your brand's potential barriers.

3. Monitor Coverage Policies and Restrictions

Once your therapy is on the market, you'll need real-time market access data to monitor coverage and policy changes and drive provider engagement as access evolves. The details of a particular restriction may reveal that a payer is using criteria that aren't supported by clinical standards, or that are more stringent than the prescribing information published on your product's label.

You'll also need to know how many patient lives are impacted by these access restrictions, as this data will help your company create and prioritize target lists for your account managers. Your company can then initiate conversations with controllers regarding their rationale for imposing access restrictions.

In some instances, this is a matter of education: the controller may not fully understand the drug's label or perhaps even the disease that is being treated. When a payer has made it more difficult for a patient to begin therapy than the FDA believes is necessary, your team can make a strong case for revisiting these restrictions.

4. Use Contracting to Negotiate a Better Position

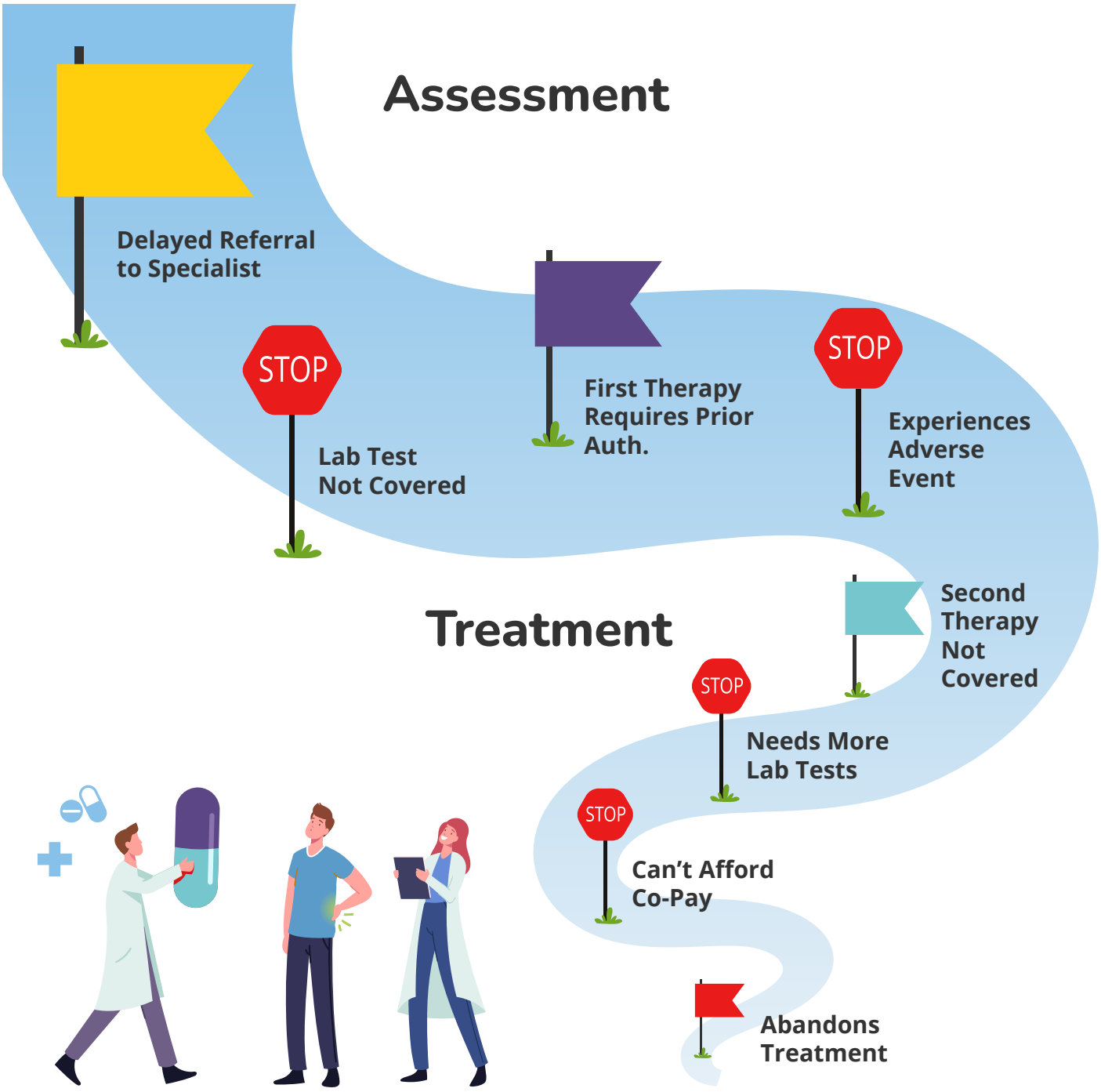
In other instances, pharma companies can use contracting and rebating to gain a better position on a health plan's formulary. By monitoring geographic areas in which your brand is currently disadvantaged, your team can leverage competitive contracting strategies with the right payers and PBMs to increase market access. Depending on the therapeutic area and the brand's value proposition, controllers may be open to negotiating an **indication-based drug contract**, a **cost-cap contract**, or an **outcomes-based contract**.

