

GHAPP National Workshop: Current and Future Payer Trends



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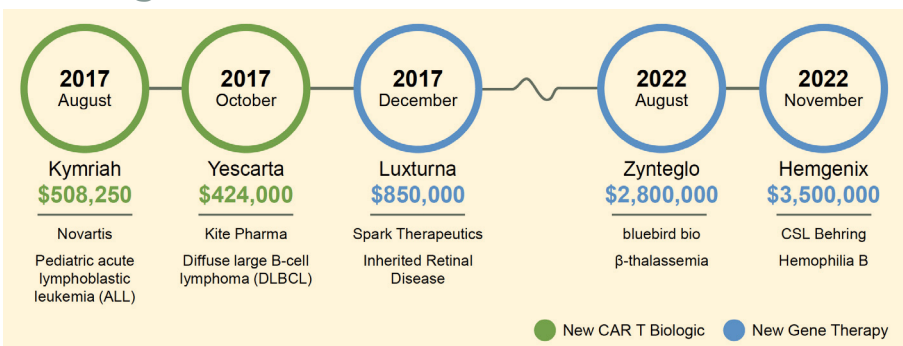
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In this session, Drs Pezalla and Dunn discussed key systemic challenges in the US healthcare system and their impact on stakeholders in the pharmaceutical ecosystem with the aim of helping providers better understand payer policies and hopefully encourage better collaboration. The key stakeholders in this complex system include payers, health plans, pharmacy benefit managers (PBMs), employers, providers, and patients. The complicated and fragmented structure of the system leaves stakeholders operating in silos and acting in their own best interest rather than in a coordinated fashion to improve patient outcomes while containing costs. This leads to misaligned incentives among the stakeholders and difficulty in implementing unified cost controls or equitable distribution of healthcare spending.

It is important to recognize that payer policies and the need for cost containment are driven by the escalating drug costs in the US. For example, the first biologics, Humira® and Enbrel®, launched in

2000 at a cost of ~\$900 per month compared with ~\$8,000 per month today. The average cost of a new entrant onto the market in 2019 of \$150,000 has doubled to around \$300,000 in 2024. These increases are consistent with a doubling of drug costs every 4 years, a rate that is not sustainable. Notably, this type of inflation is not seen globally, as other countries negotiate with manufacturers to accept lower, but still profitable, drug prices. Further, drug pricing in the US is driven by market tolerance and disease prevalence rather than by therapeutic value. For example, drugs for rare diseases may be priced in excess of a million dollars in an effort for manufacturers to recoup their research and development costs across small patient populations.

Higher cost cell and gene therapies entering the market



“We are headed toward an affordability and accessibility cliff in healthcare, and we are going to run out of money. No matter what we do, members won't be able to afford these medications so we have to collaborate and figure this out.”

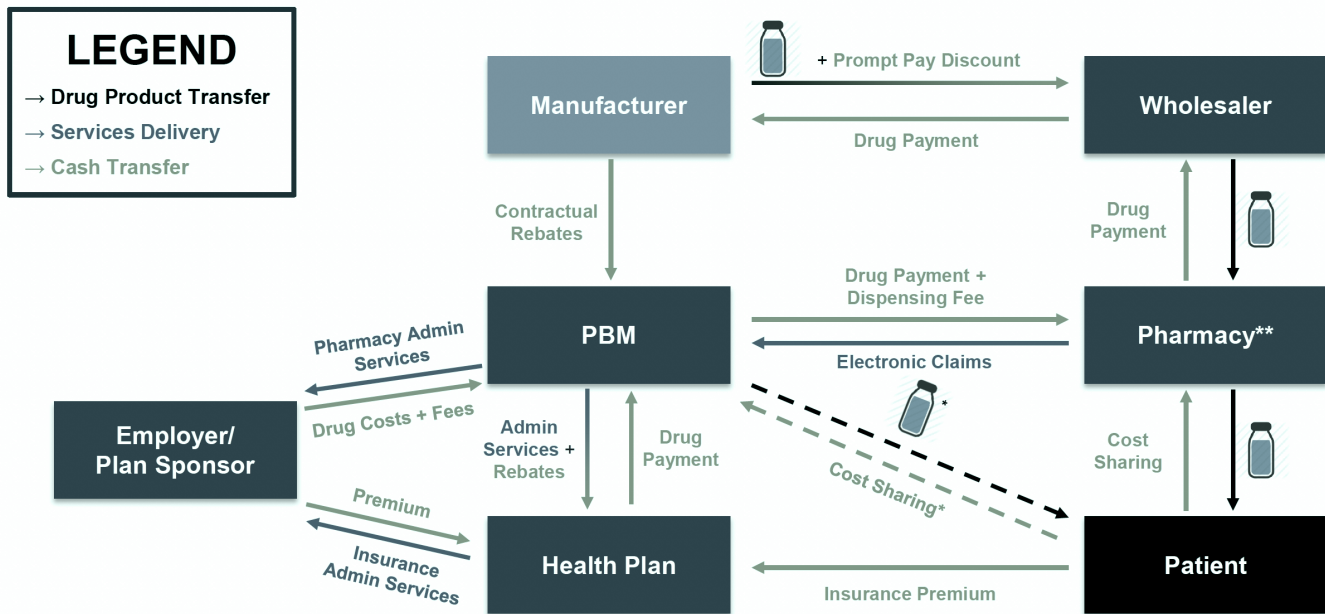
Given these escalating drug costs, prior authorization is a necessary effort to ensure that drugs are being prescribed responsibly. Despite the frustration faced by providers in the need for repeated renewals, there are contractual obligations to confirm for payers that a patient continues to need the medication(s). However, providers are reminded that most formularies and prior authorization requirements are publicly available, hopefully reducing some of the administrative burden in accessing this information.

