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PBM Best Practices Series: Standard or custom formulary: Which option is better for your plan?

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Each year plan sponsors need to assess which formulary option best fits their organization's financial and clinical goals. Current pharmacy benefit manager (PBM) options include: a standard "off-the-shelf" formulary, a custom formulary, or a partially customized formulary. This paper outlines best practices to help plan sponsors evaluate the formulary options that best fit their plan needs.

Standard PBM formularies: A turnkey solution

As PBMs have begun to offer more robust formulary options, the decision between standard formularies (sometimes called a national or template formulary) or custom formularies has come into focus in recent years. Plan sponsors are now faced with an increasingly complex "menu" of choices as PBMs have evolved their offerings to add more granular drug-level and therapeutic class-level options. Plan sponsors willing to invest in the creation and management of a custom formulary may be able to achieve better outcomes by aligning the formulary more closely with their specific needs. There are situations, populations, and certain lines of business, such as managed healthcare plans (e.g., Medicare and Medicaid), where specific needs can only be achieved by a custom formulary.

There are several advantages that a custom formulary approach has over a standard formulary. Plan sponsors can control drug movement on and off the formulary and therefore mitigate the potential volatility of a standard formulary. In addition, custom formularies give plan sponsors the freedom to create their own UM protocols. This allows increased control and visibility to prior authorization (PA) rejection rates or drug exclusions for products that don't meet satisfactory cost-effectiveness thresholds. Custom plan design arrangements can also help steer members toward plan-preferred products.

The ultimate goal of a plan sponsor is to implement a custom formulary that is financially aggressive while simultaneously providing options for plan members that are clinically appropriate. There is a delicate balance between these two competing ideas; emphasis on mitigating member disruption may increase costs in aggregate and emphasis on drug savings may increase member disruption. In other words, if a plan sponsor only focuses on low formulary costs then clinical outcomes may suffer and overall healthcare costs may increase through increased hospitalizations, non-adherence ripple effects, development of concomitant conditions, or overall nonengagement. On the other hand, a formulary that focuses on optimizing member satisfaction and maximizing clinical efficacy may struggle with increased costs through medication hoarding, inappropriate utilization of low-value products, drug abuse, and lower rebates. A plan sponsor needs to carefully balance both financial goals and clinical outcomes to achieve the lowest overall healthcare cost and best outcomes possible.

Plan sponsors thinking of the custom formulary approach should consider the following discussion points describing the custom formulary development and maintenance process.

Historically, PBMs offered one drug list and one set of utilization management (UM) requirements. Any deviations from the product list or UM edits were considered a customization that would require a reduction in either the number of rebate-eligible claims or the rebate guarantee terms themselves. This is primarily due to contractual requirements PBMs have with pharmaceutical manufacturers regarding product tiering, exclusivity, and UM.

Today, there are various formulary strategies for controlling plan costs. Some formularies primarily rely on exclusions, rather than tiering, that allow for higher rebate guarantees. Other formularies control costs using a "generics first" strategy that maximizes generic utilization while also providing moderate rebate value through the inclusion of a targeted number of brand drugs. An assortment of drug UM packages can be added to the formulary to ensure all members are receiving optimal, medically appropriate care. These levers allow PBMs to offer more flexibility to a plan sponsor concerned about balancing cost and member satisfaction.

The increased formulary and UM flexibility is accompanied with other trade-offs for plan sponsors to consider. In the last few years, we have observed cases where PBMs have made substantial changes to their standard formularies. For example, in one case, a PBM switched its preferred diabetic monitoring system to another manufacturer only to then switch back the next year. This type of drug access volatility, year over year, can have a material effect on member satisfaction and, potentially, health outcomes. PBMs will make formulary decisions from an aggregate book-of-business perspective, which may conflict with needs of individual plans. Some plan sponsors have negotiated benefits, state guidelines, and sensitive populations that cannot accommodate certain types of changes. These plan sponsors are ideal candidates for a more customized formulary approach.

