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Six essential steps for emerging biopharma companies launching a new therapy

Let your market access partner guide you in creating an optimized strategy

Perhaps you started as a rogue group of scientists, ready to be freed from the stifling bureaucracies of big pharma. A health visionary who saw an opportunity for greater innovation. Or an entrepreneur who believes in fulfilling an unmet need.

Whatever your origin story, if you're a small team with a molecule or device that is knocking its clinical trials out of the park, welcome to the world of emerging pharma.

You're nimble. You're an open-door environment. And most likely, wearing many hats. Your hiring teams and onboarding teams are going gangbusters. What budget there is, is treated preciously and with great reservation. And you've got decisions about commercializing your product that need to be made immediately.

It all begins with having one, trusted market access partner who will walk your company through the entire launch process, providing specialized guidance and access to experts trained to handle the demands and requirements at every stage.

Guru. Sherpa. Gatekeeper. Shepherd. Although they'll probably prefer to simply be called by their name, your guide will usher your entire organization through the six key steps that will position you for an optimized launch and commercialization strategy.

Step 1: Evaluating the market access landscape

Differentiating your therapy begins by understanding the current market.

Addressing an unmet need is the key to differentiating your product. Taking a deep look at the current market and where your therapy provides a unique answer is where secondary market research starts.

Together with your trusted market access partner, you will examine:

- Market trends
- Formulary and medical policy research
- Standard of care or treatment algorithms
- Competitive landscape
- Health policy
- Payment modeling and analytics
- Patient support services in your disease area

Your guide will connect you with a team of certified, professional coders with years of experience in submitting HCPCS, CPT, and ICD-10 code applications. These experts will evaluate existing codes for any proxy products, determine if new or modified codes are warranted, and if so, facilitate the application process to garner new or modified codes specific to your therapy. Learning early on in this process how coding and product payment methodologies will be addressed is critical in ensuring a smooth, timely launch, and is often overlooked at these beginning stages.

From here, health economic outcomes experts will identify any gaps that may exist between published research and your product's unique value proposition. This may lead to the need to conduct primary market research with payers, providers, patients, and other stakeholders.

Step 2: Gaining stakeholder insights

Working with a team who not only understands what payers think, but the "why" in their decisions, and most importantly, what to do with this knowledge is key in garnering insights from your stakeholders.

- **12-24 months prior to launch**. This is a recommended time frame for developing and testing your launch strategy. Creating a distinctive and compelling value proposition is tantamount in this phase, using the evidence gap analysis conducted in step one to conduct research or perform evidence synthesis. Working with one point of contact has proven to be beneficial in fostering greater collaboration between **HEOR** and brand teams on focusing research endeavors to create more distinctive and powerful value propositions.

  During this time, your one point of contact will connect you with medical communications experts to start creating your core formulary materials such as your dossier. In addition, any models key to communicating your value will also start to be created demonstrating an array of data endpoints including cost effectiveness, budget impact, or burden of disease.

- **11 months prior to launch**. This is a recommended time frame for when your partner should share insights gathering from payers to include patient and providers regarding any support programs as well as site of care strategies. In addition, any customer-facing tools and creative messages are also tested to ensure relevance and strong calls-to-action.

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Step 3: Conducting the right evidence quickly.

Real-world evidence (RWE) has become a veritable necessity for commercialization success. The 21st Century Cures Act, passed in 2016, placed additional focus on the use of RWE to support regulatory decision-making, including both drug approvals and new indications.

After clinical trials, your guide should continue to prove product value through retrospective database studies, such as:

- Customer-based research
- Compliance and adherence assessments
- Analysis of treatment and population trends
- Economic and resource utilization analysis
- Effectiveness studies

If there is the need to further develop evidence to support a product's value proposition post-launch, your market access partner will conduct prospective studies such as:

- Observational and non-interventional studies
- Burden of illness studies
- Patient registries
- Pragmatic studies
- Time and motion studies

No matter the type of study or evidence generated, getting this data in front of formulary decision makers pre-launch is key in defining payer mind space and awareness. Your one point of contact will connect you with experts in PIE – Pre-Approval Information Exchange – both to develop materials to tell your product's story, as well as training your associates

Step 4: Distilling an effective product value story

All value propositions are not created equal. In today's world of increasing evidentiary demands, transforming the product information into a presentation doesn't make it a compelling story. Your market access partner should deploy a deep bench of clinicians, brand strategists, payer communicators, and creative experts. They will use group discussion, clinical and market research, interactive workshops, key message development, and full visualization of a brand's unique evidentiary and positioning assets to showcase your concrete proof in support of value-based care.

