Volume 2

MMIT
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The Essentials of Market Access

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

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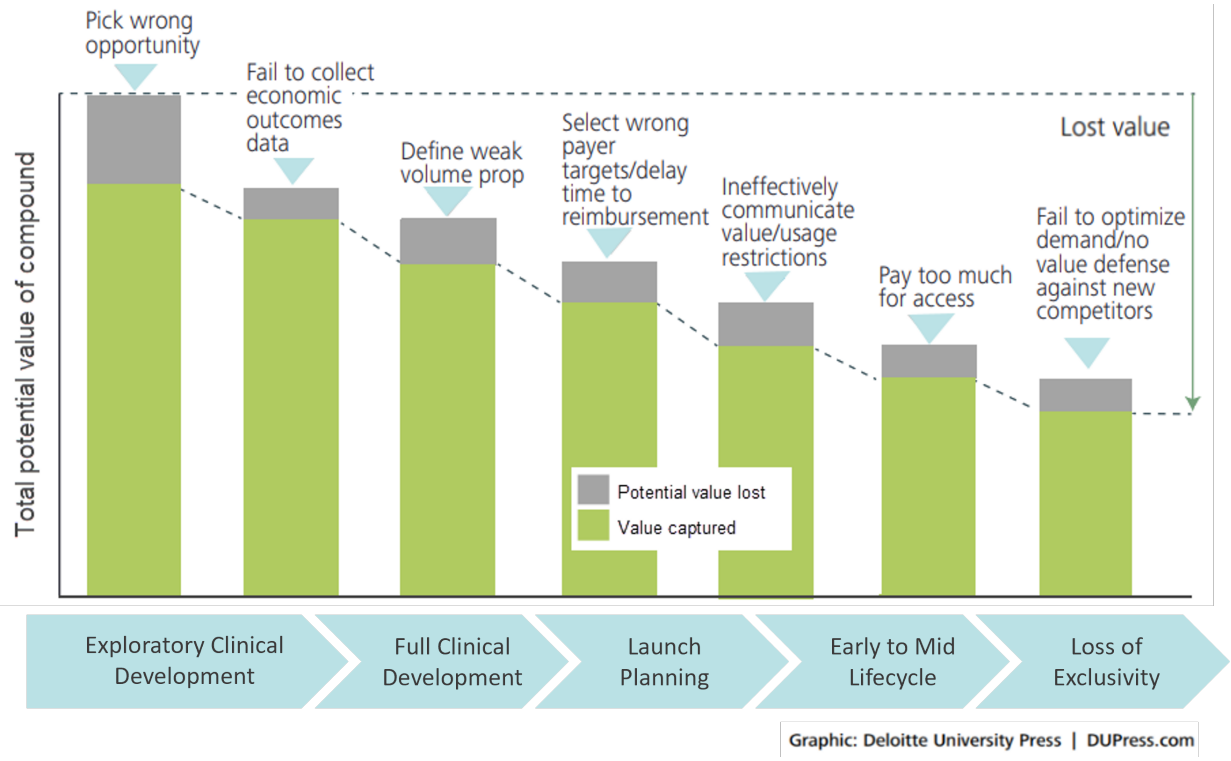
Introduction

Over the past decade, the growth of specialty pharmaceuticals has fueled increased interest from health plans in managing the cost of medical benefit drugs. Pharma companies planning on launching a drug reimbursed under the medical benefit need to start early on their market access activities, as ensuring coverage will depend on proving the long-term value of their product compared to alternative treatment options.

When manufacturers 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—a particular concern for medical benefit drugs, many which require special handling and administration. 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 lack of inclusion on clinical pathways. 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.

Securing Coverage for Your Therapy

Why Medical Policy Inclusion Matters

Section 1

While the pharmacy benefit covers mainly oral, self-administered drugs, the medical benefit covers medical care that a member receives either in the hospital, a doctor's office, or a clinic. For drugs that are covered under the medical benefit, there is no such thing as a formulary. Instead, coverage and reimbursement are determined by the payer or PBM's medical policies and treatment pathways. Your market access team will need to stay on top of payer, PBM, and provider data to optimize utilization.

