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The rise of drug prices: What will US payers do next?

Drug prices have owned the recent healthcare industry news cycle, catching the attention of patients, payers, and politicians. Among innovative therapies, Hepatitis C and advanced melanoma products have garnered significant press for both the cost per treatment and impact on total pharmacy spend.¹ In addition, price increases on existing products have accelerated in magnitude and frequency. Branded drug prices have increased nearly 10 percent per year over the past eight years, and nearly 13 and 15 percent in the past two years, respectively, with diabetes and multiple sclerosis therapies among the most prominent risers.²

Over the past 18 months, many payers have accelerated their response, wielding the leverage of national formularies to extract higher manufacturer rebates and restricting product options in order to create cost savings. Express Scripts' list of excluded drugs (defined as products that have "clinically equivalent, lower cost alternatives") on their National Preferred Formulary has grown to 66 products in 2015. CVS Health's Standard Formulary, which excluded 34 products in 2012, excludes nearly triple that number (95) in 2015. As a result, manufacturers are forced to bid against one another for a limited number of available formulary positions, thereby imperiling realized prices, product access, or both. For example, in Hepatitis C, despite a revolutionary shift in the standard of care, both competitors are now fighting for exclusive position on many payer formularies.

In this article, we seek to examine the future of payer management by exploring three key questions:

1. Have restrictive formularies met payer objectives?
2. Which drug classes will payers target next?
3. Which types of payers are most likely to move toward restrictive formularies?

We then suggest strategies that manufacturers may consider to garner competitive advantage in this evolving payer landscape.

¹ See, for example, Kim Peterson, "\$1,000-a-day miracle drug shocks U.S. Health Care System," *CBS Money Watch*, April 3, 2014; Arlene Weintraub, "Merck's melanoma 'game-changer' Keytruda likely to bolster drug pricing debate," *FiercePharma*, September 5, 2014.

² Represents an average cumulative drug price increase of 113% from 2006-2013. AARP Public Policy Institute, Rx Price Watch Report, November 2014; Truversis National Drug Index, January 2015; Ed Silverman, "Prices for Prescription Medicines Rose How Much Last Year?" *The Wall Street Journal*, January 26, 2015; Tracy Staton, "10 big brands keep pumping out big bucks, with a little help from price hikes," *FiercePharmaMarketing*, May 7, 2014; OptumRx, "Multiple Sclerosis Insight Report: Spending & cost drivers," September 9, 2014.

Have restrictive formularies met payer objectives?

Payers' effectiveness in controlling market share will dictate their ability to restrict additional drug classes, as well as manufacturers' willingness to participate in future competition. Both of the leading Pharmacy Benefit Managers (PBMs) have reported significant savings stemming from their more restrictive formularies. Express Scripts cites that it has "saved...employers more than \$1 billion in annual spending," while CVS Health expects to save its plan sponsors over \$3.5 billion between 2012 and 2015.³ However, the two case studies below suggest differences in results by drug class.

Case study #1: A manufacturer returns to negotiate – GlaxoSmithKline's (GSK) Advair

Advair has long been a leading brand in the Asthma/COPD class. In 2014, both CVS Health and Express Scripts chose to exclude Advair in favor of AstraZeneca's (AZ) Symbicort, which they viewed as an acceptable alternative. GSK's Q2 2014 sales subsequently fell by 19 percent. In 2015, GSK won back the CVS Health contract at a "highly competitive" price and returned to negotiate with Express Scripts, which reported that it "changed the formulary status of Advair in 2015 due to the improved pricing we were able to negotiate for [its] clients."⁴ Both payers leveraged the availability of alternative products to extract savings via their restrictive formularies.

While, in this case, the invitation for GSK to return to the negotiating table appears to have been driven largely by financial considerations, it is instructive for manufacturers to assess whether payers may have other motivations, such as managing provider, employer, and member satisfaction. Doing so will allow manufacturers to tailor their offers and optimize value preservation.

Case study #2: Limited upside – AZ's Byetta and Bydureon

In 2014, Express Scripts excluded Novo Nordisk's market-leading GLP-1 agonist Victoza in favor of AZ's Byetta and Bydureon. Analysts initially predicted that Novo Nordisk would lose one to two percent of market share and up to three percent of earnings per share.⁵ However, Victoza sales have increased 15 percent through Q3 2014.⁶ New-to-brand prescriptions (NBRx) for the Byetta/Bydureon family remained largely flat through Q3 2014 (and even trended downwards from January through August 2014) after an initial jump in January 2014.⁷ This may be attributable to the fact that Victoza remains viewed as a "better" product by providers, and suggests that payer ability to control share is bounded. It should be noted that, despite these initial results, Express Scripts has continued its exclusive deal with AZ for 2015.

