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Biosimilar Substitution in Michigan:
A Case Study

Prepared for The Economic Alliance for Michigan

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BACKGROUND

As health care costs continue to rise annually across the United States, perhaps no area is more challenging or more quickly escalating than the cost of prescription drugs.

According to 2019 polling by Kaiser Permanente Institute for Health Policy, one in four Americans now encounters difficulty affording the medications they need.[1] Indeed, specialty drugs, whose prices have skyrocketed over the last decade, are on pace to reach fifty percent of all U.S. pharmacy costs, despite comprising only a small percentage of total prescriptions.[2]

Caught at the center of this growing problem, employers are striving to find cost-containing alternatives on all healthcare fronts, but especially in regard to high-priced drugs. An emerging strategy, successfully utilized by employers in Michigan and ripe for implementation elsewhere, is biosimilar adoption.

ABOUT BIOSIMILARS

Biologic medicines mean life-transforming, even life-saving, treatment for serious conditions, including cancer. They also represent the fastest-growing area of drug spending.[3] Enter biosimilars.

Biosimilars are nearly exact replicas of originator (also called “reference” or “innovator”) biological drug products. Allowed in the United States (U.S.) since 2010, biosimilars must undergo a rigorous evaluation process for efficacy, safety, and quality, and must also receive Food and Drug Administration (FDA) approval before being introduced into the market. The FDA approved the U.S.’s first biosimilar product, Zarxio, in 2015.[4]

These actions place the U.S. almost a decade behind the European Union (EU), which saw introduction of its first biosimilar in 2006. While roughly 75 applications have been approved in Europe, less than 30 biosimilars are FDA-approved, and only about 15 available, in the U.S. market as of 2020.[5] Over the past year and a half, FDA approvals slowed to a sluggish three, compared to fourteen in the EU.[6]

The attraction of biosimilars lies in their substantially lower cost to produce: just $100-200 million compared to $2.6 billion for reference drugs.[7] These savings transfer to the market, driving costs down overall. Pricing for biosimilars typically ranges 10 to 37 percent lower than innovators.[8] The price of reference products declines over time as well. A 2021 report from Xcenda shows that biosimilar competition has successfully lowered the price of brand name biologics by an average of 56 percent.[9]

Biosimilar introduction creates market dynamics where innovator products cease to increase in price year over year and instead begin to decline.

ECONOMIC ALLIANCE FOR MICHIGAN

As a regional member of the National Alliance of Healthcare Purchaser Coalitions, the Economic Alliance for Michigan (EAM) has been working for a number of years to increase biosimilar adoption in Michigan. These ongoing efforts, including cooperation with managed care plans, have positioned Michigan as a leading state for biosimilar adoption.

On September 20, 2021, EAM held an employer roundtable to discuss biosimilar adoption strategies as part of employers' broader attempts to manage rising healthcare and prescription drug costs for their employees. Moderated by Alex Jung, an independent consultant formerly with Ernst & Young, the roundtable featured multiple Michigan employers, large and small, including union and association representation and a variety of industries.

To set the stage for the biosimilars conversation, employers shared their biggest concern regarding their pharmacy spend. The nearly unanimous response among the assembled participants was the increasing cost and utilization of specialty drugs, especially in the medical plan. Many employers explained that a very small percentage of their employee populations accounts for an overwhelming percentage of the total pharmacy spend due to ever rising costs of specialty medicines.

For the purposes of this case study, EAM also facilitated interviews with pharmaceutical manufacturers and Michigan health plans, in order to capture as wide array of perspectives and insights as possible.

MICHIGAN'S EXPERIENCE: EMPLOYERS PARTNERING WITH HEALTH PLANS

In Michigan, employers have been early adopters of biosimilar substitution strategies, and they have found success, both in cost savings and in member satisfaction.

Ford Motor Company (Ford) recently shared a case study of its implementation of an infliximab biosimilar strategy, which required new and current utilizers of Remicade to convert to Inflectra. In this case, the company saw transition rates of 100% within its HMO medical plan and 88.1% in its PPO, with no disruption to patients and no negative feedback from its members.[10]

This transition, begun in 2019, along with expansion to four other biosimilar drugs, has saved Ford nearly $5 million as of June of 2021.[11] Other employers in Michigan who implemented similar programs also reported no member disruption in implementing biosimilar substitutions.

A critical dynamic in Michigan has been employer partnerships with health plans. Blue Cross Blue Shield of Michigan (BCBSM) and Priority Health (Priority), in particular, have been trailblazers in advancing the use of biosimilars.

