FAST*facts*

September 2018

BIOSIMILARS POLICY IN 2018 & BEYOND

Since Congress created an approval pathway for follow-on biological drugs in 2009, nearly a dozen biosimilars have been approved by the FDA. Many more are in the pipeline.

Biological medicines, inclulding biosimilars, are derived from cells or living systems. They are typically infused or injected, either by a physician or through a self-injectable device patients can use at home. Biosimilars are highly similar to their biologic reference product and capable of offering equally powerful results. To receive approval from the FDA, biosimilars must prove to be safe, efficacious and capable of producing the same effect as the original biologic.

For patients, biosimilars mean new, and potentially lower-priced, options to treat diseases such as cancer, rheumatoid arthritis, Crohn's disease and psoriasis. For policymakers, these drugs create the need for new policies that ensure that health care providers and patients welcome biosimilars with confidence.

This Fast Facts explains how several recent policies impact biosimilars and patient access.

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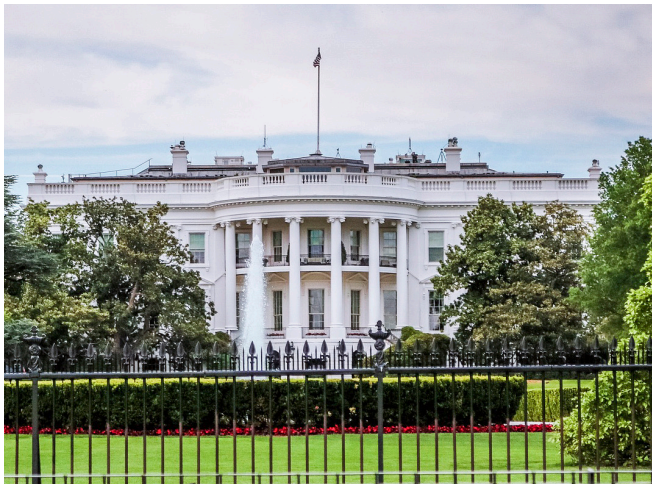
Q: Will President Donald Trump's efforts to lower drug prices impact patient access to biologics and biosimilars?

The Trump administration's blueprint, "American Patients First," introduces several ideas for reducing patients' out-of-pocket expenses and driving down drug prices. Some of these offer a straightforward benefit for patients who need biologics or biosimilars. For instance, the plan suggests using unique Medicare billing codes for biosimilars.[1]

Other provisions of the plan could be problematic for patients. In particular, the idea of shifting medications provided under Medicare from Part B to the prescription drug plan, Part D, could limit choice, complicate access for seniors and lead to higher out-of-pocket expenses.



Q: How would moving Medicare Part B drugs to Part D affect patients?

President Trump's blueprint suggests shifting Part B drugs, which are largely biologics and biosimilars administered in a physician's office, to Medicare's Part D prescription drug plan. The shift is meant to lower drug prices, but it could create new challenges for patients in at least two ways.

1.) Shifting Part B drugs to Part D could limit patient choice. Currently, Medicare Part B does not use a formulary of approved drugs; all available, FDA-approved drugs are covered. Under Part D, however, Medicare plans can operate using a formulary.[2] Medicare beneficiaries could find that their drug is not included in their Part D plan's formulary – or that it's considered "non-preferred," requiring them to pay more out of pocket.

2.) Shifting drugs from Part B to Part D could limit patients' ability to afford their medicine. Currently, patients can purchase supplemental insurance to defray their out-of-pocket costs for Medicare Part B. Supplemental insurance is not available for Part D plans.[3] This could mean significantly higher drug costs for seniors, many of whom live on a modest or fixed income.

Q: Why do Medicare policies on billing for biosimilars matter to patients?

Since biosimilars first became available, the Centers for Medicare and Medicaid Services has alternated between two different approaches to how physicians bill – and are reimbursed – when their Medicare patients use biosimilars.

One approach, used by CMS 2016-2017, assigned all biosimilars for a given reference product the same billing code and reimbursed for them at the same rate.[4] Beginning January 2018, CMS reversed course.[5] It determined that each biosimilar would have its own billing code and be reimbursed based upon its individual price.

Medicare's billing logistics matter for two reasons. The first is patient choice. If biosimilars are billed and reimbursed at the same rate, manufacturers have less incentive to invest in and develop biosimilars after an initial biosimilar has been introduced. This means fewer treatment options for patients.

The second issue is the ability to trace drugs' side effects to their source. Biological medicines, like all drugs, can cause side effects. If a patient responds poorly to a given biological drug, the patient and his or her doctor need to know with certainty which medicine caused the problem. But if some biosimilars carry the same billing code, it may be difficult to trace which medicine caused the problem – and to determine which drug the patient should try as an alternative.

Q: What do Medicare Advantage plans' new "negotiation tools" mean for patients who use biologics or biosimilars?

In August 2018, the Centers for Medicare and Medicaid Services announced that Medicare Advantage plans could use step therapy to lower prescription drug expenses.[6] Medicare Advantage plans are privately managed plans available to Medicare beneficiaries. CMS' decision allows these plans to impose utilization management, limiting beneficiaries' use of certain drugs in an attempt to rein in costs.

Allowing Medicare Advantage plans to use step therapy means that seniors who are prescribed a biologic or biosimilar may now be required to "fail first" on a different, insurer-preferred drug before gaining access to the one their physician prescribed. This can cause undue stress and unnecessary health complications for patients.