As these types of complex contracts require sophisticated risk modeling and analytics, manufacturers must choose their contracting strategy wisely. With indication-specific pricing, a payer is charged different price points for a drug depending upon which indications it is used for. Cost-cap contracts can be patient-, population-, or volume-based, and are designed to reduce financial risks for payers. Outcomes-based contracts link the cost of a drug to its clinical efficacy and/or the total cost of care in actual patients.

5. Uncover Real-World Patient and Physician Access Barriers

When access to a drug isn't fully open, your team will need to investigate the impact of payer policies on both prescribers and patients. By pairing market access data with claims data, pharma companies can gain a holistic picture of the realities of drug utilization. While market access data shows payers' intentions, claims and reimbursement data reveal the details of the patient's journey in practice.

What tests do physicians order to identify patients, and at what point? What result drives a diagnosis, or the treatment decision—and what delays this process? Can patients afford your drug? What is specifically required of physicians for compliance with your drug's utilization restrictions? When and why are patients moving to a second-line therapy? Analyzing claims and coverage data in parallel will help your team identify and resolve access gaps.



6. Engage Physicians with Omnichannel Outreach

Lack of coverage information is the primary reason physicians fail to write prescriptions for a new brand. Your company's sales team can use practice-specific data—such as a list of payer formularies used by the physician's patient population, along with local coverage information—to educate HCPs about the utilization potential for your drug. Most importantly, your reps will need a target product profile (TPP) that clearly and convincingly articulates your brand's value proposition for both patients and providers.

Since many physicians are quite selective about which pharmaceutical reps they meet with face to face, you'll need a smart cadence of both non-personal and personal promotion techniques to engage physicians. From digital assets to branded videos to private social media networks for HCPs, each element plays a complementary role that amplifies previous messaging and supports the next outreach opportunity.

7. Use Real-Time Lab and Coverage Alerts to Target Physicians at the Right Time

With the addition of real-time lab and claims data, your sales reps can prioritize physicians with a high volume of potentially eligible patients whose health plan covers your drug. Lab tests show which physicians are ordering relevant tests and which are not, while de-identified results let you track the number of patients diagnosed with a particular condition in a given region. Real-time alerts can prompt your sales team to reach out to physicians immediately after a positive test result, so your brand information is conveyed right before the prescribing decision is made.

With real-time payer coverage notifications, your reps can also keep physicians informed about favorable coverage and changing utilization management requirements for major payers in their area. If a physician has had difficulty prescribing the drug in the past, the sales team will need to explain that the drug is now in a preferred position versus its competitors. The sales team will likely need to walk through the details of payers' current requirements and restrictions, and perhaps review competitors' access requirements as a comparison.

Creating a Data-Driven Market Access Strategy

Five First Steps to Commercialization Success

Section 4

In the world of market access, success hinges on preparation. To get your drug to the patients who need it, you'll need a thorough understanding of the market you're entering, with its historical access barriers, payer preferences and provider behavior. You'll need to know where your patients are, how their disease typically progresses, and their various pathways to treatment.

For a successful launch, your team must create a data-driven market access strategy, building it during the research and development phase and extending it through to post-launch. Ideally, your strategy should be rolled out after Phase II or Phase III trial results are available. By asking the right questions in advance, you can secure patient access and achieve your utilization goals right from the start.

Here are five steps to get you started on your commercialization journey.

Step 1

Know Your Landscape

Step 2

Know Your Patients

Step 3

Segment Patients and Providers

Step 4

Create a Strong Value Proposition

Step 5

Develop a Data-Driven Commercialization Strategy

Step 1: Know Your Landscape

Long before launch, your company should have a firm grasp on the market access dynamics for your specific therapeutic area.

