ashp PHARMACY EXECUTIVE Leadership Alliance®

Strategic Directions in System Formulary, Drug Policy, and High-Cost Drug Management

PELA® Virtual Conference Report

May 23, 2024

INTRODUCTION

Paul W. Abramowitz

Nishaminy (Nish) Kasbekar

On May 23, 2024, the American Society of Health-System Pharmacists (ASHP) Pharmacy Executive Leadership Alliance® (PELA®) convened a virtual conference, Strategic Directions in System Formulary, Drug Policy, and High-Cost Drug Management. The conference provided health-system pharmacy executives and thought leaders an opportunity to discuss current experiences, challenges, opportunities, and innovative strategies for addressing the complexities of managing system-wide pharmacy and therapeutics (P&T) committees and the growing issue of high-cost drugs, including new cellular and gene therapies (CGTs). Pharmacy executive leaders from over 200 multi-hospital health systems participated in the conference, including chief pharmacy officers, directors of pharmacy, system formulary and drug policy pharmacy leaders, specialty pharmacy and ambulatory care pharmacy leaders, and infusion care pharmacy leaders. Managing drug costs and ensuring patient access to innovative, complex therapies is critical for all ASHP members. The recent ASHP report, National Trends in Prescription Drug Expenditures and Projections for 2024, found that hospital spending had slightly decreased but that drug expenditures in clinics grew 15% due to increased use of high-cost injectable medications for cancer, immunology, and neurology. The ASHP Pharmacy Forecast 2024 also addresses the practice implications of high-cost treatment innovations and provides strategic recommendations for practice leaders, including collaborating with the organization's finance experts to assess risks and sustainability of offering these treatments, evaluating impact on revenue, and incorporating this information into the P&T committee decision-making process. Management of these therapies, delivery of the service, and follow-up care are also complex and require careful planning and operational considerations, including implications for pharmacy's role.[3] Welcoming and opening remarks were provided by ASHP President **Nishaminy (Nish) Kasbekar**, vice president and chief pharmacy officer for the University of Pennsylvania Health System, and ASHP Chief Executive Officer **Paul Abramowitz**. Kasbekar stressed the importance of the PELA® conference, which was designed to identify emerging themes with how organizations evaluate and offer new therapies and how the medications challenge the traditional role and processes of the P&T committee. Abramowitz described today's shared challenges, including drug shortages, payer policies, the continuing need to be innovative in medication management and associated service lines, and how to manage these issues effectively across systems and develop drug policy. The conference also sought to find out how organizations are evolving their processes and committee structure to effectively respond to new challenges. The PELA® Virtual Summit objectives were to:

- Identify industry drug pipeline and manufacturer and payer trends influencing hospital and health-system drug policies and formulary management and potential impact on provider and patient access.
- Describe formulary and drug pipeline management strategies that meet patient care needs to maintain marketplace competitiveness and enterprise sustainability.
- Discuss the unique challenges pharmacy executives face in leading the pharmacy enterprise and identifying solutions and opportunities with innovative therapies.

This PELA® conference explored these themes by gaining insights from a healthcare thought leader on the drug pipeline and emerging market and payer trends; a thought-provoking panel discussion with four executive leaders representing PELA® peer organizations; and small breakout discussion groups designed to broaden insights from all participants. The panel discussion and breakout groups focused on business considerations, system P&T committee and subcommittee structure and processes, payer access challenges, and strategies for payer engagement and alignment.

INDUSTRY TRENDS ON DRUG PIPELINE: CONSIDERATIONS FOR HEALTH-SYSTEM FORMULARY, DRUG POLICY, AND THE PATIENT JOURNEY

Collin E. Lee, corporate director of clinical pharmacy services at Emory Healthcare, served as moderator and introduced **William Roth**, senior vice president and general manager and founding partner of the Blue Fin Group, who opened the session with insights on industry trends and predictions. Roth called out four trends that have had an impact over the past 10–15 years on the pharmaceutical marketplace and access strategies: 1) broadening of product archetypes to include ultra-high-cost, complex therapies; 2) healthcare and prescription costs and reform; 3) technology applications; and 4) shifting access channels (e.g., shift from the medical to the pharmacy benefit). Roth proposed that, when considering formularies and their management, it is essential to look beyond traditional therapeutic areas and determine how the four trends affect product archetypes, because traditional formulary approaches may no longer fit new manufacturer, payer, pharmacy, and distribution models.

