

POLICY SOLUTIONS FOR BIOSIMILARS

Expanding Access & Reducing Costs

Biologics have transformed treatment for conditions like cancer and autoimmune disease, but access is often limited. Biosimilars are clinically comparable alternatives designed to reduce spending and increase treatment options. Although more than 70 biosimilars have been approved in the United States, they account for only a small share of the market.

The FDA has been diligent in reviewing and approving biosimilars, ensuring safe and effective options are available. But FDA-approval is only the first step toward access. To help biosimilars further deliver on their promises of increased access and lower costs, policy changes should be considered.

WHAT POLICYMAKERS CAN DO NOW



REALIGN FINANCIAL INCENTIVES

Financial misalignment is a major barrier to biosimilar adoption. Even when lower-cost biosimilars are available, originator biologics are often more profitable for hospitals, providers and payers. Medicare's current payment model adds an 8% increase to biosimilars' reimbursement, on top of the biologic's average sales price, as part of the Inflation Reduction Act's efforts to encourage greater biosimilar use. But even with this added payment, the financial incentives may still favor the originator biologics because of how clinicians acquire drugs.

To improve uptake, policymakers can:

- Adjust reimbursement formulas to better reflect provider costs.
- Ensure clinicians are fairly reimbursed, regardless of whether they prescribe an innovator biologic or biosimilar alternative.
- Revisit drug pricing dynamics that encourage high list price products.



REDUCE PATIENT COSTS

Because of insurance policies, biosimilars often do not lower patients' out-of-pocket costs. Under Medicare and many commercial plans, patients may pay the same coinsurance percentage for biosimilars as for the reference biologic.

To reduce patient costs, policymakers can:

- Lower cost-sharing for biosimilars.
- Require insurers to pass savings through to patients.



SUPPORT EDUCATION

Many patients, providers and pharmacists still feel uncertain about recommending biosimilars. Confusion about switching and the meaning of interchangeability can make clinicians hesitant to recommend lower cost alternatives. Stronger education efforts can close these gaps and give providers confidence to prescribe biosimilars when appropriate.

To improve confidence and awareness, policymakers can:

- Expand education campaigns for patients, providers and pharmacists about biosimilar safety, effectiveness and the meaning of interchangeability.
- Provide clinical resources to help providers understand when and how switching is appropriate.



IMPROVE TRANSPARENCY

Formulary decisions and rebate structures often obscure the real cost differences between innovator biologics and their biosimilar counterparts, and determine which medicines are covered and preferred. These practices can limit patient access to lower cost options, even when a biosimilar is available and clinically appropriate. Increased transparency can help patients and clinicians understand how much they could save.

To improve transparency, policymakers can:

- Require clear reporting on rebate practices and formulary exclusions.
- Improve disclosure of patient out-of-pocket costs when a biosimilar is available.

WHY IT MATTERS

Biosimilars have already saved the U.S. health care system \$56 billion, yet the marketplace is still in its early stages. Without updated policy action that keeps pace with this growth, much of their potential will remain underutilized. Strengthening biosimilar policies is essential to reduce costs, increase access and protect long-term patient choice.