Potential Value of Biosimilars to Employers, Their Employees, and Dependents
Biologics have been used successfully to treat many different life-threatening and chronic diseases.\(^1,2,5-7\)

**Biologic**: Wide range of products (eg, vaccines, blood and blood components, somatic cells, gene therapy, tissues, therapeutic proteins) derived from genetically engineered living cells or organisms and intended to prevent, treat, or cure a variety of medical conditions.\(^3\) Many biologics are classified as specialty medicines.\(^4\)

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<table>
<thead>
<tr>
<th>Highest Driver</th>
<th>Overall medical inflation</th>
<th>Specific diseases or conditions</th>
<th>Specialty pharmacy</th>
<th>High-cost claimants</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>74%</strong></td>
<td><strong>29%</strong></td>
<td><strong>58%</strong></td>
<td><strong>72%</strong></td>
<td><strong>74%</strong></td>
</tr>
<tr>
<td><strong>22%</strong></td>
<td><strong>21%</strong></td>
<td><strong>21%</strong></td>
<td><strong>22%</strong></td>
<td><strong>22%</strong></td>
</tr>
<tr>
<td><strong>13%</strong></td>
<td><strong>14%</strong></td>
<td><strong>13%</strong></td>
<td><strong>21%</strong></td>
<td><strong>21%</strong></td>
</tr>
</tbody>
</table>

In 2018, Biologics Comprised 5 of the 10 Top-Selling Medications in the United States and Drove Disproportionate Costs\(^1,2\)

Biologics comprised 5 of the 10 Top-Selling Medications in the United States\(^1\)

In 2018, biologics accounted for approximately $42 billion of the $69 billion in sales for the 10 top-selling drugs\(^1,2\).

“In the United States, biologics account for 38% to 40% of all pharmaceutical spending, but fewer than 2% of Americans use them.”\(^2\)

---AMA Journal of Ethics

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*Top medicines by nondiscounted spending; spending is based on IQVIA National Sales Perspectives and is not adjusted for estimates of off-invoice discounts and rebates. Includes prescription and insulin products sold into chain and independent pharmacies, food store pharmacies, mail service pharmacies, long-term care facilities, hospitals, clinics, and other institutional settings.

A Biosimilar Is Highly Similar to the Reference Product With No Clinically Meaningful Differences in Safety, Purity, or Potency

**Biosimilars** are biologic products

- **FDA approved**
- **Highly similar** to an approved biologic product (reference product)
- Approved based on data showing **no clinically meaningful differences** in terms of safety, purity, or potency from the reference product

# The United States Continues to Gain Experience With Biosimilars

As of July 2019

<table>
<thead>
<tr>
<th>Reference Product</th>
<th>US Approved Biosimilars&lt;sup&gt;1,2&lt;/sup&gt;</th>
<th>Commerically available</th>
<th>Not yet commercially available</th>
</tr>
</thead>
<tbody>
<tr>
<td>REMICADE&lt;sup&gt;®&lt;/sup&gt;</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>NEUPOGEN&lt;sup&gt;®&lt;/sup&gt;</td>
<td>2</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>HUMIRA&lt;sup&gt;®&lt;/sup&gt;</td>
<td>-</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>ENBREL&lt;sup&gt;®&lt;/sup&gt;</td>
<td>-</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>AVASTIN&lt;sup&gt;®&lt;/sup&gt;</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
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<td>HERCEPTIN&lt;sup&gt;®&lt;/sup&gt;</td>
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</tr>
<tr>
<td>EPOGEN&lt;sup&gt;®&lt;/sup&gt;</td>
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<td>-</td>
<td></td>
</tr>
<tr>
<td>RITUXAN&lt;sup&gt;®&lt;/sup&gt;</td>
<td>-</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup>All product names, trademarks, and registered trademarks are the property of their respective owners.

<sup>2</sup>As of 2018 YTD.

<sup>3</sup>As of June 2019.


*59 biosimilars in various stages of development*
Availability of Competition Has Bent the Cost Curve of Biologics in the GCSF* Market

**Average Sales Price (ASP)**

is a manufacturer’s average price for a drug to all purchasers, net of any price concessions, such as volume discounts, prompt pay discounts, cash discounts, free goods contingent on purchase requirements, chargebacks, and rebates other than those obtained through the Medicaid drug rebate program.\(^1\)

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\*Granulocyte-colony stimulating factor is a biologic that stimulates production of a type of white blood cell.

