

## Biosimilars: Frequently Asked Questions

### **What is a biosimilar?**

A biosimilar is a biologically engineered medication that is highly similar to and has no clinically meaningful differences from an existing U.S. Food and Drug Administration (FDA)-approved innovator.

### **What is an innovator?**

An innovator is the brand biologic medication that was first to market for a unique compound. Examples: Neulasta®, Remicade®

### **Is a biosimilar like a generic?**

A generic and a biosimilar are both alternative versions of an innovator brand drug, but a biosimilar is not considered a generic. A generic is created from synthesized chemicals and a biosimilar is a biological product created from a living system, such as a microorganism, plant cell, or animal cell, and is often more difficult to characterize than small molecule drugs.<sup>1</sup>

Biosimilars and generics are approved by the FDA through different pathways. The active ingredients of generic drugs are the same as those of brand name drugs and the manufacturer of generic drug must demonstrate bioequivalence to the brand name drug. A drug is considered bioequivalent if it has the same effectiveness on the body and demonstrates the same absorption levels. In contrast, manufacturers of biosimilars must demonstrate that the product is highly similar to the innovator drug, except for minor differences in clinically inactive components. In addition, biosimilar manufacturers must demonstrate that there are no clinically meaningful differences between biosimilar and innovator/reference products in terms of safety and effectiveness.<sup>1</sup>

### **How many biosimilars are FDA approved?**

As of June 2020, a total of 25 biosimilars have been approved by the FDA, but many are still not commercially available.<sup>2</sup>

Biosimilars in the marketplace:

- Biosimilar for Epogen®/Procrit® = Retacrit®
- Biosimilar for Neulasta® = Fulphila™, Udenyca™, Ziextenzo™
- Biosimilar for Neupogen® = Nivestym™, Zarxio®
- Biosimilar for Remicade® = Avsola™, Inflectra®, Renflexis™
- Biosimilar for Avastin® = Mvasi™, Zirabev™
- Biosimilar for Herceptin® = Herzuma®, Kanjinti®, Ogivri™, Ontruzant®, Trazimera™
- Biosimilar for Rituxan® = Ruxience™, Truxima®

Biosimilars approved by the FDA, but not yet launched:

- Biosimilar for Enbrel® = Erelzi™, Eticovo™
- Biosimilar for Humira® = Amjevita™, Cyltezo®, Hyrimoz®, Hadlima™
- Biosimilar for Neulasta® = Nyvepria™

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### What management strategies are in place for available biosimilars?

Biosimilars create a more competitive pricing environment among drug manufacturers that can help drive down drug costs. UnitedHealthcare evaluates each brand name biologic and its biosimilar, one by one, and makes a strategic management decision based on the lowest-cost product in order to deliver lower costs to our members, clients and consumers.

UnitedHealthcare Commercial Plans					
Drug	Category	Innovator brand(s)	Biosimilar brand(s)	Administration method	Preferred product*
Filgrastim	Cancer support	Neupogen Granix®	Nivestym Zarxio	Physician administered or self-injected	<b>Zarxio</b> Preferred product for both the pharmacy and medical benefits
Pegfilgrastim	Cancer support	Neulasta	Fulphila Udenyca Ziextenzo	Physician administered or self-injected	<b>Neulasta</b> Preferred product for both the pharmacy and medical benefits  <b>Ziextenzo</b> Additional preferred product for both the pharmacy and medical benefits starting Jan. 1, 2021
Infliximab	Inflammatory conditions	Remicade	Avsola Inflectra Renflexis	Physician administered	<b>Inflectra or Remicade</b> Preferred products for the medical benefit
Epoetin alfa	Anemia	Epogen Procrit	Retacrit	Physician administered or self-injected	<b>Retacrit</b> Preferred product for both the pharmacy and medical benefits

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Bevacizumab	Cancer	Avastin	Mvasi Zirabev	Physician administered	<b>Mvasi</b> Preferred product for the medical benefit
Trastuzumab	Cancer	Herceptin	Herzuma Kanjinti Ogivri Ontruzant Trazimera	Physician administered	<b>Kanjinti</b> Preferred product for the medical benefit
Rituximab	Cancer	Rituxan	Ruxience Truxima	Physician administered	<b>Ruxience or Truxima (Oct. 1, 2020)</b> Preferred products for the medical benefit

\*UnitedHealthcare uses utilization management strategies, such as prior authorization or exclusions, to determine preferred products.