Understand the Nuances of Payers' Medical Policies

Most payers create medical policies for each procedure, which detail the services provided and specify the drugs that could potentially be administered during the procedure. A few payers—chiefly those affiliated with PBMs—prefer drug-specific policies centering on the drug rather than the procedure. These include a list of every procedure for which the drug can be used.

Each medical policy includes the treatment requirements to which a physician must adhere in order to be reimbursed for the procedure and/or drug administration. Treatment requirements for a drug can vary based on the indication and the product's clinical criteria. A medical policy can also cover multiple indications for a particular drug, even off-label indications that are not yet FDA-approved. All excluded therapies for a procedure may also be listed in the policy.

It's important to note that the inclusion of your drug on a payer or PBM's medical policy does not necessarily mean that the drug has preferred status. If the policy states that the patient must first try and fail a treatment with another drug, then your drug is non-preferred. Unfortunately, many payers and PBMs write medical policies to be more restrictive than the product's FDA-approved label. If this is the case with your drug, you'll need to educate and/or contract with controllers to ensure that their medical policies reflect the drug's label specifications as closely as possible.

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

Track Your Drug's Pre-Certification Requirements

Under the medical benefit, prior approval is referred to as pre-certification. When payers stipulate that a procedure must be pre-certified, the provider must confirm with the payer that the procedure—including the administration of any drugs specified in the medical policy—is appropriate and reimbursable for a particular patient.

Approximately 35% to 40% of medical procedures require pre-certification. As procedures are approved by the payer's medical director or pharmacy director, processing a pre-certification typically costs payers more than twice as much as prior authorization processing. For procedures that do not require pre-certification, physicians must be careful to follow billing requirements to the letter when they request reimbursement, or they risk denials.

If an individual procedure or treatment must be pre-certified by the health plan, the medical policy will occasionally state that upfront. **In most cases, however, the payer or PBM maintains a separate list of HCPCS codes for drugs and procedures that must be pre-certified.** Physicians are often unaware of the existence of this list.

For this reason, it's critical that manufacturers track not only the medical policies associated with their medical benefit drug, but also all pre-certification requirements. If your drug requires pre-certification, you'll need to educate providers about the requirements and encourage them to undergo the pre-certification process despite the administrative hassle. Your team should also attempt to get payers to remove the pre-certification requirements.

Promote Hassle-Free Medical Exception Processing

For drugs on the medical benefit, the exception process is typically initiated only for newly launched drugs with a coverage block. Medical benefit exceptions are always procedure-related, as the physician is essentially asking for an exception to be reimbursed for performing a procedure in a certain manner, using certain therapies.

The medical benefit exception process is not automated, as payers do not write policies or requirements for drugs they don't cover. The physician must write and submit a letter of medical necessity to the plan's medical director, which can be a hassle. **Many manufacturers create prescribed templates for the medical necessity letter to ease this administrative burden.** After filling in the patient's details, the physician can send off the letter with reasonable certainty that it will be accepted by the payer.

While this process is more involved than a simple phone call, it can still be completed within 24 hours, especially if the patient in question is a Medicare beneficiary. If the payer covers an alternative therapy that is already listed within its medical policies, it is unlikely to approve the exception.

However, if there is no alternative therapy—or if the uncovered procedure can be clinically proven to be the right procedure for the patient—payers are more likely to grant the exception. Physicians are also more incentivized to fight for an exception when they recognize that their patient really needs this particular therapy.

Understand the Factors That Influence Exception Approvals

Essentially, the two key factors that determine the likelihood of being granted a medical exception are the drug's competitive landscape and the patient's severity of disease. If a patient is very sick and the selected drug is more efficacious or less toxic than other available drugs, the non-covered drug is more likely to be approved.

As with formulary exceptions, the patient's preference, clinical history, and willingness to advocate on their own behalf can play a pivotal role. Doctors are far more likely to request an exception if their patient is educated about the process and insists on fighting for the treatment in question. If the patient has been successfully treated on the non-covered drug in the past, or if they are resistant to the offered alternative, the request is also more likely to be approved.

If a payer initially denies the medical exception request, the physician can appeal. The appeals process is more likely to be successful for Medicare patients, as Medicare and Medicare Advantage plans are preoccupied with their Star ratings—which are based largely on member satisfaction. A patient who complains to CMS can negatively impact a plan's ratings, which can have disastrous cumulative effects for the plan in question.

