

Biosimilar Frequently Asked Questions (FAQs)

What is a biosimilar?

Biological products are a diverse category of products and are generally large, complex molecules that are approved by the Food and Drug Administration (FDA) to prevent, treat, and cure diseases and medical conditions.

A reference product is the single biological product, already approved by FDA. A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

The structure and function of biosimilars are analyzed extensively to demonstrate that they are highly similar to the reference product. A manufacturer must also demonstrate that its proposed biosimilar product has no clinically meaningful differences from the reference product in terms of safety, purity, and potency (safety and effectiveness). This is generally demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.

Once a biosimilar has been approved by FDA, patients and health care providers can be assured of the safety and effectiveness of these products, just as they would for the reference product.

What is Kaiser Permanente's management strategy for available biosimilars?

Biosimilars create a more competitive pricing environment among drug manufacturers, which can help drive down drug costs. Kaiser Permanente evaluates each reference biologic product and its biosimilar, one by one, and updates coverage based on the lowest cost product to deliver affordable care to our members and patients. For coverage policies specific to the reference products and biosimilars, please refer to Kaiser Permanente's [Non-Medicare Injectable Drugs Requiring Prior Authorization](#) and [Medicare Injectable Drugs Requiring Prior Authorization](#).

What biosimilars are available and what is Kaiser Permanente's preferred product?

Table 1: Preferred Biosimilar Product(s) at Kaiser Permanente

Medication	Reference Product	Biosimilar Name(s)	Benefit	Preferred Product
Adalimumab	Humira	adalimumab-atto (Amjevita) adalimumab-aacf (Idacio) adalimumab-adaz (Hyrimoz, Adalimumab-adaz) adalimumab-adbm (Cyltezo) adalimumab-aaty (Yuflyma) adalimumab-aqvh (Yusimry) adalimumab-bwwd (Hadlima) adalimumab-fkjp (Hulio, Adalimumab-fkjp)	Pharmacy	Amjevita

		adalimumab-afzb (Abrilada) adalimumab-ryvk (Simlandi)		
Insulin glargine	Lantus	insulin glargine-yfgn (Semglee) insulin glargine-yfgn (Unbranded Semglee) Insulin glargine-aglr (Rezvoglar)	Pharmacy	Insulin glargine-yfgn (Unbranded Semglee)
Rituximab	Rituxan	rituximab-arrr (Riabni) rituximab-pvvr (Ruxience) rituximab-abbs (Truxima)	Medical	Riabni
Pegfilgrastim	Neulasta	pegfilgrastim-apgf (Nyvepria) pegfilgrastim-bmez (Ziextenzo) pegfilgrastim-cbqv (Udenyca) pegfilgrastim-jmdb (Fulphila) pegfilgrastim-pbbk (Fylnetra) pegfilgrastim-fpgk (Stimufend)	Pharmacy & Medical	Fulphila
Infliximab	Remicade	infliximab-axxq (Avsola) infliximab-qbtq (Ixifi) infliximab-abda (Renflexis) infliximab-dyyb (Inflectra)	Medical	Inflectra
Bevacizumab	Avastin	bevacizumab-bvzr (Zirabev) bevacizumab-awwb (Mvasi) bevacizumab-maly (Alymsys) bevacizumab-adcd (Vegzelma)	Medical	Mvasi
Trastuzumab	Herceptin	trastuzumab-anns (Kanjinti) trastuzumab-qyyp (Trazimera) trastuzumab-dttb (Ontruzant) trastuzumab-pkrb (Herzuma) trastuzumab-dkst (Ogivri)	Medical	Kanjinti
Filgrastim	Neupogen	filgrastim-aafi (Nivestym) filgrastim-sndz (Zarxio) filgrastim-ayow (Releuko)	Pharmacy & Medical	Granix
Epoetin-alfa	Epogen	epoetin alfa-epbx (Retracrit)	Pharmacy & Medical	Epogen/Procrit
Ranibizumab	Lucentis	ranibizumab-nuna (Byooviz) ranibizumab-eqrn (Cimerli)	Medical	Byooviz
Tocilizumab	Actemra	tocilizumab-aazg (Tyenne) tocilizumab-bavi (Tofidence)	Medical	Tyenne
Tocilizumab	Actemra	tocilizumab-aazg (Tyenne)	Pharmacy	Tyenne
Ustekinumab	Stelara	Ustekinumab-aaaz (Otulfi) Ustekinumab-aekn (Selarsdi) Ustekinumab-auub (Wezlana) Ustekinumab-kfce (Yesintek) Ustekinumab-srlf (Imuldosa) Ustekinumab-stba (Steqeyma) Ustekinumab-ttwe (Pyzchiva)	Pharmacy & Medical	Yesintek

Guidance for resuming previous biologic therapy after a biologic interchange

Patients who have switched from a reference product to a preferred biosimilar may resume the reference product if deemed clinically appropriate by the prescriber, and both outlined pre-requisites AND the following criteria are met.

