THE RX AFFORDABILITY CRISIS

The second in a series of articles bridging the predictions from our **Emerging Trends** body of knowledge to current health care realities

"**SPENDING AND UTILIZATION** for specialty pharmaceuticals" was one of the AMCP Foundation's Top 10 Emerging Health Care Trends, as published in our landmark report in 2014. Health plans, insurers, pharmacy benefit managers, and purchasers struggle to control specialty pharmacy costs and ensure the affordability of effective medications while addressing patient and consumer access issues. This ultimately affects two other key trends, increasing patient cost sharing and the migration to value-oriented health care marketplace. In this article, we update developments in several important areas.

Specialty Trend Rises, but with Rays of Hope

Overall, specialty drugs now account for 1/3 of all pharmaceutical spending. The annual increase in specialty pharmaceutical expenditures rose by 17.7% in 2015, according to Express Scripts, and slowed somewhat in 2016. The cost trends for specific specialty categories are predicted to remain high through 2020 (e.g., about 30% for inflammatory conditions and 21% for oncology). One positive sign is that expenditures for hepatitis C specialty drugs fell 34% in 2016 and may continue double-digit declines through 2020 (mainly because of lower utilization and perhaps also due to competition from other treatment options).

Since 2011, list prices for specialty drugs have increased dramatically. Although few plans actually pay the full list price, it is the baseline for price negotiations. The average price increase in the inflammatory category in 2016 was 15.1%. The cost of generic and pharmaceuticals approved decades ago have risen as well, evidenced by the recent controversies involving epinephrine, daraprim, and doxycycline, to name a few. One study found that in 2015, 268 brand-name medications increased in price by an average of 15.5% over the previous year. Upward pricing pressure continues for many categories, owing to a lack of competition, drug/ingredient shortages, or marketing strategies.

Since the publication of Top 10 Emerging Health Care Trends, the pace of FDA approvals has picked up. In 2016, 23 new agents were approved, and the majority of these would be classified as specialty products (based on biologic status or cost).

Three biosimilar agents are now available (for filgrastim and infliximab [2]), and another 3 have been approved by the FDA (for adalimumab [2] and etanercept) but are not yet marketed [note: as of 9/13/17]. The most recently launched biosimilar—infliximab-abda (Renflexis®)—comes to the marketplace at a 35% discount to the reference agent Remicade®, and may set in motion price reductions. The Supreme Court's ruling to invalidate the 180-day notification period should help bring biosimilars to market more rapidly, although patent litigation continues to delay the launch of adalimumab and etanercept.

The rise in the price of insulin has caused some upheaval in the marketplace. Expenditures for insulin increased sixfold over a 10-year span. The introduction of follow-on insulins and push back from payers, providers, and patients over the cost of these medications have resulted in manufacturers pledging to limit price hikes.

Value-Based Formularies Rely on Comparative Effectiveness Research

Health plans continue to seek ways to optimize their pharmacy budgets. One area that continues

to hold promise is "value-based" formularies (not based on pricing alone). The paucity of comparative effectiveness research poses a challenge to formulary decision-makers.

Comparative effectiveness research is just now routinely considered by drug manufacturers. However, these additional studies cost money. Sponsors other than pharmaceutical companies (e.g., National Institutes of Health, Patient-Centered Outcomes Research Institute, Agency for Healthcare Research and Quality, academic institutions, and health plans) have the opportunity to lead in this important research.

Patient Affordability a Growing Concern

Managing drug prices has spurred many proposals (e.g., CMS negotiating drug prices for Medicare, drug importation) but little agreement or action. Today's political environment and practical realities have prevented more definitive next steps.

High prescription prices have only begun to compel discussions about affordability in the doctor's office. A poll by AARP found that 27% of those at least 50 years old believe the costs of their drugs are financially burdensome. A similar percentage have talked about the problem with their doctors over the past 2 years; one-third stated that their physicians offered a lower-cost alternative.

In certain disease states, like cancer, patient cost sharing can be such a burden that the term "financial toxicity" is used to reflect patient difficulties in paying for care. This term is commonly associated with cost sharing in oncology medications, which can exceed $100,000.

Cost Transparency a Major Issue

Pharmacy deductibles represent an opportunity to share drug pricing information with patients for informed decision making. Consumer shopping for best drug value will require clear and accurate cost information.

More than 2 dozen states have worked on legislative proposals to impose cost transparency requirements on manufacturers, plans, and pharmacy benefit managers. However, negotiated contracts between drug manufacturers and payers or health systems are considered proprietary—mandating the release of this information could affect price negotiations.

Pharmacists can play a vital role assisting, coaching, and informing patients of actual costs and their alternatives.

Targeting Treatment for Better Value

If specialty pharmaceuticals are to fulfill their promise, progress in personalized medicine and genomic science is needed to support more efficient patient selection for targeted therapies.

One diagnostic organization announced free gene sequencing of tumors of up to 100,000 patients with cancer, in an effort to break into the personalized medicine market and jumpstart clinical trial activity around targeted therapies.

TAKEAWAYS FOR PATIENTS

- Be active participants during the office visit: asking physicians about the possibility of using lower-cost alternatives, such as generics and biosimilars; asking pharmacists for medication-related advice
- Understand that specialty medications cannot be of value unless you adhere to the prescribed regimen
- When evaluating plan options, consider the possible cost burdens of the prescriptions you may need, such as the effect of drug deductibles and formulary exclusions

TAKEAWAYS FOR PHYSICIANS

- Discuss drug costs and alternatives with patients during the office visit
- Advocate publicly for more affordable medications
- Ask the pharmaceutical industry to frame the value proposition of drugs in terms that relate to the Triple Aim

- Consider newly approved biosimilars as a less-expensive alternative for some patients, based on their insurance coverage

TAKEAWAYS FOR INDUSTRY

- Work with health plans and insurers to improve drug price transparency for consumers and patients
- Invest in comparative effectiveness research and engage payers about incorporation, along with real-world evidence
- Continue to develop companion diagnostics or biomarkers to help identify which patients will most likely benefit from specialty pharmaceutical treatment

TAKEAWAYS FOR PHARMACISTS

- Discuss with patients their out-of-pocket pharmacy costs—and be the expert pharmaceutical resource for advice on medication management
- Be a resource for physicians to support their prescribing decisions
- Consider the best ways clinically and administratively to develop value-based contracts
- Consult with experts like AMCP on what constitutes best practices in comparative effectiveness research

TAKEAWAYS FOR HEALTH PLANS

- Request comparative effectiveness studies to speed formulary review
- Mine your own treasure trove of data for comparative effectiveness and real-world outcomes information
- Consider innovative value-based contracts for pharmaceuticals
- Weigh the balance between drug out-of-pocket costs and the risk of nonadherence
- Improve price transparency for patients by designing tools that can help inform better purchasing decisions
- Modify medical and pharmacy benefit designs to require proven companion diagnostics or measure biomarkers, when available, before prescribing specialty pharmaceuticals to ensure optimally targeted therapy

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