Track Distribution Methods for Your Drug

The distribution of drugs covered under the medical benefit differs from pharmacy benefit drugs, which are all dispensed to the patient at the pharmacy. For most provider-administered drugs, a physician's office, clinic, or IDN will maintain an on-site inventory of the drug. The drug is acquired in bulk quantities from the manufacturer's contracted specialty pharmacy wholesaler, and then administered as needed when patients come in to receive care.

In this distribution method, known as **buy-and-bil**l, providers incur a financial risk in storing the drug, but they often profit by marking up the cost of the therapy beyond the payer's reimbursement. As providers become more integrated, payers are more likely to be forced to negotiate the reimbursement rate for a particular therapy with large IDNs.

As a result, many payers are transitioning to **white bagging** and **brown bagging** for high-cost specialty drugs. With this method, providers must submit an order for an individual patient's therapy to the payer, who then distributes the drug directly to the provider organization. In this scenario, providers can request payer reimbursement only for the administration of the drug, and not for the therapy itself.

While many providers are not able or willing to maintain an extensive inventory of therapies necessary for buy-and-bill distribution, larger IDNs have invested significantly in their capacity to store and distribute specialty products. These integrated provider organizations are likely to chafe against payer mandates for a white bagging distribution model.

Include Distribution Details in Your Contracting

Understanding the dynamics at play in distribution decisions is important for your commercialization strategy. If your team is launching a drug that requires hospitals and clinics to be certified in order to handle it, understanding which locations are already in a payer's network is crucial. Your team will want to ensure that all certified distribution centers are networked to the payers you are targeting. In payer discussions, you can use patient prevalence data to suggest that an ideally located, certified center be preemptively added to the network.

If your team has strong evidence regarding the best distribution method for your drug to the relevant patient population, you also might want to negotiate a payer contract that includes storage and distribution terms. With therapies that are administered to patients in multiple settings, such as in the hospital and later at a care facility, your team should also take care to engage providers at all stages in your market access strategy.

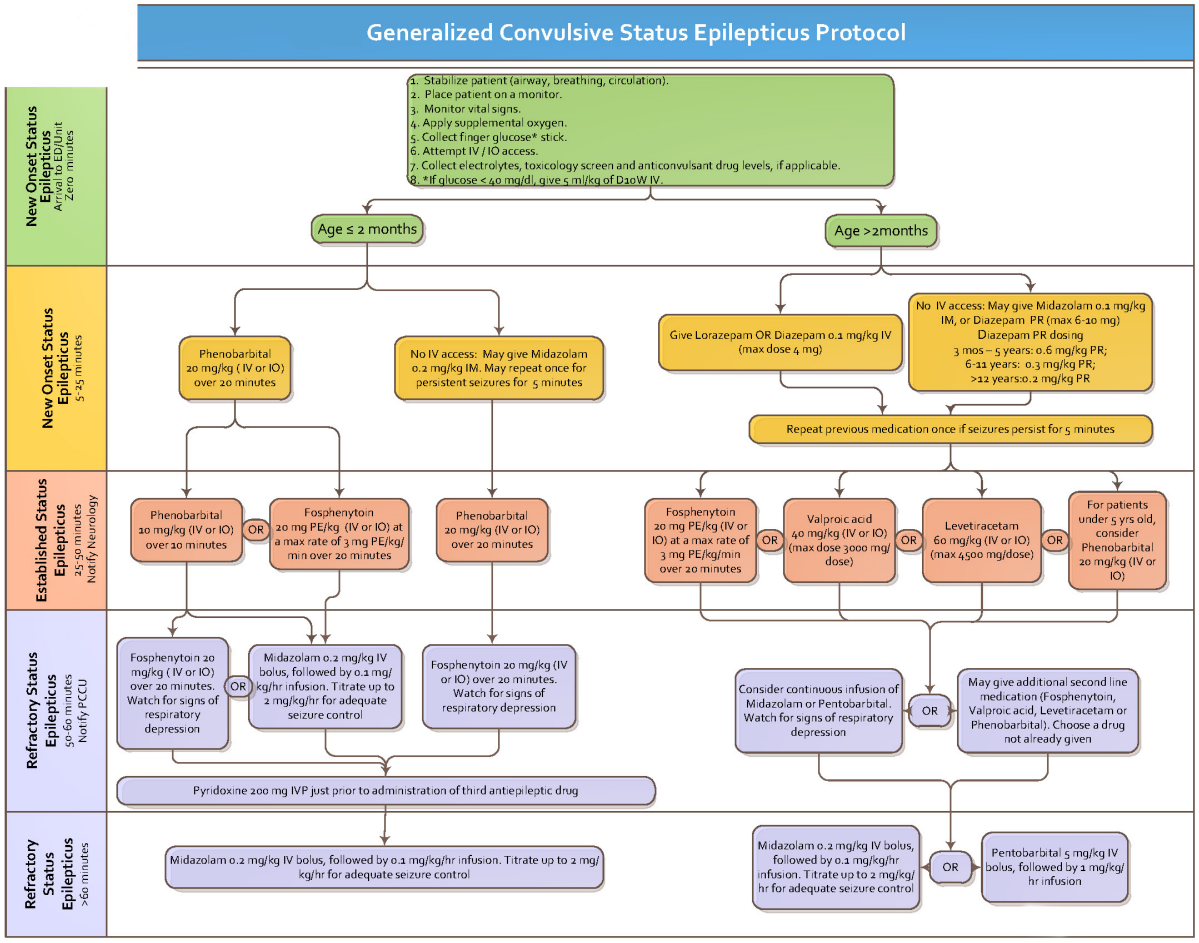
Monitoring Your Drug's Placement on Clinical Pathways