Collin E. Lee

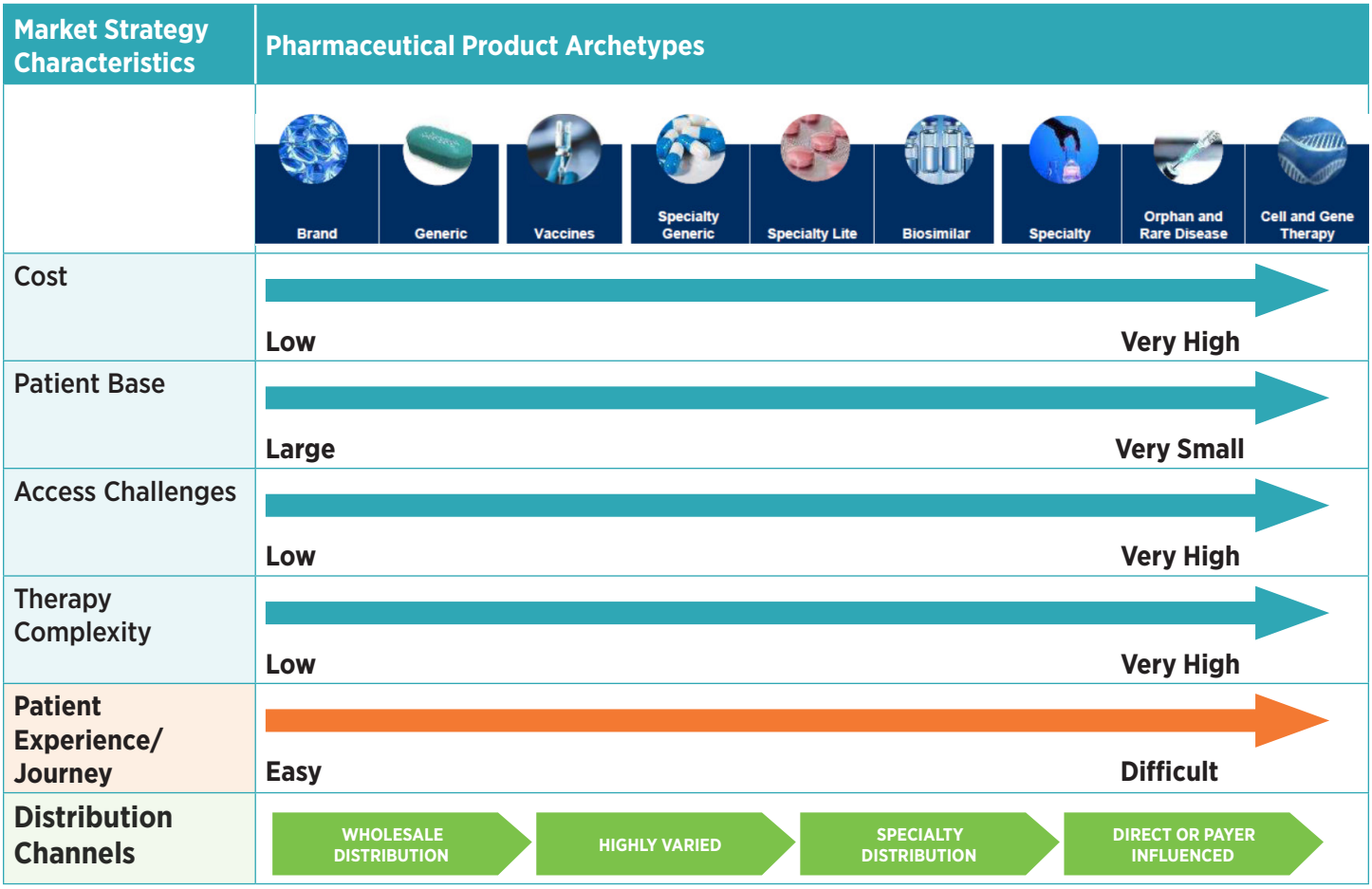
William Roth

Key Trends Driving Prescription Drug Market Strategies

- **Product archetypes** are driving commercialization strategies.
- **Healthcare and prescriptions costs and reform** are putting more emphasis on the value equation (delivering quality for cost).
- **Technology and services** are transforming healthcare processes, providing better insights into patient journeys and cost-effective care through digitization of records, transactions, and decision-making processes.
- **Access channels are shifting** because manufacturers take different approaches to drug distribution depending on product price, access hurdles, and therapy complexity.