Looking ahead, a critical signal regarding the effectiveness of restrictive payer management will be Viekira Pak's (AbbVie) performance at Express Scripts, given the perception that its therapeutic and patient convenience profile lags behind those of other Hepatitis C brands.

³ Reuters interview with Express Scripts Chief Medical Officer, Dr. Steve Miller. Deena Beasley, "Exclusive: Express Scripts presses for more drug savings with coverage list," *Reuters*, December 23, 2014.

⁴ Carly Helfand, "Note to Big Pharma: Discounts work. GSK price cuts score Advair a payer boost," *FiercePharma*, August 5, 2014.

⁵ Tracy Staton, "Novo Nordisk loses big U.S. contracts; Victoza, NovoLog sales to suffer," *FiercePharma*, September 3, 2013; Teis Jensen, "Novo could see U.S. sales hurt after losing two contracts," *Reuters*, September 3, 2013.

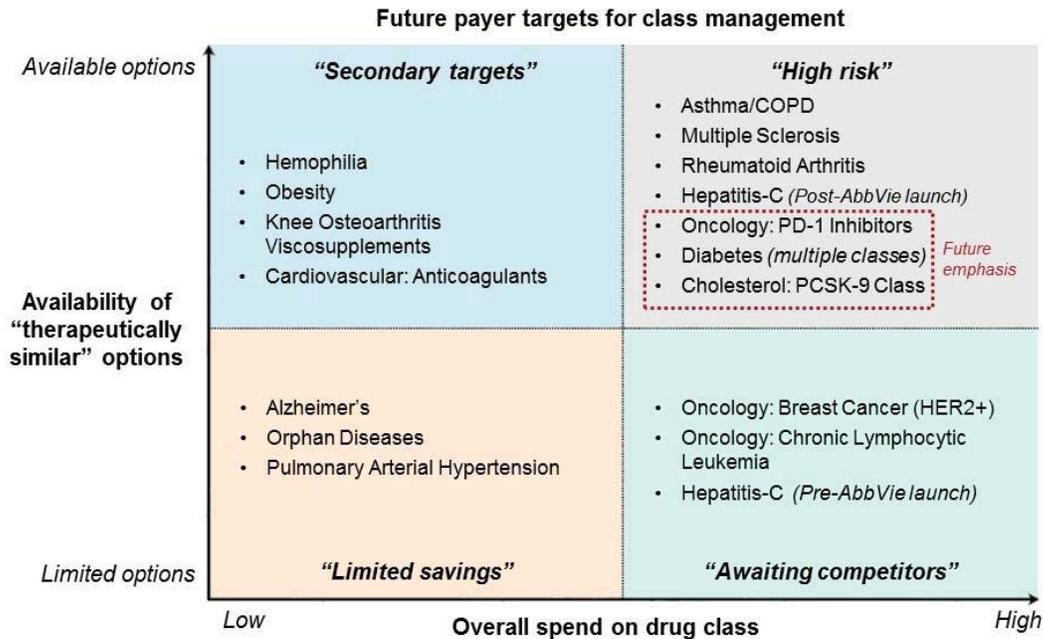
⁶ NNI Investor Presentation, 1st 9 months 2014.

⁷ AstraZeneca Investor Report, Q3 2014.

Which drug classes will payers target next?

We expect two main factors to inform which drug classes payers will target for more restrictive management in 2015 and beyond:

1. Drug classes with high current spend or expected to have high future spend; and
2. Drug classes with multiple current or anticipated “therapeutically similar” options, which may be due to new product entries, biosimilar entries, or both.



Note: Overall spend based on PMPY therapeutic area spend for the class
Sources: CRA Analysis, ESI Drug Trends Report 2013

Below, we highlight three major drug classes where pricing competition will play a key role in determining both the overall financial value of the class and the ultimate winners and losers:

Cholesterol (PCSK-9 class)

The new class of PCSK-9 cholesterol busters is highly anticipated, projected to garner up to \$10 billion in sales annually.⁸ Sanofi/Regeneron and Amgen plan to launch clinically comparable products in 2015, with Pfizer also in hot pursuit. Payers are likely to force head-to-head competition and interject their view of “therapeutically similar options” onto the market from the outset, before either product can gain significant uptake. Payers are already suggesting that their reactions to the pricing of the PCSK-9 class could emulate their reactions to the pricing of the new Hepatitis C products, although the actual payer management approach may differ.⁹

Diabetes (Basal analog insulin class)

While payers have historically maintained relatively open access in basal analog insulins (Sanofi’s Lantus and Novo Nordisk’s Levemir), this drug class is rapidly becoming significantly more

⁸ Tracy Staton, “Payers fret about the next drug doomsday: Pricey PCSK9 cholesterol meds,” *FiercePharmaMarketing*, May 7, 2014.