Q: Do physicians have the information they need about biosimilars?

Like all drugs approved by the Food and Drug Administration, biosimilars are packaged with an insert known as "prescribing information." Some call it the drug's "label."

The information typically includes details about a drug's administration and side effects, as well as data from clinical trials performed with the drug.

Prescribing information is slightly different for biosimilars than for reference products.

Biosimilars are tested not to independently prove their safety and efficacy but rather to prove this indirectly by demonstrating their similarity to the reference product, which has been proven safe and efficacious. In July 2018, the FDA determined that prescribing information for biosimilars would include clinical trials data on the original, reference biologic's safety and efficacy.[7-8]

The FDA did not, however, opt to include clinical trials data demonstrating a biosimilar's similarity to its reference product. While this information may be available elsewhere, physicians could benefit from having it directly provided on the biosimilar's label.

Q: Are any biosimilars interchangeable with their reference biologic?

Not yet. Though the FDA issued draft guidance on interchangeability in January 2017, the agency has not yet made its criteria final. The FDA has yet to designate any biosimilars as interchangeable.

Pharmacists will be able to replace a prescribed biologic with an interchangeable biosimilar without the involvement of the prescribing physician. That capability means that standards for achieving interchangeability status must be especially rigorous.

In particular, it's important that clinical trials of potentially interchangeable biosimilars study the impact of multiple switches between a biologic and its biosimilar.

In real-world use, patients may very well experience multiple switches, whether due to physician or patient preference, changes in out-of-pocket costs that influence treatment choices or alterations in health plan coverage. Studying multiple switches in clinical trials allows manufacturers to collect data on how switches impact patients' response to treatment.

Having complete data and rigorous testing also helps to ensure that physicians will feel confident in prescribing or administering biosimilars to their patients.

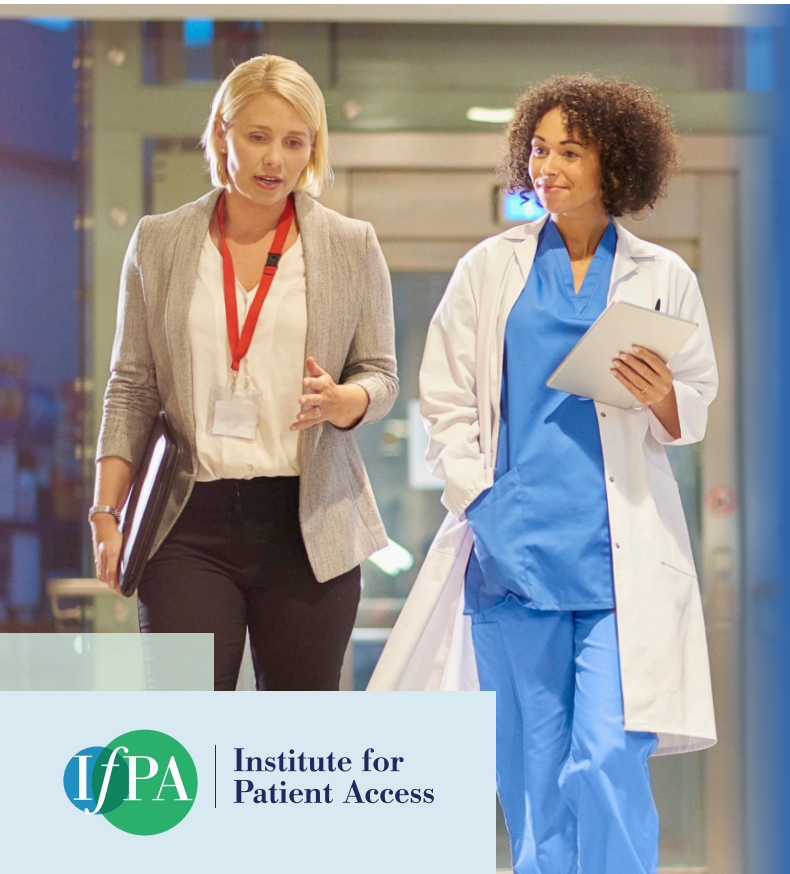
Q: What is the FDA's Biosimilars Action Plan?

The Biosimilar Action Plan was designed by the FDA in 2018 to encourage market competition – leading to more biosimilars, more overall treatment options and lower costs for patients. The plan aims to:

- Make the biosimilar approval and development process more efficient
- Increase clarity for manufacturers about scientific and regulatory issues
- Provide education to improve people's understanding of biosimilars
- Boost market competition by reducing inappropriate delays in approval of biosimilars.

To achieve these goals, the FDA plans to take steps such as creating a standard template for reviewing biosimilars and developing online educational materials for patients.[9]

The Biosimilars Action Plan also notes that the FDA plans to provide "timely guidance" on other topics that impact the regulation of biosimilars. Issues include manufacturing changes that occur after a biosimilar has been approved, criteria for determining which biosimilars are distinguished as interchangeable, and how the FDA evaluates the similarity between a biosimilar and its reference product. Showing its commitment to make good on this promise, the FDA released final guidance on biosimilar labeling the same day it announced the Biosimilars Action Plan.[10]



CONCLUSION

Biosimilars continue to present exciting new treatment options for patients with complex, chronic and life-threatening diseases. Policymakers must work to strike the right balance – crafting policies that encourage innovation and competition but that also protect patient access and ensure that the physician-patient relationship continues to drive health care decisions.

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This document was revised for clarity in October 2018