Custom PBM formularies: A more tailored approach

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DEVELOPING A CUSTOM PBM FORMULARY

The first step in developing a custom formulary from the ground up is to create a Pharmacy and Therapeutics (P&T) committee. This group is responsible for devising a strategy, ensuring regulatory compliance, enacting drug and UM changes, considering ongoing updates, determining new-to-market product placements, and managing other general oversight responsibilities.

THE ROLE OF P&T COMMITTEES[1]

A P&T committee comprises clinical experts, such as physicians, nurses, and pharmacists, as well as financial experts (administrators or directors). The committee has two main goals: (1) to ensure that the formulary's efficacy standards meet the health needs of a population, and (2) to achieve that at minimal cost.

To accomplish this, committee members are responsible for making equitable coverage decisions, selecting treatments offering the best therapeutic outcomes, and minimizing potential risk and cost to patients. To that end, plan sponsors can refer to the list in Figure 1 as a best practice checklist.

[1] AMCP Partnership Forum: Principles for Sound Pharmacy and Therapeutics (P&T) Committee Practices: What's Next? (2020). Journal of Managed Care & Specialty Pharmacy, 26(1), 48-53.doi: https://www.jmcp.org/doi/pdf/10.18553/jmcp.2020.26.1.48.

FIGURE 1: COST-EFFECTIVENESS QUADRANTS

✔ **Include the appropriate experts**

- Physicians, pharmacists, or other healthcare professionals with clinical expertise.
- A financial underwriter or an administrator who has direct insight into financial outcomes and potential costs of formulary decisions. This person is commonly the chief financial officer (CFO) or a person from the CFO's staff.
- Quality assurance staff dedicated to assessing member experience in relation to formulary changes.

Note: It is necessary to require full disclosure of conflicts of interest from committee members with connections to other industry stakeholders such as those with financial connections to a pharmaceutical manufacturer. These situations may be handled on a case-by-case basis.

✔ **Develop standardized guidelines for discussion and decision-making**

- Keep detailed records of meeting notes including an auditable record of keystone clinical and financial decisions (e.g., product tier changes, removals, additions) and the supporting evidence behind them.
- Create a process for committee members and their supporting staff to author, present, and review resources that will be used to make formulary decisions.
- Maintain compliance-based policy and procedures (P&P) documents that define, educate, and give direction on how impacted pharmacy programs are to be administered.

✔ **Ensure quality and accuracy of implementation**

- Certain committee members should be delegated the task of overseeing that the outcomes and decisions of the P&T committee are carried out effectively.
- Typically, this role would fall to the director of pharmacy and corresponding support staff.
- An additional function of this staff is to assist the plan when audited by an internal or external auditor.

The members serving on a P&T committee are responsible for using their expertise to evaluate potential formulary changes. These decisions should take into account things such as clinical trial evidence, published practice guidelines, member perspectives, and cost-effectiveness research. In particular, estimating the financial impact of potential formulary changes can be a complex task. One method for doing this is to use existing pharmacy claims experience to model and project the financial impact of future formulary changes. This type of complex analysis may require additional expertise from outside the P&T committee. Many consulting firms have developed models and tools that committees can leverage in the decision-making process.

MANAGING A CUSTOM FORMULARY

As part of managing a custom formulary plan sponsors will need to review the fast-paced and highly competitive drug pipeline. Examples of some challenges plan sponsors may face while managing a formulary include:

- **Creating formularies is a time-intensive process** that typically requires P&T committee members to invest a significant number of hours in the creation of the initial formulary. This endeavor must then be repeated every three to five years, depending on contract terms with the PBM. Examples of time-consuming, but necessary, activities include P&T committee meetings, clinical/financial impact analysis creation and exploration, P&P development, and compliance activities. Additional hours are needed for the ongoing management of the formulary; plans may find themselves requiring one or more full-time employees solely dedicated to this task.
- **Maintaining formularies requires monthly and annual changes** to evolve with the prescription drug landscape. The frequency of formulary updates is dependent on the launch of new products and the availability of existing ones. Therefore, it is important to keep current with market events such as patent losses, clinical trial data, regulatory updates, drug shortage reports, and other factors that would affect formulary placement decisions.
- **Maintaining formularies requires updating National Drug Code (NDC) data to ensure drug lists remain current**. Drug Information databases, such as Medi-Span, update NDC designations weekly. This creates the need to frequently evaluate new NDCs and update formulary drug lists to remain current. The task is straightforward, but inevitably introduces the potential for error into the process.