⁹ Ibid.

competitive. Sanofi recently launched Toujeo and potential near-term market entrants include Novo Nordisk's Tresiba as well as multiple biosimilar glargines (e.g., from Eli Lilly and Merck). The upcoming evolution of payer formularies will show the extent to which payers view biosimilars, current products, and next-generation products as therapeutically similar. Additionally, the biosimilar glargine launches will provide insights on the extent to which anticipated biosimilar launches in other drug classes place branded reference products as well as their branded competitors at risk.

Oncology (PD-1 inhibitor class)

In September 2014, Merck's Keytruda was the first of many PD-1 inhibitors in development to be approved. At a cost of over \$140,000 per year of therapy, and with sales of the class projected to reach \$32 billion by 2025,¹⁰ payers are likely to step up their response. Competition has increased with approval of Bristol-Myers Squibb's Opdivo in late 2014. Express Scripts has already indicated an interest in managing the class, particularly as more indications are approved for each of these products and later entrants (Roche, AZ, etc.).¹¹ This would represent a game-changing move toward more active management of budget-straining oncology products, which have been historically allowed to coexist on payer formularies due to management complexity and risk of provider and patient dissatisfaction.

Which types of payers are most likely to move toward restrictive formularies?

CVS Health and Express Scripts have led the movement toward more restrictive formularies. Smaller PBMs have followed their lead (e.g., Catamaran's new optional formulary excluding 54 drugs in 2014),¹² and some health plans have followed suit in certain drug classes (e.g., Humana, Harvard Pilgrim in Hepatitis C). It remains to be seen how widespread this trend will become. We expect three segments of payers to emerge:

i. Payers that actively manage and favor the lowest-cost products

Some payers may elect to find the lowest-cost products in a broad array of drug classes by using a more inclusive definition of "therapeutically similar." For example, despite perceived clinical and dosing differences between the new Hepatitis C products, Express Scripts has chosen to prefer Viekira Pak on its national formulary due to its lower cost. The same set of circumstances also applies to its decision to prefer Byetta/Bydureon over Victoza. Payers making such decisions may be characterized by high economies of scale, ability to effectively implement restrictions and control share, and a corporate value proposition that emphasizes client cost savings. In particular, Express Scripts' actions can be seen as a signal to its existing and prospective employer customers that it is a market leader in delivering cost savings, thereby differentiating it relative to its competitors.

¹⁰ Peter Loftus, "FDA Approves Merck's New-Wave Cancer Drug," *The Wall Street Journal*, September 4, 2014.

¹¹ Robert Langreth, Drew Armstrong, "Skyrocketing Cancer Drug Prices Are Express Scripts' Target," *Bloomberg Business*, January 22, 2015. It should be noted that competition for these products may play out on a disease by disease basis, as new indications may be approved at different times and with different labels – for example, both are indicated for advanced melanoma, but Opdivo is anticipated to gain an earlier approval for lung cancer while Keytruda's label may cover a more broad set of patients. Tracy Staton, "Bristol-Myers scores lung cancer survival data on Opdivo as Merck preps for Keytruda filing," *FiercePharma*, January 12, 2015.

¹² Andrew Pollack, "Health Insurers Pressing Down on Drug Prices," *The New York Times*, June 20, 2014. Note that Catamaran Corp. was recently purchased by UnitedHealth Group Inc., with plans for Catamaran to be integrated into UnitedHealth Group's OptumRx unit. It is unclear if and how Catamaran's optional exclusive formulary will continue. Anna Wilde Mathews, Joseph Walker, "UnitedHealth to Buy Catamaran for \$12.8 Billion in Cash," *The Wall Street Journal*, March 30, 2015.

ii. **Payers that actively manage and favor the “better” products**

Other payers may choose to actively manage as many drug classes as possible, but to prefer products they view as better clinical options. These payers will also group similar options together into market baskets and choose one product in each market basket for preferred formulary position. However, these payers place greater value on clinical attributes and, in classes where they perceive enough differentiation among products, they will select the “better” options. For example, CVS Health, Humana, Coventry, and Prime all have preferred Victoza on their Medicare Part D formularies. While these payers cite cost as a key consideration, and likely extract rebates from manufacturers such as Novo Nordisk, they appear more inclined to differentiate themselves against their competition with respect to product quality and member choice.