How to Keep Policies and Pathways Aligned

Section 2

To help reduce variations in care, many provider organizations (IDNs, community practices, health systems and cancer institutes) create clinical pathways for highly differentiated classes, plus areas with numerous treatment options in which patients vary significantly from one another.

Historically, clinical pathways have been used predominantly in oncology, but many payers and IDNs are now using them to manage additional therapeutic areas. Clinical pathways are often based on national guidelines for the treatment of a specific disease, but they are much narrower in scope. **Pathways account for the type, stage, and progression of the disease—as well as the cost, safety, and efficacy of treatment.**



A drug's inclusion or omission from clinical pathways is a key factor in its utilization rates. Many IDNs incentivize physicians to adhere to the pathway, and physicians may even be unable to select an off-pathway drug in their EMR system. Off-pathway requests are typically routed through a lengthy committee approval process, which can cause delays for patients in urgent need of treatment.

Use Real-World Evidence to Correct Pathway/Policy Misalignment

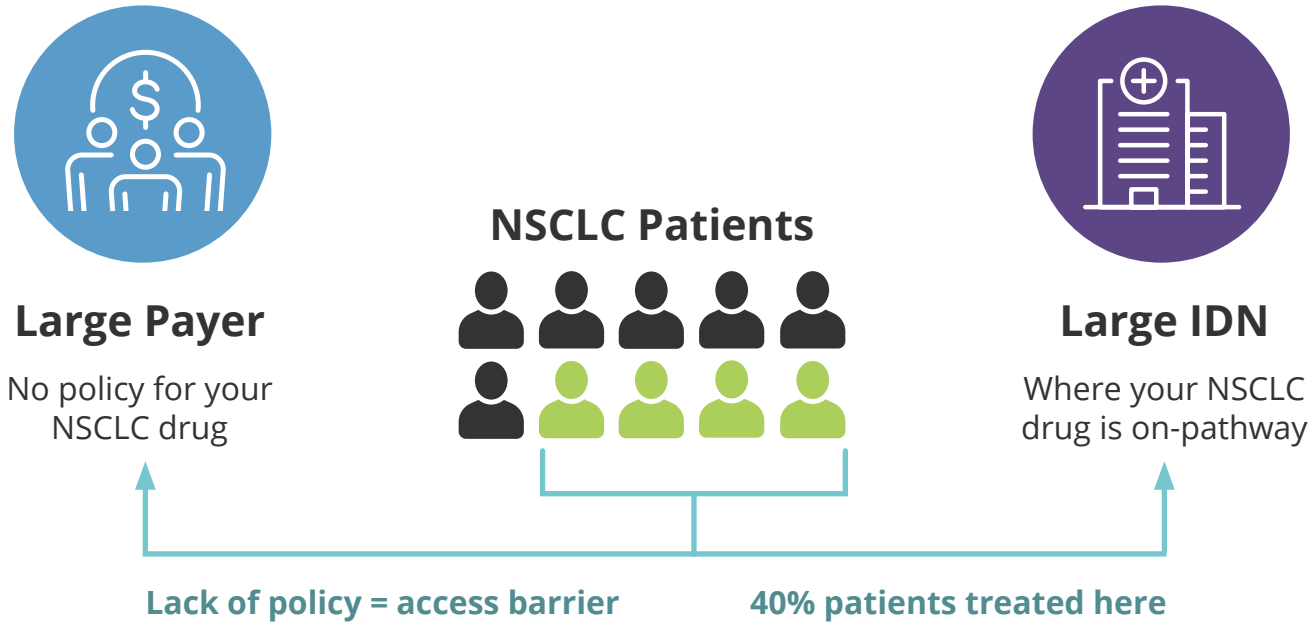
Surprisingly, drugs that are included on a clinical pathway are not necessarily covered by payers. In some cases, payers and institutions disagree about what treatment is appropriate. Even if a policy and a pathway are developed by the same payer, they don't always align. In addition, physicians rarely know in advance when to alter the treatment plan to meet a payer's requirements, such as a step-through therapy.