In separate conversations with these health plans, each reported significant savings in the millions of dollars for both group customers and members as a result of their biosimilar strategies.

The Michigan health plans related these additional results:

- Competition from biosimilar drugs lowered prices overall.
- Post-transition analysis revealed no increase in biosimilar dosage or frequency of prescribing due to belief that it might be less effective than the reference drug.
- Patients viewed lowering drug costs in order to maintain lower premiums as an incentive to switch to biosimilar medications.
- The biosimilar adoption rate was higher in oncology than other specialties.
- Health plans expressed that it was a necessary part of developing their biosimilar programs to make sure copay assistance was available from the biosimilar manufacturer.

STRATEGIES FOR ADVANCING BIOSIMILAR ADOPTION

Priority, BCBSM, and Ford shared several factors that contributed to the success of their biosimilar substitution programs in Michigan.

❖ Educate and Communicate

Persuading physicians is the best way to get patients on board. The doctor-patient relationship is the closest and most trusted in the health care arena, and physicians can heavily and reliably influence patient decision-making:

- Use analytics and data to increase confidence about efficacy of biosimilars in the physician community. Share success stories such as those from Europe, where biosimilars have enjoyed wide acceptance.
- Engage physicians with education outreach at conferences, forums, and other presentations. Write articles and letters.
- Provide an academic detailer to educate physicians on cost and efficacy. One health plan ranked its drugs in a continuum of pricing, and shared comparisons of prescribing across physician colleagues to illustrate the cost difference of prescribing biosimilars.
- Share FAQs with patients.

❖ Remove Prior Authorization

After educating physicians on the clinical efficacy and cost savings of biosimilars, both health plans incentivized biosimilar transition by eliminating prior authorization for biosimilar drugs while maintaining it on originator drugs. Removing the administrative burden for biosimilars made the transition easier for physicians and increased uptake.

❖ Focus on Lowest Net Cost

Priority and BCBSM both pursued a lowest net cost strategy for their drug spend, taking into consideration the many factors affecting cost, including average wholesale cost, discounts, rebates, coupons, and more. By gathering all this information, health plans and employers can evaluate whether any of these measures would lower costs as much as could be achieved via other mechanisms, such as biosimilars. In utilizing this strategy, one health plan found success by forgoing savings through rebates, and instead focused on the big picture to realize even greater savings through uptake in biosimilars.

❖ Streamline Delivery

Both health plans implemented site of care programs, allowing specialty drugs to be administered to patients where they are, in their homes or infusion centers, instead of only in hospitals where facility fees are incurred. By combining this strategy with a biosimilar program, the health plans made health care more affordable and convenient for members.

Employers indicate this policy was received very favorably by members, and one health plan indicated they have achieved savings in the millions of dollars from their “site of service” plan.

❖ Minimize Patient Disruption

In addition to its partnership with BCBSM and early work with community providers, Ford Motor Company credited the use of limited grandfathering of originator drugs for the success of their biosimilars program:

- For patients who are already undergoing treatment, extend authorization of the originator drug for six months to grandfather its use.
- Grant a switch to the biosimilar if and when patient treatment is renewed.
- Allow case-by-case reviews. Assure patients that if there is a problem, the employer and health plan will evaluate patients' individual circumstances.

COMMON BARRIERS TO BIOSIMILAR ADOPTION

Employers, insurers, and pharmaceutical manufacturers discussed several factors that have delayed or made it difficult to realize the promise of biosimilar drugs.

Internal Factors

- **Time and Money**. Many employers shared they do not have internal staff capacity to manage the complex nature of a biosimilar program. Additionally, many employers indicated they lack funds to hire an outside firm to manage such a project.
- **Sophistication of Benefit Strategies**. Several employers at the roundtable indicated their current benefit strategies are still maturing, and they must currently dedicate resources to prioritize establishing or growing wellness programs.

External Factors

- **Transparency.** A consistent theme in conversations with roundtable participants and all other interview subjects was the lack of transparency among many players in the space. Employers often do not know what incentives or rebates are being offered from drug manufacturers to their pharmacy benefit managers (PBMs). In some cases, a PBM and pharmacies are owned by the same firm. Often PBMs' best interests do not match employers' best interests. Without accurate knowledge of the marketplace, it is difficult to develop an effective biosimilar strategy.