iii. **Payers that prefer to offer multiple options**

Finally, we expect some payers to continue to maintain relatively open access in many drug classes for multiple reasons. First, the link between pharmacy benefit savings and overall healthcare savings is still up for debate.¹³ At a time when reimbursement is increasingly tied to overall quality of care and other outcomes measures, disruptions to patient therapy can have a painful impact to the overall bottom line. Second, some payers may lack the tools and commitment to control share via formulary restrictions to the same extent as higher control plans, and therefore would be unable to realize comparable savings. Third, payers run the risk of membership erosion with many formulary restrictions, and lost clientele can be particularly impactful to smaller, regionally focused payers, or to payers aligned to integrated provider groups that focus on overall quality and outcomes. For example, Prime Therapeutics (a PBM owned by smaller regional plans) has decided to keep both Hepatitis C products on formulary for 2015, while gaining price concessions from both manufacturers.¹⁴ It remains to be seen how UnitedHealth, which tends to favor a holistic, overall cost of care approach (as indicated by its move to bring their PBM business, OptumRx, back in-house), will integrate the acquisition of Catamaran, with its exclusive optional formulary.

A major stakeholder group influencing the prevalence of restrictive formularies is employers. Payers compete for employer business, and employers fall along a broad spectrum with respect to their preference for cost savings vs. quality and choice for their employees. Monitoring trends in employer perspectives will be instructive in gauging how the above payer segments may evolve in the future.

What does this mean for manufacturer strategies?

Traditionally, manufacturers have favored open access, allowing them to de-emphasize price-based competition. Manufacturers with strong brands can win in an open access environment. However, as some drug classes have become saturated, late-to-market entrants and manufacturers with clinically undifferentiated or inferior brands have embraced the trend toward narrow payer formularies. Gaining a preferred formulary position with price-based strategies can be a springboard

¹³ “...according to a major benefits consulting group who has reviewed this strategy and its data over the past two years, there has not yet been independent third party validation of the impact on pharmacy spend. At this time, employer groups with and without exclusion strategies do not exhibit discernible differences in per member per month costs, nor trend. Further, the resulting impact on the larger medical spend is also unknown.” National Business Coalition on Health (NBCH) action brief, “Value-based Purchasing: Pharmaceutical Management,” August 2014.

¹⁴ “Five Prime Therapeutics Announces Closing of Public Offering,” Prime Therapeutics Press Release, January 12, 2015.

to market share growth that would be otherwise unattainable. With the prospect of significant share gains, manufacturers of these brands can be expected to negotiate aggressively, particularly when encouraged by payers.

Of course, payers often have an ulterior motive in leveraging other manufacturers as “credible threats” to extract better pricing terms from market leading brands. When this situation occurs, market leading brands face difficult decisions. They can respond and protect their position by offering price concessions, or face the risk of share loss. Their strategic evaluation will vary by drug class, and should consider the following questions:

- What price will it take to maintain or regain access?
- How much share is at risk?
- Is it possible to activate other stakeholders to influence payer access decisions?
- Can their brand still succeed while in a disadvantaged access position?
- How will their strategy impact competitor actions and bidding strategy in the future?

How can manufacturers optimize access for their products?

Manufacturers, particularly those with new, innovative products could consider the following steps to enhance the likelihood of payer receptivity to their offering.

Product level strategies

- Develop multi-stakeholder engagement plans (at payer, provider, and patient levels) to communicate clinical need and mitigate market reactions to price
- Build cost effectiveness evidence that encourages payers to view products in terms of impact on overall cost of care, rather than only unit price
- Design segmented pricing strategies, identifying high and low value customers and tailoring an approach that explicitly considers expected competitor response to preserve price discipline where possible and optimize impact of price concessions where necessary
- Explore alternative pricing methods that emphasize clinical outcomes and leverage creative ways to deliver value to payers
- Engage in realistic simulations (“war gaming”) to guide competitive response strategy and improve the skill with which the pricing strategy is implemented

Industry level strategies

- Broadly promote the benefits of open access to employer groups, key opinion leaders (KOLs), providers, and patient organizations in order to influence payer access decisions
- Develop supporting clinical evidence for continuity of care associated with open access, which can include improvements in adherence, patient satisfaction, and overall outcomes

Summation: Future payer management and manufacturer strategies

Manufacturers should expect payers to increasingly restrict drug classes in response to price pressures and other industry trends. By looking at total spend and availability of therapeutically similar alternatives, manufacturers can identify likely payer cost savings targets. However, manufacturers should not expect all payers to follow the trend towards more restrictive formulary management, particularly as emerging healthcare trends include patient-centricity, continuity of care, and overall clinical outcomes. Manufacturers may have opportunities to influence future formulary decisions by developing strategies that identify key segments and stakeholders, and take advantage of leverage points in the payer space.

Contacts

Lev Gerlovin

Principal
Boston
+1-617-425-3083
lgerlovin@crai.com

Ezra Josephson

Consulting Associate
Boston
+1-617-425-6522
ejosephson@crai.com

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