When a patient's health plan doesn't cover a drug indicated on a pathway, providers are in a conundrum. If they don't prescribe the drug, they are professionally and/or financially at risk; on the other hand, the patient faces enormous health risks if they can't afford treatment. In these instances, manufacturers often end up using allocated funds from their patient assistance programs to supplement the patient's out-of-pocket expenses.

It's critical that your market access team monitor and track discrepancies in medical policies and clinical pathways. By reviewing integrated claims, lab, and EMR data alongside payer coverage and clinical pathway data, your team can conduct your own checks-and-balances review of the patient journey.

This real-world data can help your team make a strong case for coverage and/or pathway inclusion directly to payers and provider organizations. For example, if 40% of qualifying patients with a certain type of cancer are being treated at specialty clinics where your drug is on-pathway, payers might be persuaded to develop a policy for this large patient population. Developing a proactive clinical pathway strategy can also insulate your company from using up the funds intended for uninsured patients for insured patients without coverage.

Pathway / Policy Misalignment Opportunity



Engaging in Medical Benefit Contracting With Payers

How to Know When It's Time to Start

Section 3

Essentially, all pharma companies want to know which of their competitors is contracting, but nobody wants to be the first to take the plunge. After all, once manufacturers begin payer/PBM contracting within an indication, it's almost impossible to stop.

Determining when payer contracting is necessary to maintain your product's existing coverage—or to improve it—is the million-dollar question for manufacturers of medical benefit products.

Why is GPO Contracting Relevant?

Before we talk about contracting with payers, we must first talk about GPO contracting. Healthcare **group purchasing organizations (GPOs)** negotiate discounts for drugs and products by buying in bulk from manufacturers and medical supply distributors. In certain therapeutic areas—most notably oncology, rheumatology and dermatology—almost all large specialty practices belong to at least one GPO.

Given their size and distribution network, large GPOs commonly negotiate a 3% to 6% discount from manufacturers, who in turn benefit from the potential for a larger sales volume. Group purchasing also saves manufacturers the time and effort of contract negotiation with hundreds of hospitals and specialty practices. While many hospitals and practices can purchase drugs either directly from manufacturers or from multiple GPOs, others are bound by exclusivity contracts, which either award providers for single-source contracts or directly prohibit their membership in competing GPOs.

GPO contracts are highly competitive, especially in therapeutic areas inundated with multiple agents with similar profiles and efficacy data. As physicians want to be able to choose which drug to prescribe, hospitals and specialty practices tend to prefer at least three options for treating any given indication. For agents in a crowded class—such as breast cancer, multiple myeloma, or follicular lymphoma—GPO contracts for largely interchangeable therapies historically resulted in steep discounts, some as high as 50% or more.

In 2005, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, CMS began calculating the **average selling price (ASP)** for each drug, which indicates the average price of a drug's sales to all purchasers, including commercial payers. Medicare now uses the market-based ASP plus a 6% add-on fee to set reimbursement rates for providers.