FORMULARY PLACEMENT TERMS

In most cases, a plan sponsor can collaborate with the PBM to underwrite rebate guarantees for a custom formulary. All PBMs secure competitive agreements with manufacturers that trade favorable formulary placements for more generous rebate payments. For example, a PBM that prefers Humira may not allow any preferential formulary placements of Enbrel or other competing products. Aligning the PBM's pharmaceutical contract incentives with the plan sponsor's goals will maximize rebate guarantee amounts. If there is misalignment, the opportunity cost must be understood and, hopefully, compensated for elsewhere.

MAINTAINING MULTIPLE PRODUCTS

When managing a custom formulary, we recommend that plans allow access to multiple products for the same indication on a custom formulary, when possible. This gives providers the flexibility to prescribe the treatments most appropriate for their patients. However, this clinical flexibility must be balanced with fiscal responsibility to create the most cost-effective formulary possible. As mentioned before, one common practice that forces compromise between flexibility and cost control is the implementation of UM edit strategies. Examples of UM include step therapy, where a member must first fail treatment with cheaper options before transitioning to more expensive options, and prior authorizations, where providers must submit documentation justifying the medical necessity of certain products before a member can begin treatment. UM allows members access to multiple treatment options while also stratifying them in a way that encourages the choice of the lowest net-cost options. The member benefits by having access to an appropriate variety of treatments and the plan benefits by retaining a process that allows for some degree of steerage toward preferred products.

What is a custom-standard formulary?

In some cases, a PBM can be flexible with some aspects of its standard formulary offering while still allowing clients to earn high rebates. PBMs might give different names for this practice (e.g., quasi-standard, custom-standard, or 99% alignment), but the concept is the same. An example of this custom-standard approach is negotiating the ability to deviate from the standard formulary for specific therapeutic classes. This will impact rebate amounts but may be the best choice for the plan's membership.

Market insights of standard vs. custom formularies

In today's market, the value of a single plan fully creating and managing its own custom formulary is decreasing even with a large plan sponsor or coalition able to negotiate rebates directly with manufacturers or even with some rebate aggregators. PBMs have evolved their standard offerings to meet a variety of plan sponsor goals and can often accommodate a range of formulary strategies—from generic-only formularies to lowest net-cost formularies to highest rebate-yield formularies. Options for varying degrees of utilization management overlays allow for further modification. As a result, custom formularies are decreasing in the commercial space and are becoming less common in the managed healthcare space (Medicare, Medicaid)—even among adept, established organizations with experienced P&T committees. However, plan sponsors should still consider and examine the opportunity to determine whether it is the correct fit.

PBMs are becoming more strategic and will present the plan sponsor with a choice of standard formularies and UM criteria that meet some or all of the financial and clinical goals. If the plan sponsor is not satisfied with the standard PBM formularies, it might be beneficial to inform the PBMs that the plan is considering moving to a custom formulary. From this point, a negotiation might move the standard formulary into a partially customized formulary that is still fully managed by the PBM. If the partially customized approach is not sufficient, another PBM vendor or a fully custom formulary should be considered.

How consultants can help

Pharmacy benefit consultants have considerable experience helping plan sponsors navigate different PBM formulary options and estimating the impact of specific changes to drug coverage or utilization management. A good first step in navigating the often-asked question—*should a payer move to a custom formulary versus standard?*—is to have a conversation with those keeping the pulse on the PBM, payer, and drug manufacturing industries. Market dynamics can change quickly; what was relevant three years ago might not be today and the same is true for three years from now.

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