Neupogen® is a registered trademark of Amgen, Inc.
Zarxio® is a registered trademark of Novartis AG.
Nivestym® is a registered trademark of Pfizer Inc.

\*Zarxio® launched in September 2015.\(^3\)
\*Granix® launched in November 2013.\(^4\)
\*Nivestym® launched in October 2018.\(^5\)

Biosimilars May Help Bridge the Transition From Volume-Based Care to Value-Based Care

As the health care market shifts from fee-for-services to value-based care, biosimilars may help bridge this transition by reducing costs of biologic drugs\textsuperscript{1-3}

• Through availability of lower-cost treatment options resulting in reduced drug spend, biosimilars may potentially\textsuperscript{3,4}
  
  o Better position providers for emerging value-based care initiatives from payers and employers
  
  o Help meet established cost targets and position for future risk-sharing for OCM practices

Biosimilars: The Potential Opportunity

While the opportunity is growing, employers may not be aware of the potential opportunity biosimilars may present

Why?

• As of December 2018, coverage of biosimilars is primarily under the medical benefit.
  
  o Specialty medical costs are projected to comprise about 58% of total medication costs under the medical benefit in 2016.
  
  o Employers often have limited visibility into spend and pricing under the medical benefit, in the aggregate or on a drug-by-drug basis.
  
  o Many of the potential biosimilar opportunities include top-spend specialty drugs that have a major impact on the employer’s bottom line.
    ▪ As of July 2019, biosimilars for three top-spend oncology agents (Rituxan®, Herceptin®, and Avastin®) have received FDA approvals and two biosimilar options are already available on the market.
  
• An interchangeability designation is not required for a physician to switch a patient to a biosimilar.

Many Commercially Insured Patients Have High Co-Insurance Requirements for Medical Specialty Drugs

>50% of commercial payers required co-insurance for specialty drugs covered under the medical benefit in 2018

Co-Insurance for Specialty Drugs in Medical Sites of Care

<table>
<thead>
<tr>
<th></th>
<th>Physician Office</th>
<th>Home Infusion</th>
<th>Outpatient Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co-insurance %</td>
<td>23%</td>
<td>26%</td>
<td>25%</td>
</tr>
<tr>
<td>(mean)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

High cost-sharing requirements may negatively impact medication adherence

- With increases in cost-sharing, patients are
  - Less likely to initiate therapy
  - More likely to discontinue existing therapy

The Evolution of Benefit Designs to Allow Access to Biosimilar Products Remains Slow\(^1\)

As of 2017, only 22\% of health plans indicate that they have or will make adjustments to benefit designs for biosimilars under the medical benefit\(^1\)

Potential reasons *WHY*...

- Exclusionary contracting and rebate strategies by originator product manufacturers\(^2,3\)
- Lack of resources to comprehensively manage medical specialty drugs\(^4\)
- Lack of financial risk for self-insured lives

Employers and other stakeholders need to actively encourage physicians, payers, and appropriate patients to consider biosimilars for their potential cost savings\(^2\)

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Need Exists for Broad Stakeholder Involvement and Stronger Market Incentives to Help Overcome Barriers to Biosimilars in the US

• Only **13% of biologic spending** is currently subject to competition from biosimilar alternatives\(^1\)
  - Low uptake and barriers to successful market launches may discourage investment in biosimilar development\(^2-4\)
  - Without competition from biosimilars, potential lower cost savings may not be attainable\(^2-4\)

> “We need **broad stakeholder involvement** and **shared responsibility**...Congress and regulatory agencies can help by scrutinizing anti-competitive behavior by pharmaceutical companies that prevents biosimilars and generics from coming to market. **Addressing the barriers to biosimilar development** in a thoughtful and targeted way can help assure **greater access to treatment alternatives** and **drive affordability** throughout the healthcare system.”\(^5\)

—Gregory Gierer

Senior Vice President (SVP) of Policy, America’s Health Insurance Plans (AHIP)

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Employers Are Increasingly Playing an Active Role to Drive Change in Health Care Delivery

Actions Employers Can Take...