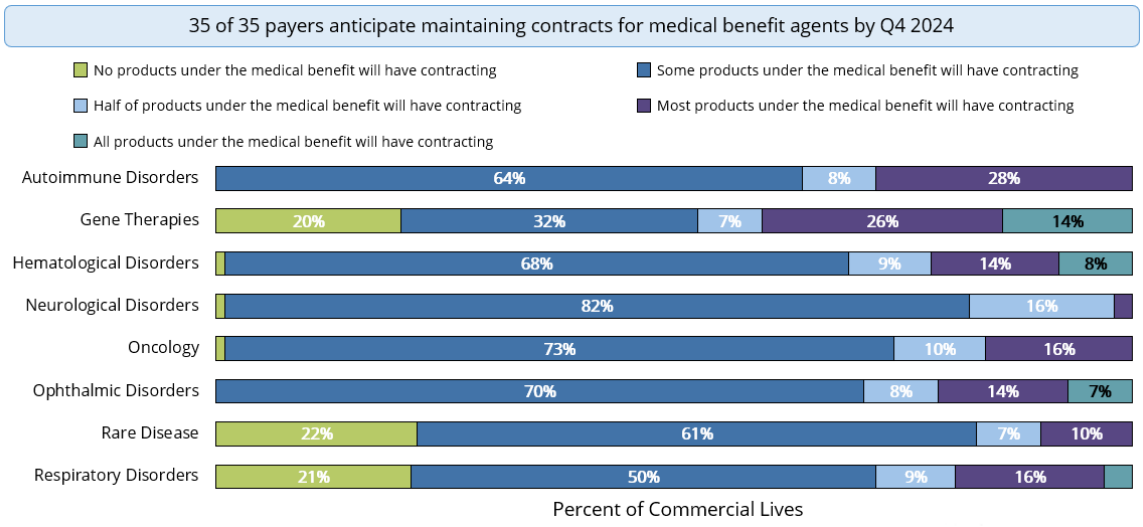
As providers are reimbursed based upon the ASP, hospitals and specialty practices must purchase drugs at a lower price in order to make any profit. While discounts are not nearly as high as they were in the past, GPO contracting remains quite competitive in some classes.

Why is Payer Contracting Increasing for Speciality Products?

Given that manufacturers are already contracting with GPOs, many actively avoid contracting with payers and PBMs for their medical benefit products. Ten years ago, payer/PBM contracting in the medical benefit space was quite rare, as payers were not practicing utilization management for these products; as a result, patient access was not an issue for manufacturers.

In the past few years, treatment options have grown significantly. In some therapeutic areas, especially oncology and rare disease, a host of pharmacy benefit drugs have been introduced to what was previously a medical benefit-only space. **When treatment options include oral and self-injectable drugs on the pharmacy benefit side, the restrictions commonly used to manage formulary drugs tend to bleed over to an indication's medical benefit counterparts.**

While in-office GPO contracting is still much more prevalent than payer contracting, MMIT data reveals that payer contracting for agents under the medical benefit is already robust. In an MMIT Index survey of large national and regional MCOs and PBMs, payers representing 51% of commercial lives reported contracting is in place for at least some medical benefit products, while payers representing 28% of lives said that most of their covered medical benefit products have contracting.



In the next few years, increased payer/PBM consolidation will likely drive additional contracting, as we've seen with the mergers of Aetna/CVS and Cigna/Express Scripts. As PBMs' utilization management practices have proven quite effective at reducing costs, we're likely to see them spread into the medical benefit space.

What is the Focus of Manufacturer/Payer Contracting?

Manufacturer/payer contracts run the gamut from traditional rebate agreements, which offer rebates based on the contractual terms, to more creative value-based contracts, which may use outcomes-based metrics to assess a drug's performance.

One of the factors that has historically driven heavy manufacturer/payer contracting for pharmacy benefit products is that it is relatively easy to track formulary placement. If a payer places the drug on tier two as their manufacturer contract requires, then the manufacturer pays them a rebate; if the payer keeps the drug on tier three, then they don't receive a rebate.

For medical benefit products, manufacturers are more often focused on easing providers' administrative burden, as pre-certifications for these products are both more frequent and more complex than those for pharmacy benefit drugs.