Common pharmaceutical product archetypes include brand, generics, vaccines, specialty drugs (including biosimilars and so-called specialty lite), orphan and rare disease, and CGTs. Roth suggested that health systems consider structuring their formulary management framework and considerations on the basis of these archetypes rather than the traditional drug- or therapeutic-class-specific alignment (Figure 1). For example, when evaluating specialty drugs for formulary inclusion, decision-makers need to consider distribution channels and the site of care (e.g., provided under the prescription or pharmacy benefit). These channels will also have revenue implications. For CGTs, there will be even tighter control through limited distribution networks and value expectations (e.g., patient outcomes or the patient journey). Four key characteristics to consider when defining archetypes are the patient base (large or small numbers of patients); cost (low to high); access challenges (prior authorization required, qualifying patient); and complexity of the therapy (low to high) (Figure 1).

FIGURE 1: ALIGNMENT OF PHARMACEUTICAL ARCHETYPES WITH MARKET STRATEGY CHARACTERISTICS *(SOURCE: ROTH)*



It is important for health-system pharmacy leaders to recognize market shifts related to these archetypes and to plan for the impact. For example, prescription benefit managers (PBMs), pharmacies, and distributors historically focused business strategies on the generic market. However, the return on generic profits has diminished. Retail pharmacy has seen significant decreases in profitability because generic drugs can no longer offset losses on name-brand drugs due in large part to industry consolidation, government price caps, and fewer generics entering the market.[4] This has downstream implications. For example, glucagon-like peptide 1 agonists, which could be considered specialty light, were launched direct-to-consumer because of low uptake by pharmacies. Other archetypes with high-dollar market share (name-brand drugs, specialty, and orphan rare) will continue to grow in volume, but each drug type operates differently, with implications for access, complexity of distribution channels, and buying strategies (e.g., direct contracting with manufacturers). PBM profits, once driven largely by rebates, are increasingly derived from administrative and service fees and by limiting distribution networks, which is shifting

> “New distribution channels and business models are disrupting the status quo. Legacy models will need to adapt or will struggle to maintain relevance and effectiveness in the pharmacy industry’s innovations.
>
> - **Bill Roth**
> Blue Fin Group

PBM business models. Roth urged pharmacy leaders and their contracting teams to prepare now for a push by PBMs to move oncology drugs to limited distribution networks or to the pharmacy benefit. When evaluating the business implications and sustainability of offering high-cost therapies, health systems should consider both the cost of goods and the cost to deliver the service. Finally, Roth, said, health-system pharmacy leaders must assess their procurement and contracting processes, which are shifting away from traditional models and will require new strategic partnerships that go beyond basic cost-of-purchase models.

To summarize, the growth in high-cost, complex therapies will require health systems and P&T committees to assess more than just cost. Committees must also consider delivery channels, access and revenue implications, and how these factors will affect sustainability and, ultimately, how decisions will affect the patient journey.

PANEL DISCUSSION: OPTIMIZING SYSTEM P&T STRUCTURES FOR INTEGRATED DELIVERY NETWORKS

Vicki Basalyga, ASHP, Section of Clinical Specialists and Scientists, served as moderator and introduced the panelists, who discussed their strategic approach to aligning with and developing enterprise-wide solutions for challenges and opportunities related to the P&T committee structure and formulary management processes. Panelists included **Erin R. Fox**, associate chief pharmacy officer shared services, University of Utah Health; **Mary Ghaffari**, director, UMMS clinical pharmacy services, University of Maryland Medical System; **Ann Nadrash**, system manager of ambulatory care clinical pharmacy services, UCHealth; and **Jason Trahan**, pharmacy director, medication safety, quality, clinical, and education, Baylor Scott & White Health.

PHARMACY EXECUTIVE PANEL


Vicki Basalyga


Erin R. Fox


Mary Ghaffari


Ann Nadrash


Jason Trahan

EVOLUTION OF THE PHARMACY AND THERAPEUTICS COMMITTEE: ROLE IN MANAGING HIGH-COST DRUGS

Basalyga opened the discussion by asking panelists to describe their established or planned framework for managing high-cost drugs. Fox said her organization has established a new category of formulary drugs called high-coordination medications, which include, as examples, bispecific agents, oncology drugs, and CGTs. Fox said it is challenging to get the right people at the right table at the right time, so the organization created ad hoc subcommittees to address specific requests and issues. Ghaffari said UMMS has its own High-Cost Value Assessment Committee, an ad hoc subcommittee of the P&T committee. The P&T committee co-chairs also lead the ad hoc committee, whose members represent pharmacy (clinical, specialty, and retail pharmacists), infusion services, and revenue cycle and integrity teams. The triggers that convene the group include cost thresholds, such as cost per dose, annual cost to the patient, or annual cost to the health system. Nadrash said UCHealth has a Therapeutic Value Review Committee (TVRC), which is separate from but aligned with the system P&T committee and is accountable to the senior executive group. There is cross-representation on the TVRC from multiple areas, with a chief medical officer as chair, representation from medical staff, pharmacy, operations, nursing, and finance, and ad hoc representation as