Step 5: Engaging with payers

Many payers want to see study results, product pricing, and patient utilization projects at least 12-18 months prior to approval. As an emerging biopharma company, it is understandable your footprint can be limited, especially 18 months prior to launch. Augment your account executives calling on payers to review product evidence with an **online platform** linking health care decision makers with more than 3,000 FDA-approved and pipeline products. This offers access to your product information compliantly and consistently.

Beyond providing health care decision makers with online access to your product's evidence, payers still appreciate and desire face-to-face relationships. Given the bandwidth challenges facing many emerging biopharma companies, outsourcing the role of managed care account executive has proven to be highly effective in delivering feet on the street and securing vital early decision maker engagement. These roles are filled by former payers, pharm and sales executives. They are also often health policy specialists and skilled in professional trade relations. As members of payers and pharmaceutical associations, many currently know the customers they will be calling on.

By outsourcing seasoned managed care account executives, your organization can decrease time-to-onboard-and-contribute without adding to organizational headcount, while increasing speed to:

- Target account identification and prioritization
- Conduct top-line medical content discussions with appropriate payer customers
- Negotiate for optimal coverage policies based on approved rules of engagement

Step 6: Breaking through patient access barriers

Even though you may have created an incredible therapy, received FDA approval, and secured formulary placement, if patients can't gain access, your time and investment has been wasted.

Due to proactive and early examination of the patient access, coding, and payment methodologies shaping our product's position, the key in this step is ensuring you can help providers and appropriate patients gain product access at the individual level. In short, you need a **field reimbursement** team.

The top two key areas that challenge provider offices are practice reimbursement/financial challenges and increasing complexity of care. Outsourcing a team of experts in provider education and reimbursement has proven to be highly effective in ensuring provider offices understand not only how to properly acquire the product but also get reimbursed.

Every field reimbursement team is hand-selected and built by meeting key criteria:

- A minimum of 5 years of experience in public or private third-party reimbursement arena, practice management, or pharmaceutical industry
- Understanding national, regional, and local health policy
- Possess extensive experience with specialty products
- Has deep knowledge of payer payment systems
- Understands practice revenue cycle management
- Is degreed or possesses equivalent practice management experience
- Certified through one or more of the following:
  - Registered Nurse (RN)
  - Certified Hematology and Oncology Coders (CHRONC)
  - Licensed Vocational Nurse (LVN)
  - Radiology Coding (RCC)
  - Medical Technologist (MT)
  - Physical Agent Modalities (CPAM)
  - Certified Medical Practice Manager (CMPE)
  - Certified Professional Coder (CPC)
  - Registered Pharmacist (RPh)
  - Certified Pharmacy Technician (CPhT)
  - Certified Professional Medical Auditor (CPhT)
  - Certified Medical Office Manager (CMOM)
  - Certified Evaluation and Management Coder (CEMC)
  - Cardiovascular Technologist (CVT)
  - Six Sigma

These valued specialists teach practice management staff optimized methods in coding, billing, and successfully navigating patient access challenges. And as a result, products with field reimbursement management teams consistently see greater patient access with a significant reduction in incomplete insurance verification forms.

Being an emerging biopharma company means facing some very big decisions. You've taken an idea from discovery to development to regulatory filing. But how do you ensure your commercialization path forward is strategically sound every step of the way? One point of contact can guide you effectively through the six key steps outlined above, and work with a market access partner ready to connect you with experience, expertise, and a strategy specifically designed for emerging biopharma.

Connect with an expert

Our leading team of value experts transforms evidence, policy insights, and market intelligence into effective global market access strategies helping clients effectively navigate today's complex healthcare landscape.

Contact us