- **Litigation.** Pharmaceutical manufacturers and health plans stated that originator drug manufacturers regularly pursue legal action against biosimilar drug manufacturers to delay biosimilar drugs coming into the market.
- **COVID-19.** Employers highlighted two ways in which the pandemic is currently affecting their thinking about benefit plans and will continue to do so:
    - **Worker Shortages**: To retain and attract employees in a very tight labor market, several employers mentioned they are maintaining current contracts, benefit levels, and employee cost-share, and will not be changing them anytime soon.
    - **Massive Needs Increase**: Employers explained that employees missed physicals and other physician visits during the pandemic, and age-appropriate preventive care was delayed or neglected. This interruption in care will create a massive increase of health care needs, and will impact the system for years to come.

  COVID-19 disruptions have left employers feeling more stretched and risk adverse than usual, and therefore biosimilar adoption may not be an area they can prioritize for years to come.
- **Increasing Incidence of Disease.** Several employers expressed concern over the increased utilization of specialty drugs due to more and more patients being diagnosed in disease categories that are treated with specialty drugs.

RECOMMENDATIONS FOR DEVELOPING A SUCCESSFUL BIOSIMILAR PROGRAM

Employers and health plans offered the following suggestions for employers seeking to develop a biosimilar program or roll out an additional program for a new drug.

❖ Strong Data & Trusted Partners

Employers don't need to be data experts, but they do need to be well-informed. Keep asking tough questions of medical carriers, PBMs and consultants. Ask medical carriers for member data, information regarding available programs, and where medical carriers are innovating on behalf of plan sponsors. Consider hiring an expert pharmacy consultant and a rebate aggregator.

❖ Aggressive Contracting

Employers must ensure they are doing everything to lower costs, not just receiving the lowest unit price of a particular drug. Ask for a utilization review, and ask for the cost of inpatient administration of drugs compared to outpatient administration.

❖ Thoughtful Plan Design

- **Seek Non-Disruptive Member Outcomes.** Don't put the member in the middle. Consider limited grandfathering so as not to disrupt patients during their treatment cycle, and ensure clear communication with members.
- **Avoid a One-Size-Fits All Approach.** Develop a strategy for each drug, its market dynamics, level of physician acceptance, and treatment situation.

❖ Member & Provider Communication

For a smooth transition to preferred products, engage the provider community early, secure their support by sharing data and evidence, and adjust the program based on feedback received. If possible, find a physician champion. One health plan encouraged engagement with a key opinion leader in the provider community.

❖ Reconsider Rebates

Rebates significantly impact the employer-sponsored health care arena, and they must be carefully considered. Employers should not be afraid to implement a lowest net cost without rebates strategy. If, however, a rebate model is used, the rebates should be reexamined regularly as the rebate landscape is constantly changing and employers will need to adapt the strategy to ensure the lowest net cost.

❖ Explore the possibility of contracting directly with drug manufacturers.

One health plan indicated this helped them get better rates.

❖ Work with disease societies to understand concerns before roll-out.

One health plan explained that working with the American Hematology Society helped to engage the full spectrum of stakeholders and resolve concerns prior to their biosimilar program rollout.

[1] Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, Kaiser Family Foundation, 2019.

[2] "Medicine Use and Spending in the US." *IQVIA Institute Report*. April 19, 2018.

[3] Miller, Steve. "Unlocking the Potential of Biosimilars." Cigna.

[4] Raedler, Lisa A. Raedler. "Zarxio: First Biosimilar Approved in the United States." *American Health & Drug Benefits*. 2016 Mar; 9: 150–154.

[5] Chase, Lauren. "A Guide to Biosimilar Prices: How Much They Cost and How You Can Save." *GoodRX Health*. April 14, 2020.

[6] Harston, Aydin, Ph.D. "How the US Compares to Europe on Biosimilar Approvals and Products in the Pipeline." *JDSupra*. March 9, 2021.

[7] Sullivan, Thomas. "A Tough Road: Cost to Develop One New Drug is $2.6 Billion." *Policy & Medicine*. March 21, 2019.

[8] Chase, Lauren. "A Guide to Biosimilar Prices: How Much They Cost and How You Can Save." *GoodRX Health*. April 14, 2020.

[9] Jeremias, Skylar. "Xcenda Report Shows Biosimilar Competition Lowered Drug Prices of Reference Oncology Biologics." *AJMC*. June 23, 2021.

[10] Employer Forum on Pharmacy Benefits and Specialty Drugs: "Managing Drug Spend for High-Cost Therapies." Midwest Business Group on Health. June 23, 2021. Video available at: https://www.youtube.com/watch?v=BLdN_MZZ1pg.

[11] Employer Forum on Pharmacy Benefits and Specialty Drugs: "Managing Drug Spend for High-Cost Therapies." Midwest Business Group on Health. June 23, 2021. Video available at: https://www.youtube.com/watch?v=BLdN_MZZ1pg.