- What is the prevalence of this condition among each payer's covered lives?
- How do payers currently manage this patient population?
- What policies, requirements, and restrictions are associated with available therapies?
- What unmet needs still exist?
- What's the average cost of treatment for both payers and patients?
- What kind of utilization rates are payers seeing?
- What clinical attributes will be most appealing to payers in a formulary review?
- Which contracting terms and price points would be well-received?

Step 2: Know Your Patients

This can't be repeated often enough. It's critical to know not only how many patients exist within a given therapeutic class, but also how those patients progress through testing and specialists to receive a diagnosis and begin therapy. Make sure you can answer questions like:

- What's the average length of time between diagnosis and treatment?
- How are physicians managing these patient populations? How do clinical pathways drive their treatment decisions?
- What is the typical length of treatment? How are outcomes measured?
- Are physicians prescribing products off-label? Are drugs prescribed too early or too late?
- What are the current NPI referral patterns? When does a patient move from a community setting to a hospital setting?
- How does access impact utilization?
- What comorbidities do patients experience? Do patients abandon treatment?
- What does disease progression look like for most patients?

Step 3: Segment Patients and Providers

Using integrated lab, claims and market access data, your team can identify and segment a starting cohort of patients by age, disease severity, testing results, and other markers to determine where the largest number of newly diagnosed patients are and will be in the future. This data can help you answer questions like:

- Where are these patients currently being treated? Where does opportunity exist?
- Where are the relevant first-, second- and third-tier institutions and community hospitals?
- Which of these providers are ordering relevant diagnostic tests, and which are not?
- Which lab tests are performed in the hospital setting, and which in reference labs?
- What is the total addressable market for each specific institution?
- Which regions have the highest number of prime potential patients?
- Which regions have a higher concentration of specialists and covered patients?

Step 4: Create a Strong Value Proposition

Every new drug needs a convincing value proposition, which will differ quite a bit depending on the therapeutic area, the treatment options available, and the current landscape. The trick for manufacturers lies in determining how payers will weigh the drug's efficacy versus its cost.

After conducting your initial market research, leverage your drug's clinical and financial proof points to create a clear, compelling narrative of your therapy's value. If your team begins planning early enough, a well-designed clinical trial will provide you with pivotal data to include in this value proposition. If your drug has competitors, your value proposition should include a comparison statement, such as "this drug improves two-year survival rate at a lower cost than Competitor B" or "this drug also reduces readmissions by X%, unlike Competitor B."

Anticipating how payers, PBMs and providers will respond to your drug will require in-depth data analysis. Before launch, your team should test and refine these value propositions, as well as your drug's target product profile, with both payers and providers.

Step 5: Develop a Data-Driven Commercialization Strategy

Before you decide how you want to price your therapy—and whether or not you will need to engage in contracting—you'll need to know how insurers will likely evaluate your drug's efficacy, price point, and comparative value. Running a launch analog analysis is highly recommended, as this information will help you anticipate how your drug will be received.

Will your pharmacy benefit drug be listed, unlisted, or excluded from formulary? What percentage of exception requests will be granted? Will contracting for your medical benefit drug prove beneficial, or might it backfire given the coverage restrictions or competitive landscape?

To answer questions like these, your market access team will need extensive, integrated data. In order to have a 360-degree view of the patient's journey, disparate data sets must be linked through common denominators. If possible, your market access team should aim to use pre-integrated data sets that have already been reconciled with each other, so your business queries are immediately productive.

How MMIT Can Help

At MMIT, we integrate coverage data with real-world data sources such as claims and lab data to gain a holistic understanding of the patient journey. Our data assets include:

- Payer coverage, policies and restrictions
- Clinical pathways and treatment paths
- Medical and pharmacy claims
- EHR data
- Laboratory tests and results

With MMIT's integrated data, your team can track a patient cohort from diagnosis to treatment, noting the critical events and triggers along the way—from test results to payer restrictions that impact provider behavior. We take the burden of analysis off your shoulders, delivering dashboards of bridged data to answer your critical questions.

Of course, no matter how comprehensive your data is, it's meaningless unless you can draw actionable insights from it. Our team of clinical and market access experts can help you chart your course and develop a successful commercialization strategy for your new drug.

Learn how our data and expertise can help you make smarter decisions to improve access to your therapies.

LEARN MORE

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MMIT, a Norstella company, believes that patients who need lifesaving treatments shouldn't face delays because of the barriers to accessing therapies. As the leading provider of market access data, analytics and insights, our expert teams of pharmacists, clinicians, data specialists and market researchers provide clarity and confidence so that our clients can make better decisions.