ISSUE DIGEST

Specialty Pharmacy

How can health plans promote adoption of biosimilars to reduce pharmacy spend?

PREPARED FOR

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In this digest:

How can health plans promote adoption of biosimilars to reduce pharmacy spend?

- The Advisory Board's take
- Recommendations for your team
- Highlights from recent publications

Our Issue Digests cover top strategic priorities for the health plan Chief Medical Officer.

Each digest focuses on a question, opportunity, or challenge facing the health plan CMO. We summarize key insights—which may include thoughts on relevance, urgency, and value—on a particular issue, offer recommendations for your team, and provide an overview of recent publications on the topic.

A sampling of other topics covered:

- **The cost curve is bending—now what?** *How plan CMOs should respond to changing trends in health spend*
- **Why are providers reluctant to engage in downside risk?** *A comparison of findings from the top five industry surveys*
- **What role should plans serve in addressing social determinants of health to improve patient outcomes?** *Identifying effective programs to address patients' non-clinical needs*
- **What are the potential costs of cost-sharing?** *An examination of the health care affordability crisis*
- **How are wearables influencing care outcomes?** *A look into the wearable industry and evaluation of potential health plan use cases*

How can health plans promote adoption of biosimilars to reduce pharmacy spend?

Weighing policy reform vs. health plan operations to address the growing cost of biologics

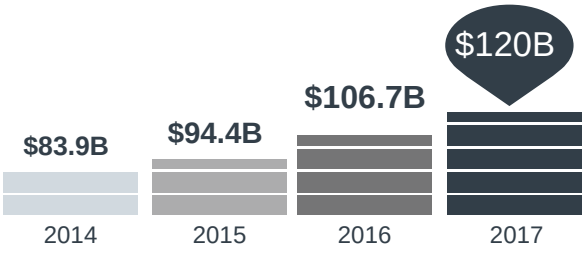
OUR QUICK TAKE

- Biologic drugs—complex, large-molecule pharmaceutical products derived from living organisms—account for approximately 70% of prescription drug spending growth in the U.S. in the past decade. Plan CMOs face significant barriers in managing medical spend in biologics, including the immense costs of producing and administering biologics, small patient volumes that cannot absorb these costs out-of-pocket, and limited price competition and negotiation power. **As a result, plans must contend with ultra-high cost members, less predictable medical cost spikes, and more frequent formulary redesign.**
- Replacing biologics with biosimilars—drugs that are similar, but not identical, to a licensed **biologic—may reduce direct spending on biologics by 3%, or $54 billion, over the next decade.**[1]
- **Biosimilar adoption is low in the U.S. due to a lagging development and manufacturing pipeline, physician prescribing patterns that favor biologics, and pharmacy rebate disincentives, sometimes referred to as "the rebate trap."** Although the FDA has approved 15 biosimilars since 2015, nine are not presently available on the market due to delayed launch or patent litigation.
- **In the short-term, plan CMOs will benefit most from leveraging their provider relationships to educate physicians on clinically comparable, cost-effective biosimilar prescribing behavior.** Longer-term change will likely need to occur at the policy level to grow the biosimilar pipeline and enhance clinical data-sharing opportunities among stakeholders to demonstrate biosimilars' clinical efficacy.

DATA SNAPSHOT

Spend on biologics dramatically increases with no near-term solution in sight

Growth in U.S. net spending on biologics[2, 3]



65% **Overall growth** in spend on biologics between 2011-2017

Annual cost of biologics per patient[4]

$100k + **Cost** of ~50% of the 225 new specialty drugs coming to the market by 2021

Most-expensive biologic drugs come with six-figure price tags

$793k	$700k	$487k
Ravicti	Brineura	Soliris

1. RAND, 2017.
2. AJMC, 2018.
3. AHIP, 2018.
4. Drugs.com, 2018

Source: Chief Medical Officer Roundtable research and analysis.

Recommendations for your team

DISCUSSION QUESTIONS

Targeted questions to bring to your next team meeting

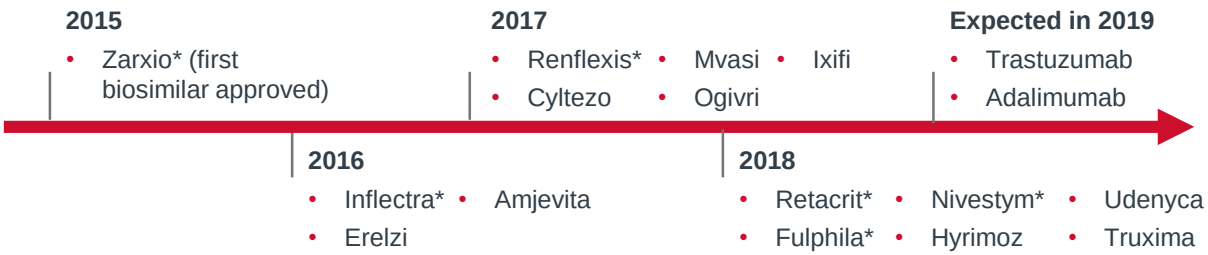
- Which biologic drugs have been largely responsible for driving cost growth among our members?
- Which providers in our network prescribe biologics more frequently, and how are we addressing this?
- How are we promoting the use of biosimilars for our high-prescribers?