A fundamental problem stemming from the fragmented pharmaceutical ecosystem is the lack of shared financial risk (ie, paying for therapies). Currently employers, health plans, and/or the government bear the burden of drug costs, while

patients pay a lesser amount through co-pays and premiums. However, the drug distribution chain is a convoluted and opaque network where rebates, discounts, and spread pricing obscure true costs. For example, although rebates and co-pay assistance programs benefit individual patients in the short term, they often raise systemic costs by encouraging the use of higher-priced drugs. Further, the financial risk in the US is distributed across populations rather than across time, an important limitation given the inevitable rising cost of care as people age. Drs Pezalla and Dunne noted that moving toward a more transparent system where the financial risk is shared across time would likely change behavior and help control costs.

Although treating patients appropriately ultimately improves outcomes and can be cost-effective, the US healthcare system is not coordinated enough to reap those gains.

Shareholders in the pharmaceutical ecosystem



* Applicable to mail-order drugs only.

**May be a traditional retail pharmacy or a specialty pharmacy.

PBM = Pharmacy Benefits Manager.

Adapted From: Danzon PM, PBM Compensation and Fee Disclosure, 2014 Employee Retirement Income Security Act (ERISA) Advisory Council, July 2014.

Overview of utilization management

Copay	<ul style="list-style-type: none"> • Patient OOP • Based on tier for pharmacy • 20-25% for medical benefit
Prior Authorization	<ul style="list-style-type: none"> • Treatment approval • Dx, severity, other criteria
Step Therapy	<ul style="list-style-type: none"> • Requirement to use another drug first • For pharmacy may be automated • For medical built into the PA criteria
Site of Care Policies	<ul style="list-style-type: none"> • Governs where patient can receive a medical benefit drug • Usually requires lowest cost appropriate site

Multiple other issues drive problems in the US healthcare ecosystem. Drs Pezalla and Dunne noted that collectively, waste and system inefficiencies comprise one of the largest contributors to US healthcare costs. Enormous financial waste is generated from factors such as redundant prior authorizations, duplicated laboratory testing, vial size mismatches for weight-based drugs, and lack of interconnectivity between electronic health record (EHR) systems across institutions. In the absence of reliable strategies for predicting patient response to therapies, insurance coverage remains population-based, focusing on standardized cost-control policies such as stepped therapy. These policies are not favored by providers, who view them as delaying their patients from receiving appropriate treatment, or by insurers, who incur the cost of failed therapies. However, these policies are likely to stay in place until more reliable biomarkers and genotype/phenotype-driven guidance are available to better predict drug response and guide coverage at the individual patient level.

In light of the fundamental problems in the US healthcare system, policy reform should prioritize transparency, risk-sharing models, and value-based pricing. Recognizing that a complete overhaul of the system is not likely to occur soon, Drs Pezalla and Dunne encourage collaboration between providers, insurers, and professional organizations (eg, American Medical Association) to help understand different stakeholders' perspectives and improve efficiencies. For example, providers are encouraged to talk to insurance companies to advocate for individual patients and to determine precisely what information is needed for prior authorizations. Investing in data that identifies reliable predictors of drug response and tolerability should also be a priority, as this information could reduce the use of "try and fail" policies. Additional efforts should be aimed at reducing waste and promoting the use of generic drugs and biosimilars, both of which can help control escalating drug costs.