1. **Quantify the biosimilar opportunity**
   - Understand your biosimilar fill rate and potential savings opportunity

2. **Review health plan and request modification to improve uptake of biosimilars**
   - Through prior authorization, formulary, or physician reimbursement
   - Request health plan design to include step therapy when possible
   - Ensure health plan drug formulary tier assignments are based on cost-effectiveness

3. **Consider the value to employees and their dependents**
   - Co-pay differentials or co-insurance
   - Use “cost sharing” tools as part of plan benefit design to incentivize patients and prescribers

4. **Educate employees and their dependents**
   - Work with vendor to build employee understanding of available therapy options

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**For more information on biosimilars, please visit:**
- PfizerBiosimilars.com/Downloadable-Resources
- Fda.gov/drugs/biosimilars

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Quantify the Opportunity

Questions employers should ask their benefit managers:

- What is your total spend on biologics?
- What is your spend for biologics that have biosimilars available?
- How many members are using a drug with a biosimilar available?
- What is the estimated potential savings opportunity net of all discounts?
- What are the potential benefit design interventions to accelerate biosimilar uptake?
Discuss Biosimilars With Your Health Plan

Questions employers should ask their benefit managers:

✅ Are biosimilars being promoted?

✅ If yes, how?
  - Through prior authorization
  - Through a formulary

✅ If no, why not?
  - What is the rationale for not promoting use of lower-cost biosimilars?
  - Has your vendor ever evaluated the potential savings from biosimilars?
  - Is the vendor receiving pharmaceutical revenues on the originator product? If yes, are rebates being passed through to the employer?
Align Incentives for Your Covered Lives

Questions employers should ask their benefit managers:

- What is the **difference in cost share** between the originator product and the biosimilars?

- If there is a cost-share difference, **is it significant** enough to encourage patients and physicians to consider a lower cost option, assuming there are no clinically meaningful differences in efficacy and safety?

- If the difference in cost share is not meaningful, **how can cost-sharing requirements be modified** to help address financial barriers to access?
Member Education

Questions employers should ask their benefit managers:

✓ What are the **best opportunities to drive awareness** given that impacted populations are relatively small?

✓ Is there a **way to leverage existing educational materials** from the FDA, medical societies, pharmaceutical manufacturers, or others to help drive awareness?

For more information on biosimilars, please visit:
• PfizerBiosimilars.com/Downloadable-Resources
• Fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products
Summary

• Biologics are a **large and growing budget item** for employers and their employees

• **Biosimilars potentially offer much needed budget relief** without compromising quality of care

• **Time is now for employers to advocate for benefit designs** that promote utilization of lower net cost options among employees and their dependents
Thank You
The Number of New Biologic Approvals Remains Significant, Increasing Pressure on the US Health Care System\textsuperscript{1-3}

Biologics Have Almost Doubled as a Percentage of New FDA Approvals Over 10 Years\textsuperscript{1,2,*}

\begin{itemize}
  \item By 2020, \textbf{$5$ out of every $10$} that the country spends on prescription drugs will be spent on specialty medicines, including biologics\textsuperscript{3}
\end{itemize}

\textsuperscript{*}Includes approvals of oligonucleotide-based drugs; excludes biosimilar drug approvals.
Through 2021, Annual Spend on Drugs for Inflammation, Diabetes, and Oncology Is Forecast to Grow

<table>
<thead>
<tr>
<th>Disease</th>
<th>2018 PMPY Cost</th>
<th>2021 PMPY Cost (Projected)</th>
<th>Trend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory conditions</td>
<td>$174</td>
<td>$229</td>
<td>+ 31.1%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>$115</td>
<td>$145</td>
<td>+ 26.3%</td>
</tr>
<tr>
<td>Oncology</td>
<td>$80</td>
<td>$110</td>
<td>+ 36.8%</td>
</tr>
<tr>
<td>Multiple sclerosis</td>
<td>$56</td>
<td>$57</td>
<td>+ 2.2%</td>
</tr>
<tr>
<td>HIV</td>
<td>$49</td>
<td>$60</td>
<td>+ 22.0%</td>
</tr>
</tbody>
</table>