UnitedHealthcare Community Plans					
Drug	Category	Innovator brand(s)	Biosimilar brand(s)	Administration method	Preferred product*
Filgrastim	Cancer support	Neupogen Granix	Nivestym Zarxio	Physician administered or self-injected	<b>Zarxio</b> Preferred product for both the pharmacy and medical benefits
Pegfilgrastim	Cancer support	Neulasta	Fulphila Udenyca Ziextenzo	Physician administered or self-injected	<b>Neulasta</b> Preferred product for both the pharmacy and medical benefits
Infliximab	Inflammatory conditions	Remicade	Avsola Inflectra Renflexis	Physician administered	<b>Inflectra or Renflexis</b> Preferred product for the medical benefit

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Epoetin alfa	Anemia	Epogen Procrit	Retacrit	Physician administered or self-injected	<b>Retacrit</b> Preferred product for the pharmacy and medical benefits
Bevacizumab	Cancer	Avastin	Mvasi Zirabev	Physician administered	<b>Mvasi</b> Preferred product for the medical benefit
Trastuzumab	Cancer	Herceptin	Herzuma Kanjinti Ogivri Ontruzant Trazimera	Physician administered	<b>Kanjinti</b> Preferred product for the medical benefit
Rituximab	Cancer	Rituxan	Ruxience Truxima	Physician administered	<b>All products</b> preferred for the medical benefit

\*UnitedHealthcare Community Plan uses utilization management strategies, such as prior authorization, determine preferred products. Different preferred products may exist in some markets due to state Medicaid requirements.

UnitedHealthcare Medicare Plans					
Drug	Category	Innovator brand(s)	Biosimilar brand(s)	Administration method	Preferred product*
Filgrastim	Cancer support	Neupogen Granix	Nivestym Zarxio	Physician administered or self-injected	<b>Part D:</b> Zarxio preferred product  <b>Part B:</b> Zarxio preferred product

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Pegfilgrastim	Cancer support	Neulasta	Fulphila Udenyca Ziextenzo	Physician administered or self-injected	<b>Part D:</b> Udenyca and Neulasta preferred products  <b>Part B:</b> Udenyca and Neulasta preferred products
Infliximab	Inflammatory conditions	Remicade	Avsola Inflectra Renflexis	Physician administered	<b>Part D:</b> Inflectra and Renflexis preferred products  <b>Part B:</b> Inflectra and Renflexis preferred products
Epoetin alfa	Anemia	Procrit	Retacrit	Physician administered or self-injected	<b>Part D:</b> Retacrit preferred product  <b>Part B:</b> Retacrit preferred product
Bevacizumab	Cancer	Avastin	Mvasi Zirabev	Physician administered	<b>Part D:</b> Avastin preferred product  <b>Part B:</b> All products are preferred products
Trastuzumab	Cancer	Herceptin	Herzuma Kanjinti Ogivri Ontruzant Trazimera	Physician administered	<b>Part D:</b> Herceptin preferred product  <b>Part B:</b> All products are preferred products

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Rituximab	Cancer	Rituxan	Ruxience Truxima	Physician administered	<b>Part D:</b> <b>Rituxan</b> preferred product  <b>Part B:</b> <b>All products</b> preferred
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\*UnitedHealthcare uses utilization management strategies, such as prior authorization or step therapy, to prefer products.

**Who can I contact if I have questions?**

If you have questions, please contact your UnitedHealthcare representative.

<sup>1</sup>[fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars](https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars)

<sup>2</sup>[fda.gov/drugs/biosimilars/biosimilar-product-information](https://www.fda.gov/drugs/biosimilars/biosimilar-product-information)

Insurance coverage provided by or through UnitedHealthcare Insurance Company or its affiliates. Health plan coverage provided by UnitedHealthcare of Arizona, Inc., UHC of California DBA UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Colorado, Inc., UnitedHealthcare of the Mid - Atlantic, Inc., MAMSI Life and Health Insurance Company, UnitedHealthcare of New York, Inc., UnitedHealthcare Insurance Company of New York, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare of Pennsylvania, Inc., UnitedHealthcare of Texas, Inc., UnitedHealthcare Benefits of Texas, Inc., UnitedHealthcare of Utah, Inc., UnitedHealthcare of Washington, Inc., Optimum Choice, Inc., Oxford Health Insurance, Inc., Oxford Health Plans (NJ), Inc., Oxford Health Plans (CT), Inc., All Savers Insurance Company, or other affiliates. Administrative services provided by OptumHealth Care Solutions, LLC, OptumRx, Oxford Health Plans LLC, United HealthCare Services, Inc., or other affiliates. Behavioral health products provided by U.S. Behavioral Health Plan, California (USBHPC), or its affiliates.