# **Biosimilars**

Frequently asked questions

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#### 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 – for example, Neulasta® and 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 January 2021, a total of 29 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<sup>®</sup> = Fulphila<sup>™</sup>, Nyvepria<sup>™</sup>, Udenyca<sup>™</sup>, Ziextenzo<sup>™</sup>
- Biosimilar for Neupogen<sup>®</sup> = Nivestym<sup>™</sup>, Zarxio<sup>®</sup>
- Biosimilar for Remicade<sup>®</sup> = Avsola<sup>™</sup>, Inflectra<sup>®</sup>, Renflexis<sup>™</sup>
- Biosimilar for Avastin<sup>®</sup> = Mvasi<sup>™</sup>, Zirabev<sup>™</sup>
- Biosimilar for Herceptin<sup>®</sup> = Herzuma<sup>®</sup>, Kanjinti<sup>®</sup>, Ogivri<sup>™</sup>, Ontruzant<sup>®</sup>, Trazimera<sup>™</sup>
- Biosimilar for Rituxan<sup>®</sup> = Riabni<sup>™</sup>, Ruxience<sup>™</sup>, Truxima<sup>®</sup>

Biosimilars approved by the FDA, but not yet launched:

- Biosimilar for Enbrel<sup>®</sup> = Erelzi<sup>™</sup>, Eticovo<sup>™</sup>
- Biosimilar for Humira<sup>®</sup> = Abrilada<sup>™</sup>, Amjevita<sup>™</sup>, Cyltezo<sup>®</sup>, Hyrimoz<sup>®</sup>, Hulio<sup>®</sup>, Hadlima<sup>™</sup>
- Biosimilar for Remicade<sup>®</sup> = Ixifi™



#### 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					
Medication	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 Nyvepria Udenyca Ziextenzo	Physician administered or self-injected	<b>Neulasta</b> and <b>Ziextenzo</b> Preferred products for both the pharmacy and medical benefits
Infliximab	Inflammatory conditions	Remicade	Avsola Inflectra Renflexis	Physician administered	<b>Avsola</b> and <b>Inflectra,</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
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> and <b>Trazimera</b> Preferred product for the medical benefit
Rituximab	Cancer	Rituxan	Riabni Ruxience Truxima	Physician administered	<b>Ruxience</b> and <b>Truxima</b> Preferred products for the medical benefit

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



Medication	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 Nyvepria 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>Avsola</b> and <b>Inflectra</b> Preferred product for the medical benefit
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	Riabni Ruxience Truxima	Physician administered	<b>Ruxience</b> and <b>Truxima</b> Preferred for the medical benefit

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



Medication	Category	Innovator brand(s)	Biosimilar brand(s)	Administration method	Preferred product*
Filgrastim	Cancer support	Neupogen Granix	Nivestym Zarxio	Physician administered or self-injected	Part D: Zarxio preferred product Part B: Zarxio preferred product
Pegfilgrastim	Cancer support	Neulasta	Fulphila Nyvepria Udenyca Ziextenzo	Physician administered or self-injected	Part D: Udenyca and Neulasta preferred products Part B: Udenyca and Neulasta preferred products
Infliximab	Inflammatory conditions	Remicade	Avsola Inflectra Renflexis	Physician administered	Part D: Inflectra and Renflexis preferred products Part B: Inflectra and Renflexis preferred products
Epoetin alfa	Anemia	Procrit	Retacrit	Physician administered or self-injected	Part D: Retacrit and Procrit preferred products Part B: Retacrit preferred product
Bevacizumab	Cancer	Avastin	Mvasi Zirabev	Physician administered	Part D: Avastin preferred product Part B: All products are preferred products
Trastuzumab	Cancer	Herceptin	Herzuma Kanjinti Ogivri Ontruzant Trazimera	Physician administered	Part D: Herceptin preferred product Part B: All products are preferred products
Rituximab	Cancer	Rituxan	Riabni Ruxience Truxima	Physician administered	Part D: Rituxan preferred product Part B: All products preferred

\*UnitedHealthcare uses utilization management strategies, such as prior authorization or step therapy, to prefer products.



Medication	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
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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

<sup>2</sup>fda.gov/drugs/biosimilars/biosimilar-product-information

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