POLICY SPOTLIGHT

U.S. policies that foster development of biosimilars

MAR 2010	• The Biologics Price Competition and Innovation Act of 2009 created a shorter approval pathway for biological products proved to be "highly similar" or "interchangeable" with an FDA-approved biologic.
FEB 2012	• FDA issued three draft guidance documents on biosimilar product development, which were then finalized in 2015.
MAR 2015	• CMS issued guidance to states on the classification of biosimilars for rebate purposes and on how to use these products to reduce costs while improving access in the state Medicaid preferred drug lists.
JAN 2017	• The FDA issued draft guidance for achieving interchangeability that requires manufacturers to conduct switching studies to show there is not a greater risk in safety or efficacy in switching to the biosimilar.
JUN 2017	• The Supreme Court ruled that manufacturers do not have to wait six months to launch their biosimilar after FDA approval, and can now offer notice of commercial marketing before FDA approval.
JAN 2018	• Biosimilars with a common reference product will no longer be grouped into the same billing code, and CMS will reimburse at the current rate of average sales price + 6%.
DEC 2018	• 45 states and Puerto Rico have enacted laws around biosimilar substitution requirements.

Timeline of FDA biosimilar approvals



RELEVANT READING

Recommended for your internal teams

- Daily briefing: Biosimilars as effective, less costly than their biologic counterparts, analysis finds
- Daily briefing: Biosimilars could cut US health care spending by $150B over next decade, report finds

External journal articles

- Simmons-Stern N, et al., "The State of US Biosimilars Market Access: Payer Perceptions of Past, Present, and Future Hurdles to Adoption," Trinity Partners, 2018.
- Mai J, et al., "Why New Reimbursement Guidelines for Biosimilars Could Increase Uptake," Modern Medicine Network, May 10, 2018.
- "Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines," The Biosimilars Council, August 28, 2017.

** Denotes drugs that are presently available in U.S. markets*

Highlights from recent publications

American Pharmacists Association (Sept 2018): BiosImilar pipeline not growing fast enough Learn more

+ **Summary of major findings:** Although the biosimilar pipeline is growing, it is not expanding at a fast enough rate to keep up with the growth and cost of biologics. As of September 2018, 12 biosimilars had been approved by the FDA in the United States. Three more biosimilars were approved between September and December of 2018, bringing the total to 15 approved biosimilars since 2015. However, only six biosimilars are currently available on the U.S. market due to delayed launches from manufacturers, many of which are because of patent litigation.
+ **Methodology:** A reporter analyzed the biosimilar pipeline in the U.S. on behalf of the American Pharmacists Association.
+ **Limitations:** Since the publication of this article, three additional biosimilars have been approved in October and November of 2018.

ADVISORY BOARD INSIGHTS

Growing the biosimilar pipeline will likely require federal health policy changes. However, health plan CMOs could advance adoption of available biosimilars by sharing data with physicians on biosimilar efficacy and safety, financially incentivizing and rewarding physicians for prescribing biosimilars, and evaluating the use of value-based payment for biosimilars.

JAMA (June 2017): Europe offers more progressive approach to biosimilar adoption Learn more

+ **Summary of major findings:** Biosimilar adoption is very low in the United States compared to other developed countries in Europe. Providers in the U.S. note the lack of indication-specific clinical data as a barrier to their willingness to recommend and/or prescribe biosimilars to their patients. European markets, on the other hand, have demonstrated that biosimilars are equivocal in terms of efficacy and safety to biologics through agencies like the National Institute for Health and Care Excellence in Britain. Therefore, most markets promote biosimilars as first-line agents in physician prescribing guidelines. Since 2006, Europe has approved 22 biosimilars, yielding a 66% price reduction.
+ **Methodology:** A PharmD researcher performed an extensive literature review of biosimilar adoption and pushback from physicians for the American Journal of Managed Care.
+ **Limitations:** The article is published in the “Viewpoints” section of JAMA, and therefore the policy recommendations reflect the personal opinions of the authors.

The difference in biosimilar pipeline and physician prescribing behavior among the U.S. and European market is primarily driven by policy changes, rather than operational or analytics barriers.

While policy changes are outside of the CMO’s span of control, CMOs should stay appraised and complement any new FDA policies or guidance around biosimilar development.

Center for Biosimilars (June 2017): Lack of physician education hinders their willingness to prescribe biosimilars Learn more

+ **Summary of major findings:** A quarter of physicians report they lack familiarity with biosimilars, and 23% report no knowledge of biosimilars’ regulatory process. While over three-quarters (78%) of physicians believe that the efficacy of biosimilars is comparable to reference products, 46% require additional evidence before prescribing a biosimilar for cancer treatment, and 45% note that familiarity with a product’s manufacturer is critical in choosing the biosimilar. Cost savings is also an important consideration for physicians, with 79% needing the biosimilar to equate to at least 11-30% of a price discount.
+ **Methodology:** Researchers from Cardinal Health Specialty Solutions surveyed 61 community-based oncologists and hematologists about their perceptions of biosimilars.
+ **Limitations:** Responses may be positively skewed toward biosimilar acceptance since the survey was completed in-person.

Health plans should try to address biosimilar knowledge gaps among providers.

Focus education on the benefits of biosimilars from the patient’s perspective (e.g., lower copays and similar quality outcomes) and basic regulatory processes and timelines for biosimilar approval by the FDA.

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