> “It is challenging to get the right people at the right table at the right time. The decisions today are more complex and require additional interdisciplinary team members … those traditionally at table and those with broader expertise such as revenue cycle integrity.
>
> - **Erin Fox**

needed. The TVRC reviews drugs that reach a certain financial threshold. Trahan indicated that his organization, instead of creating new committees, has increased the representation within existing P&T subcommittees and uses ad hoc representation as needed. High-cost drugs and those that need high coordination (e.g., more resources to operationalize) are reviewed by the reimbursement subcommittee, which meets every other month. Representation includes revenue cycle, revenue integrity, and clinic-based staff (administrators, lead nurse, and sometimes a physician).

RESPONDING TO EXPANDING ARCHETYPES: FORMULARY MANAGEMENT OF HIGH-COST AND COMPLEX THERAPIES

> Our Therapeutic Value Review Committee sets a cadence for clinical and financial follow-up allowing us to assess performance in real time, then course correct if we're not performing as expected. It's a completely new world. The learning curve is steep, but it's fascinating.
>
> - **Ann Nadrash**

Basalyga asked the panelists to expand on the characteristics of their systems' formulary management for high-cost and complex therapies and to describe how the process and decision pathways for these archetypes differ from the traditional approach. Fox said providers and patients often have an urgent need for these drugs, which creates tension; for example, a patient who is coming off a clinical trial requires faster access than traditional processes may support. Outpatient-only (chronic, not immediately lifesaving, or immediately effective) medications still require a formulary request, but that is essentially a paper review to assure timely access to the medications and appropriate documentation in the electronic health record (EHR). The university's centralized prior authorization (PA) process is a safeguard for these therapies, because the medications must meet PA requirements before they are administered. The reimbursement team is also involved early on to avoid denials. Nadrash noted that all medication reviews at her organization go through the P&T committee first (relatively the same as for other medications) and include an evidence-based review with an evaluation for safety, unique logistics, payer considerations, and where therapies are going to be administered (inpatient, ambulatory, or both). When the review reaches this point and meets certain thresholds, the TVRC evaluates it. The TVRC presentation begins with a high-level clinical overview, followed by a review of financial implications (reimbursement, payer mix, expected utilization). The TVRC also defines the cadence for follow-up clinical care as well as financial review (e.g., does reimbursement meet expectations, or is there a need to adjust).

ORGANIZATION ALIGNMENT: SYSTEMIZATION AND DRUG POLICY IMPLEMENTATION

> Review of financial impact and (determining) the best site of care helps to guide the P&T committee on the final decision. Communication is key to everything.
>
> - **Mary Ghaffari**

Basalyga asked panelists what drug policy strategies they have employed to systematize their emerging committees, including the P&T committee, formulary, and drug policy structure overall, how these new committees fit in, and how decisions are implemented and enforced. Panelists were at different time points and stages in the systemization process, but they all described the P&T systemization process as a work-in-progress. Most panelists described a centralized, system-level committee with representation either from each individual entity or a region. Most panelists said decisions made by the system P&T committee are expected to be implemented at individual hospitals. Individual hospitals may develop stricter criteria for medication use or choose not to stock a drug, but hospitals may not broaden the scope of the P&T committee decision. Panelists commonly described committees

led by co-chairs, either two physicians or a physician and pharmacist. The number and type of subcommittees varied widely across the organizations; some had standing committees whose decisions and work flowed up to the system-level P&T committee; others were convened ad hoc based on a specific need or used a combination of the two approaches. Subcommittees were sometimes based on therapeutics (antimicrobial stewardship) or, less commonly, by archetype (high-cost or high-complexity drugs subcommittee).