For example, when the first PCSK9 inhibitor drugs came out to reduce low-density lipoprotein cholesterol, pre-certifications required physicians to answer a list of 45 questions and include a copy of their chart notes. Manufacturers of both Repatha and Praluent offered rebates to payers who agreed to remove the requirement for extra documentation, as it places an unnecessary burden on providers.

How are Traditional Payer Contracts Structured?

In a traditional contracting scenario, a payer or PBM will pay the full WAC for the drug, and then receive a percentage of that cost back once they meet their contractual requirements.

Medical benefit rebates are typically based on the full cost of the medical procedure. Manufacturers can try to negotiate for their drug to be billed separately through a specialty pharmacy so the rebate is on the drug only, but prescribers rarely prefer being forced through pharmacy benefit for a physician-administered product. Your team should consider the needs of all parties in the transaction and safeguard the provider's profit margin, which will increase the likelihood that your drug is prescribed.

Your team might also negotiate with the payer or PBM to grant your product **preferred status** within their medical policies, indicating that your drug is considered the first line of treatment, which must be tried and failed before the patient tries any other drugs.

Payers/PBMs might also signify a drug's preferred status by reimbursing it at a higher rate over the ASP relative to its competitors, thereby nudging providers to prescribe it. Less commonly, a manufacturer might be able to negotiate for the **removal of pre-certification restrictions**.

Contracts can also include **graduated rebate scales**, which can specify a higher or lower rebate given the degree of product preference. For example, removing all step requirements for only your drug might warrant the highest rebate percentage, while removing step requirements for both your drug and a competitor's might reduce that rebate percentage.

How are Value-Based Payer Contracts Structured?

According to the MMIT Index survey, payers representing 56% of commercial lives report occasional use of value-based contracts for medical benefit products, a percentage which is expected to climb. The use of value-based agreements varies significantly by therapeutic area; currently, rare diseases and hematological, neurological, and respiratory disorders are the most likely to be associated with such a contract.

Typically, a value-based agreement uses measurable clinical outcomes to assess the efficacy of treatment. Payers and manufacturers must agree upon an expected outcome, as well as the reimbursement or rebate terms if the product fails to produce that outcome. For example, a patient getting an infusion to treat urothelial cancer might be assessed based on four comorbidities. If the cancer metastasizes in another part of the body, or if the patient ultimately loses a kidney, the manufacturer might be required to pay for the patient's past infusions, because they were not beneficial.

Less common examples of value-based agreements include a differentiated rebate structure based on the patient's indication or diagnosis, or capping the cost of a curative drug that is only used for a definitive period. In cost-cap scenarios, a payer might agree to prefer a product as long as the manufacturer agrees to reimburse them if the payer exceeds a specific per-patient total expense.

When Should You Consider Contracting with Payers?

Despite widespread reluctance, medical benefit contracts are already happening at scale, primarily in indications where there are multiple therapies available for the same patient. A good rule of thumb to frame this question is the rule of three. **If your ideal patient population has three available therapeutic options, the fourth entry into this space is likely going to need to contract with payers/PBMs.** When there are only one or two drugs available for a given patient, access is generally not controlled.

With the advent of three or more therapies designed for the exact same patient population, however, payers and PBMs will undoubtedly create utilization management restrictions to guide providers and reduce costs. Once the first manufacturer in an indication negotiates a payer/PBM contract for improved access to their drug, the rest of the manufacturers in that space will eventually follow suit—or lose access and market share.

How are Contracting Requirements Tracked?

Tracking whether a payer has met the requirements set forth in a manufacturer's contract is much more difficult for medical benefit drugs than it is for pharmacy benefit drugs. If your company enters into contractual agreements, you assume the administrative burden of determining payer compliance, which typically requires hundreds of hours of manual verification.

As the rebate payment process is neither transparent nor easily monitored, most manufacturers end up losing millions of dollars every year in rebate leakage. By automating the contract validation process, your team can simplify verification and prevent leakage. Your contractual formulary and medical benefit requirements can be automatically crosschecked against payer coverage data to confirm compliance—and ensure that your company is not paying for unrealized market access.

Ensuring a Favorable Status for Your Drug

How to Influence Coverage and Communicate Changes

Section 4

While it may seem like coverage decisions and clinical pathways placement are out of manufacturers' control, there are several proactive steps your team can take before launch to secure optimal market access for your medical benefit drug.

