Coverage for Biosimilars vs Reference Products Among US Commercial Health Plans

The greater use of biosimilars may have the potential to help reduce drug costs. However, biosimilars have yet to gain traction in the US. In 2010, Congress created an abbreviated licensure pathway for biosimilars, but it is unclear whether and how health plans prioritize coverage of these products. We examined how commercial health plans cover biosimilars relative to reference products.

Methods | We identified biosimilar coverage policies from the Tufts Medical Center Specialty Drug Evidence and Coverage (SPEC) database, which includes specialty drug coverage decisions issued by 17 of the largest US commercial health plans that make their decisions publicly available (approximately 60% of commercially covered lives). The database details plan coverage and the evidence that plans cite to support their decisions.

We included coverage decisions for all biosimilars available in the US in August 2019. When the US Food and Drug Administration approves a drug for multiple indications, the SPEC database includes each drug-indication pair separately. For example, because bevacizumab-awwb is indicated for 5 cancers, the database includes a separate decision for each one.

We categorized biosimilar coverage as preferred if the plan covered a biosimilar ahead of the reference product (ie, the plan required patients to try the biosimilar before gaining access to the reference product); nonpreferred if the plan covered the reference product ahead of the biosimilar (required patients to try the reference product before gaining access to the biosimilar); or on par if the plan did not prioritize either the biosimilar or the reference product. We recorded how frequently plans confer different levels of coverage for biosimilars and how often each biosimilar received each coverage level.

Results | There were 9 biosimilars available and 40 drug-indication pairs were included. Of the 535 decisions issued by plans, 14% granted the biosimilar preferred coverage, 33% nonpreferred coverage, and 53% on par coverage. Plans issued a median of 32 biosimilar decisions (range, 18-40). The median number of coverage decisions for a biosimilar across plans was 56 (range, 12-134).

Health plans varied in how they covered biosimilars. Only 7 of 17 plans covered a biosimilar as preferred in at least 1 decision, and only 2 of these plans covered biosimilars as preferred in 50% or more of their decisions (Table 1). Thirteen plans covered biosimilar products as nonpreferred in a proportion of their decisions, and 6 did so in at least 50% of their decisions. Two health plans always covered biosimilars on par with the reference product in each decision. Health plans covered biosimilars consistently across their indications (eg, the plan that covered infliximab-dyyb as preferred did so for each of its indications: rheumatoid arthritis, ulcerative colitis, etc).

Plans also varied in how they covered particular biosimilars. Fifty-one percent of plans covered filgrastim-sndz as preferred (Table 2). In contrast, 65% and 59% of plans covered infliximab-abda and infliximab-dyyb as nonpreferred, respectively.

Discussion | This study found that, in 2019, US health plans covered biosimilars as preferred in only 14% of decisions. It also revealed biosimilar coverage differences across health plans.

### Table 1. Variation in Coverage of Biosimilars Across Commercial Health Plans

<table>
<thead>
<tr>
<th>Health plan No.</th>
<th>No. of biosimilar coverage decisions</th>
<th>Biosimilar coverage vs reference product, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Preferred coverage(^a)</td>
</tr>
<tr>
<td>1</td>
<td>32</td>
<td>50</td>
</tr>
<tr>
<td>2</td>
<td>37</td>
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<td>38</td>
</tr>
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<tr>
<td>17</td>
<td>40</td>
<td>0</td>
</tr>
</tbody>
</table>

\(^a\) Issued by the health plan.

\(^b\) Plan required patients to first try the biosimilar before their physician could prescribe the reference product.

\(^c\) Plan did not require patients to first try the biosimilar or reference product before gaining access to the alternate product.

\(^d\) Plan required patients to first try the reference product before their physician could prescribe the biosimilar.
Reasons for this variation are unknown but may include more successful negotiation of rebates at some plans than others. Because rebate agreements are not publicly disclosed, however, it was not possible to examine this hypothesis empirically. This research also revealed coverage variation across individual biosimilars, with some plans covering some biosimilars as preferred products more often than others. Biosimilar characteristics, such as time since approval by the US Food and Drug Administration, or whether the drug treats cancer, may explain some of this variation.

Limitations include that the appeals process for coverage denials was not considered, nor were the benefit design features of the plans, including patient cost-sharing, which likely affects use of these products.³

The slow uptake of biosimilars in the US has been attributed to factors such as patent disputes and reference product manufacturer tactics to delay biosimilar market entry.¹ This study suggests that a lack of preferred coverage among health plans may also be delaying uptake.

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<table>
<thead>
<tr>
<th>Biosimilar</th>
<th>Date of biosimilar approval</th>
<th>No. of FDA-approved indications</th>
<th>No. of coverage decisions</th>
<th>Biosimilar coverage vs reference product, %</th>
<th>Preferred coverage⁴</th>
<th>On par coverage⁵</th>
<th>Nonpreferred coverage⁶</th>
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<tbody>
<tr>
<td>Bevacizumab-awwb</td>
<td>September 2017</td>
<td>5</td>
<td>60</td>
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<td>98</td>
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<td>Epoetin alfa-epbx</td>
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<td>56</td>
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<td>71</td>
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<td>Filgrastim-xafi</td>
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<td>51</td>
<td>39</td>
<td>57</td>
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<td>59</td>
<td>51</td>
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<tr>
<td>Infliximab-abda</td>
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<td>134</td>
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<td>65</td>
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<tr>
<td>Infliximab-dyvb</td>
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<td>7</td>
<td></td>
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<tr>
<td>Pegfilgrastim-jnmd</td>
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<td>14</td>
<td>64</td>
<td>21</td>
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<td>Trastuzumab-anns</td>
<td>June 2019</td>
<td>3</td>
<td>12</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td></td>
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</tbody>
</table>

Abbreviation: FDA, Food and Drug Administration.

¹ Plan required patients to first try the biosimilar before their physician could prescribe the reference product.

² Plan did not require patients to first try either the biosimilar or reference product before gaining access to the alternate product.

³ Plan required patients to first try the reference product before their physician could prescribe the biosimilar.

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COMMENT & RESPONSE

Cognitive Screening of Older Practitioners

To the Editor A JAMA Performance Improvement article⁴ reported the use of a cognitive screening battery as the primary basis of recredentialing older practitioners by Yale New Haven Hospital. Some modifications and caveats would enhance this program and those at other centers for testing the cognition of physicians.