PHARMACY'S ROLE: BUILDING ON SUCCESSES WHILE RESPONDING TO NEW PARADIGMS

Panelists acknowledged a rapidly changing landscape for pharmacy with the advent high-cost, high-complexity medications like bispecifics and CGTs. There are dimensions that go beyond the traditional P&T committee considerations, creating new roles for pharmacists. When evaluating these complex therapies, decision-makers must addresses access (prior authorizations), site of care (which facilities within a system should provide treatments), and the role of pharmacy. The panelists said the process is evolving at their own institutions, with some decisions made on a case-by-case basis. For example, UCHealth has established a Cell Therapies Advisory Council for guidance on these medications, which have distinct storage and preparation requirements and require a coordinated approach to use; pharmacy expertise is often requested. Nadrash encouraged organizations to build additional lead time into their P&T process when evaluating and implementing complex therapies. Nadrash noted that contracting can take up to a year, with additional time needed for coordination and post-implementation processes. Fox concurred that considerable advance work and post-implementation review are necessary, and coordination can be difficult.

> "Coordination is sometimes a challenge for ultra-rare disease therapies as manufacturers are also reaching out directly to patients, which makes having a proactive organizational structure in place that much more important.
>
> - **Erin Fox**

LESSONS LEARNED: THE PATH FORWARD

Finally, panelists were asked to share what they have learned from responding to the changing paradigms of formulary management and P&T committee structure and function. Lessons learned included:

- Be flexible and willing to adapt to needed changes as needs and processes evolve.
- There is a need for interdisciplinary collaboration with contracting and finance; engage team members early in the process.
- Integrate drug policy into informatics tools and clinical decision support.
- Communication mechanisms need to be timely, varied, and reach all levels of the organization (e.g., newsletters, updates by clinic chairs at service line council meetings).
- Do not underestimate the pre-work needed before bringing requests to the P&T committee or delivering therapy to the patient.
- Develop a post-implementation plan to validate assumptions and make adjustments if needed.
- Keep the end game in mind when adapting; trial and error is OK.

> "Our organizations are leaning on pharmacy since there are already established committees and processes within pharmacy, but we are continuing to gain lessons learned to address the nuances of each specific agent.
>
> - **Jason Trahan**

BREAKOUT SESSIONS: THE PULSE ON PRACTICE

The PELA® conference attendees participated in breakout sessions that built on the panel discussions and broadened insights on practices and strategic priorities around P&T committee composition and processes and the approach to formulary management for ultra-high-cost therapies. Panelists were assigned to facilitated discussion groups. Five domains for strategic priorities emerged from the discussions: 1) business strategy, 2) formulary management processes, 3) payer engagement and alignment, 4) system-wide P&T committee structure, and 5) the new paradigm of ultra-high-cost therapies. To supplement these discussions and understand takeaways from the plenary sessions, participants were also sent a post-conference survey and asked to share their key takeaways from the Roth presentation and panel discussion.

DOMAIN #1: BUSINESS STRATEGY

> We're good at looking at reimbursement — and the cost of goods sold — but not as good at looking at cost to provide the care; this has been harder.
>
> - **Breakout Participant**

Most organizations are establishing an internal framework for a P&T committee formulary management structure with processes that consider the unique aspects of high-cost, innovative therapies, with a greater focus on ambulatory vs. acute care. Participants noted a particular emphasis on infusion centers and physician-based clinics, which historically have not fallen under the purview of the P&T committee. This ambulatory space is changing rapidly. Nuances for decision-making include whether entities within the organization are 340B Drug Pricing Program participants; how to align formulary decisions with multiple payers; and PBM dynamics, such as requiring the use of limited distribution networks. When considering a new formulary drug, some organizations use decision algorithms or tools that include reimbursement assumptions and cost triggers for additional evaluation. The greatest challenge to navigating ambulatory formulary drugs is the lack of alignment with payers and multiple payers with disparate policies. Another challenge is that systems within organizations are sometimes unable to track whether reimbursement meets goals, and there are often long turn-around times within the denials process.

Key Takeaways

- Health-system formulary and drug policy decision processes must assess reimbursement, site of care, and overall impact on the organization, especially for current and future high-complexity, high-cost medications.
- Health systems must plan to sustain their infusion business, especially for oncology, which PBMs are shifting to other sites of care.
- Carefully evaluate infusion business performance and contracts and consider the cost to deliver the service and reimbursement, not just the costs of goods.
- Collaborate proactively with the health-system contracting and revenue cycle teams.
- Health systems need to expand their value-based contracting, particularly for high-value, high-cost, and high-complexity medications.
- Understand how service delivery challenges can affect the patient experience or journey, health-system financial performance, and operations (e.g., chair time, preparation and storage implications), and incorporate these factors into formulary decisions.
- Consider situations where direct contracting with manufacturers may be beneficial, but understand that scaling of direct contracting opportunities requires staff resources.