By analyzing the existing coverage landscape, your team can predict how payers and IDNs are likely to respond to your drug—and develop strategies to influence key decision-makers. 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

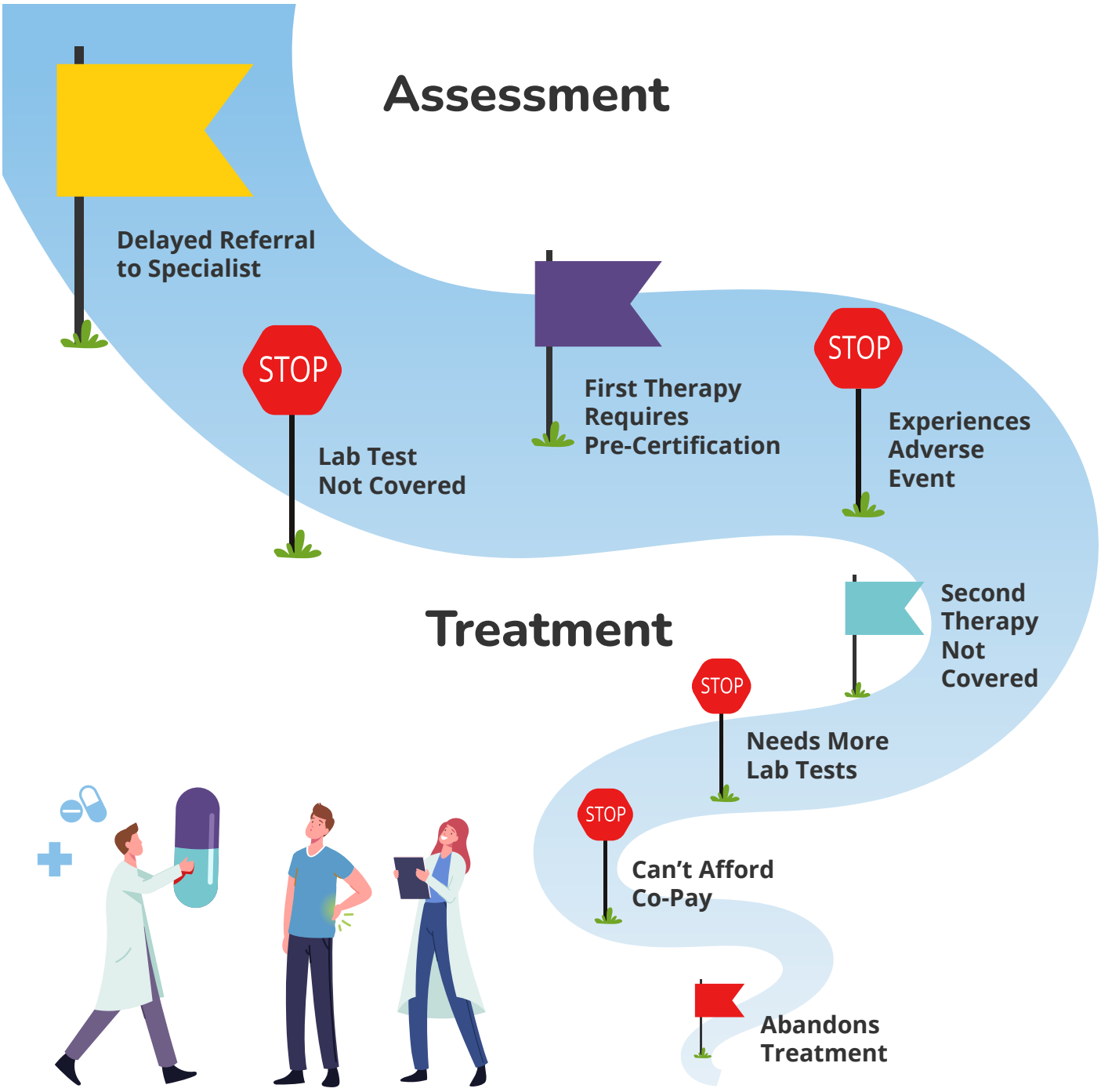
In other instances, pharma companies can use contracting and rebating to ensure their medical benefit therapy has a preferred status on a health plan's medical policies. By monitoring geographic areas in which your brand is currently disadvantaged, your team can leverage competitive contracting strategies 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.