DOMAIN #2: FORMULARY MANAGEMENT PROCESSES

> We are already implementing some of the strategies discussed, but I really liked the idea of having a post P&T coordination meeting with purchasers, IT, revenue cycle/integrity, to keep everyone informed.
>
> - **Breakout Participant**

To implement business strategies that are responsive to market changes, health systems must reimagine their formulary management structure and processes. For example, the formulary decision-making process often requires a more rapid turnaround time than traditional P&T committee processes, as when there is a need to continue outpatient infusion therapies that were previously managed by physicians or that involved patients in research trials. Other factors driving changes in the formulary management process include the financial risk and resources needed to manage high-cost, complex therapies. Some health systems have established dollar values to trigger a more in-depth review (e.g., >$5,000 per month, $100K per course). Most sites indicated that the threshold value is usually arbitrary, and even established thresholds often require a reset. Collaboration between different departments, including revenue cycle and pharmacy, is essential for effective decision-making and aligning implementation with financial assumptions. Conference participants said their organizations already include finance and revenue cycle team members on the P&T committee and relevant subcommittees or plan to do so. Finally, organizations are taking care delivery processes into account before making formulary decisions. Breakout participants said financial impact was a key factor in decision-making, and they have expanded their formulary review and management process to cover post-implementation monitoring, including a review of reimbursement (revenue integrity and revenue cycle). Although their approach is not always formalized, organizations are implementing new strategies that align with the archetypes Roth described. Participants felt that one of the greatest challenges to optimal formulary management is that PBMs and health plans call all the shots and unilaterally decide which drugs are on their own formularies or require their designated distribution channels. Although not discussed at length, several participants noted the importance of building formulary management tools into the EHR, including prescribing information regarding formulary status and restrictions, and the need to ensure all systems align and are up to date.

Key Takeaways

- Consider distribution channels, cost (drug product and cost of services delivery, revenue, and complexity of care delivery), when establishing formulary management processes.
- Establish processes to oversee complex workflows, and use dashboards to monitor formulary compliance and financial performance.
- Build formulary management processes that specifically address ultra-high-cost and complex therapies. Consider aligning archetypes with formulary management processes, including an assessment of how these therapies and PBM practices affect the health system's bottom line.
- Consider a more formalized process for reviewing the reimbursement potential of drugs used in the outpatient setting before to adding them to the formulary. Make a plan for follow-up review to validate assumptions and performance.
- Involve the finance and revenue teams at all levels of formulary management, from pre-approval review to post-approval monitoring.
- Involve and leverage informatics to support the formulary management process (e.g., order set review, clinical decision support, prior authorization).
- Engage with clinical subject matter experts to establish care coordination needs before formulary approval.

DOMAIN #3: PAYER ENGAGEMENT AND ALIGNMENT

The complex payer landscape for health systems usually involves multiple payers and may include an affiliated health and employee (self-insured) health plan. Even when plans are affiliated with the health system, there is usually a separate committee for formulary reviews. This can conflict with the health system's initiatives, because incentives may not be structurally or financially aligned. Conference participants said employee health plans typically report through different channels and have their own pharmacy requirements, PBM, and provider P&T committees. Among the minority of participants who work with their external P&T committees, some said they don't participate in decision-making but provide after-the-fact insights after a revenue loss or other event. The attendees emphasized that even imperfect collaborative processes can enhance coordination and improve overall drug policy and formulary decisions across the health system and affiliated insurance plans. Health systems vary in their ability to align with the formularies of external health plans. Areas for collaboration include conducting joint medication class reviews to improve alignment (achieving uniform pricing remains difficult) and jointly developing value-based metrics or prior authorization criteria. The lack of transparency around pricing and rebates sometimes leads to misinformed decisions that negatively affect organizational revenue and may increase costs for patients. At some organizations, a subcommittee or group focuses on the employee health plan formulary without necessarily reporting to the P&T committee.

> "The revenue cycle and revenue integrity pose significant challenges; pharmacy is ready to progress, but other organizational parts need to catch up to ensure cohesive operations."
>
> - **Breakout Participant**

> "Unpacking the role of PBMs with hospital executives and explaining how drug pricing works is crucial, despite the challenge of many individuals lacking knowledge in this area."
>
> - **Breakout Participant**

Key Takeaways

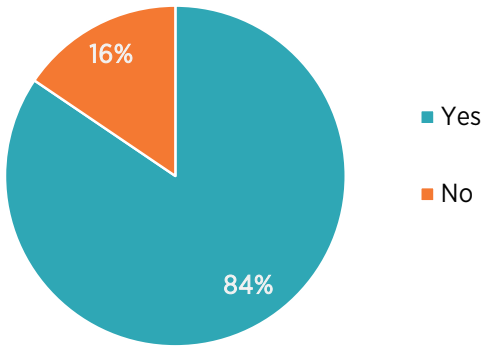
- Health-system pharmacy leaders should collaborate with health plans to align formulary incentives, particularly when there is an affiliated health plan, predominant payer, or self-insured employee plan.
- Take advantage of opportunities to align with payers on structural incentives, such as facilitating smooth transitions of care.
- The ability to align incentives with PBMs and health plans is severely limited by their lack of transparency about cost and rebate structures. Engage the health system's contracting team to assist with proactively addressing formulary issues.
- To avoid insurance denials, better communication between prior authorization and pharmacy operational teams is essential.

DOMAIN #4: SYSTEM-WIDE P&T COMMITTEE STRUCTURE

Most breakout participants said they have or are working toward a single system-wide P&T committee. This was consistent with the post-event survey results, where 84% responded that they had a system P&T committee structure (Figure 2). The committees typically have a bottom-up workflow, with review preparation and vetting occuring at the subcommittee or entity level before presentation to the system P&T committee. Most organizations retain a local committee or subcommittee structure or have regional representation on the system-level committee to provide feedback and implement decisions. Coordination may occur with medical executive committees when they serve a local P&T function or act as the final approval body at the local or system level. Some health systems have subcommittees or separate P&T committees (sometimes with common membership or chairs) specific for outpatient formulary decision-making. While some subcommittees align with services lines (e.g., oncology, infusion), most still address therapeutic categories (e.g., anticoagulation, antimicrobial stewardship) (See Table 1).

FIGURE 2

Do you have a system P&T structure?
(n=58)



> Forecasting future needs is crucial to ensure adequate resources and anticipate patient populations.
>
> - **Breakout Participant**

One organization uses a system-level committee to vet and assign requests before proceeding with committee review. The sheer number of committees presents a major challenge for coordinating decisions and ensuring timely implementation. Participants from several health systems said a financial analyst was assigned to the pharmacy department or the committee or worked within the pharmacy to run financial data, discuss opportunities for improvement (e.g., non-formulary purchases), and participate in committees to learn about complexities and terminology. The frequency of system P&T committee meetings varies but is usually monthly or quarterly, and subcommittees or executive committees have heavy pharmacy representation.

THE PROCESS

Participants described four phases to the P&T committee process: preparation, decision-making, implementation, and post-implementation. Each phase requires collaboration with other stakeholders in the organization, including information technology, finance, revenue, and clinicians. This aids the decision process and supports a seamless implementation and follow-up monitoring, which are critical for process improvement.

TABLE 1: EXAMPLE P&T COMMITTEE SUBCOMMITTEES

Subcommittee Examples Provided by Breakout Participants	
Based on Archetype/ Service Line	• Oncology/Infusion • Ambulatory/Specialty • Revenue/Reimbursement (high-cost drugs) • High-Coordination Medications • High-Cost Value Assessment Committee
Based on Therapeutic Category	• Antimicrobial Stewardship • Anticoagulation Stewardship • Operations/Medication Safety • Pediatrics • Analgesia Management/Opioid Stewardship
Based on Service Line	• Oncology • Critical Care • Behavioral Health

BROADEN REPRESENTATION ON THE P&T COMMITTEE

Key Takeaways

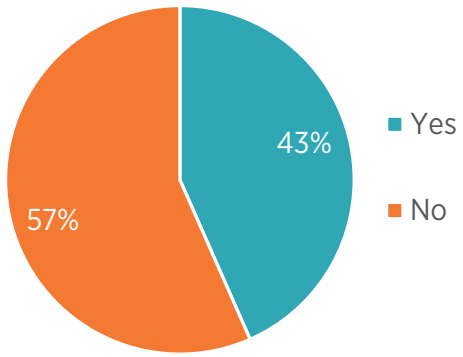
- Subcommittees that specifically address high-cost, high-complexity drugs are useful and should include participants with the expertise to conduct financial assessments and to vet assumptions before presentation to the P&T committee.
- Coordination between the institutional review board and the P&T committee is essential; physicians want their study drugs to be on the formulary and available as soon as the Food and Drug Administration approves them.
- Consider aligning subcommittees that are in accordance with the archetypes or service delivery complexity.
- Subcommittees, whether standing or ad hoc, allow for timely review and inclusion of subject matter experts who can address care coordination and service delivery requirements.

DOMAIN #5: THE NEW PARADIGM OF ULTRA-HIGH-COST THERAPIES

Most breakout participants are developing new processes or committee structures to manage and monitor ultra-high-cost drugs. Just over half of post-event survey respondents indicated that they had developed a separate committee for high-cost drugs (Figure 3). One organization created a separate cost center for ultra-high-cost drugs to separate the expenses from normal pharmacy business. (The response did not state whether separate personnel expenses were also associated with that cost center.) Thresholds defining ultra-high cost varied greatly across sites, and established thresholds changed over time or in certain situations. Organizational investment in infrastructure that ensures fiscal responsibility seems practical, given the substantial cost impact of these therapies. At some organizations, a separate committee evaluates specific requests for mega- or ultra-high-cost drugs to determine the feasibility and sustainability of the request, allowing for more timely, informed decisions. Two examples included the high-value-drug review" and CAR-T committees. In the absence of a formalized committee, high-cost drug assessments are often made on a case-by-case basis involving physicians and pharmacy personnel.

FIGURE 3

Do you have a committee(s) established to manage high-cost drugs at your organization?
(n-53)



Key Takeaways

- Engage the revenue cycle team to actively review claim denials and cash flow and to identify opportunities for improvement, particularly for ultra-high-cost drugs.
- Engage the informatics team to build functionality into the EHR that facilitates the prior authorization process.
- Build collaborative processes to proactively review drug requests and ensure timely access for patients.
- Consider establishing committees with the necessary expertise (clinicians, pharmacists, data/informatics, revenue cycle) to review ultra-high-cost drugs.
- Create communication mechanisms that keep senior leadership informed about the impact of ultra-high-cost drugs (positive or negative) and new roles for pharmacy.

CLOSING REMARKS

Leigh Briscoe-Dwyer

Closing remarks were delivered by **ASHP President-Elect Leigh Briscoe-Dwyer.** She thanked the PELA® conference participants for their work and the event's thought-provoking content and engaging discussions. Briscoe-Dwyer said the conference produced actionable information for participants and provided an unprecedented opportunity to network with peers about strategies for system P&T committee and formulary management, identify drug policy implications, and establish pharmacy's role in providing high-cost, high-value therapies.

REFERENCES

1. Tichy EM, Hoffman JM, Tadrous M, et al. National trends in prescription drug expenditures and projections for 2024. Am J Health Syst Pharm. Published online April 24, 2024. doi:10.1093/ajhp/zxae105
2. DiPiro JT, Hoffman JM, Schweitzer P, et al. ASHP and ASHP Foundation Pharmacy Forecast 2024: Strategic Planning Guidance for Pharmacy Departments in Hospitals and Health Systems. Am J Health Syst Pharm. 2024;81(2):5-36. doi:10.1093/ajhp/zxad231
3. Shay B, Storey M. Gene therapy: Practical considerations for clinical and operational pharmacy practice. Am J Health Syst Pharm. 2024;81(12):479-482. doi:10.1093/ajhp/zxae036
4. Commonwealth Fund. August 12, 2021. Issue brief. Competition, Consolidation, and Evolution in the Pharmacy Market Implications for Efforts to Contain Drug Prices Spending, Accessed on June 18, 2024. https://www.commonwealthfund.org/publications/issue-briefs/2021/aug/competition-consolidation-evolution-pharmacy-market

ASHP RESOURCES

1. Medication Cost-Management Strategies for Hospitals and Health Systems
2. Pharmacy and Therapeutics Committee and the Formulary System
3. Pharmacist's Role in Providing Drug Information

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Vice President Hospital Pharmacy and Laboratory Services
Avera Health

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Oregon Health and Science University

Toni Fera, BS Pharm, PharmD
Independent Healthcare Consultant

Emily Gajda, PharmD
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WVU Medicine – WVU Hospitals

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WVU Medicine – WVU Hospitals

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WVU Medicine – WVU Hospitals

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