Criteria

- Patient was established on a reference product for at least 3 administrations (injections or infusions), OR as specified in the drug table below.
- Patient has received at least 2 administrations based on route and frequency of the preferred biosimilar(s), OR as specified in the table below, with one of the following:
 1. Increased side effects or development of a new side effect not experienced with the reference product.
 - Side effect must be moderate or severe (CTCAE Grade 2 or 3[^]) in nature and persist despite intervention to mitigate.
 2. Loss of efficacy with preferred biosimilar(s) after objective findings on physical exam or lab abnormalities.
 - Lab evaluation as deemed appropriate by specialty department per specific biologic.

[^] Common Terminology Criteria for Adverse Events (CTCAE):		
General Side Effect Grading	Grade	Description
	1	<u>Mild, asymptomatic or mild symptoms</u> ; clinical or diagnostic observations only; intervention not indicated
	2	<u>Moderate; minimal, local or noninvasive intervention indicated</u> ; limiting age-appropriate instrumental activities of daily living (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.)
	3	<u>Severe or medically significant but not immediately life-threatening</u> ; hospitalization or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living (bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden)
	4	Life-threatening consequences; urgent intervention indicated
	5	Death related to adverse event

Injection Site Reaction Grading	1	<u>Clinical or diagnostic observations only</u> ; Tenderness with or without associated symptoms (e.g., warmth, erythema, itching)
	2	<u>Moderate; minimal, local or noninvasive intervention indicated</u> ; Pain (local or noninvasive intervention indicated); lipodystrophy, edema; phlebitis
	3	<u>Severe or medically significant but not immediately life-threatening</u> ; Ulceration or necrosis; severe tissue damage; operative intervention indicated

	4	Life-threatening consequences; urgent intervention indicated
	5	Death related to adverse event

https://ctep.cancer.gov/protocoldevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_8.5x11.pdf

Table 2: Drug-Specific Guidance to Resume Previous Biologic after Trial of Preferred

Drug Name	Established use guidance	Guidance to resume previous biologic after trial of preferred
Adalimumab (Humira) Adalimumab-xxxx*	6 administrations or 3 months, whichever duration is longer	<p>[Non- GI specialty] 3 administrations or 1.5 months of preferred biologic, whichever duration is longer</p> <p>[GI specialty] lack of response or flare</p> <ul style="list-style-type: none"> Obtain CRP and fecal calprotectin prior to resuming prior biologic
Infliximab (Remicade) Infliximab-xxxx*	4 administrations or 4 months, whichever duration is longer	<p>[Non- GI specialty] 2 administrations or 2 months of preferred biologic, whichever duration is longer</p> <p>[GI specialty] lack of response or flare</p> <ul style="list-style-type: none"> Obtain CRP and fecal calprotectin prior to resuming prior biologic
Subcutaneous Tocilizumab (Actemra) Tocilizumab-xxxx*	6 administrations or 3 months, whichever duration is longer	3 administrations or 1.5 months of preferred biologic, whichever duration is longer
Intravenous Tocilizumab (Actemra) Tocilizumab-xxxx*	4 administrations or 4 months, whichever duration is longer	2 administrations or 2 months of preferred biologic, whichever duration is longer
Ustekinumab (Stelara) Ustekinumab-xxxx*	3 administrations or 5 months	<p>[Non-GI specialty] 2 administrations</p> <ul style="list-style-type: none"> Consider increasing frequency of administration prior to resuming prior biologic, if clinically appropriate <p>[GI specialty] 2 administrations, or lack of response, or flare</p> <ul style="list-style-type: none"> Consider increasing frequency of administration prior to resuming prior biologic, if clinically appropriate Obtain CRP and fecal calprotectin prior to resuming prior biologic

* Inclusive of all biosimilar products for a named reference product

Date Created/ Updated	Description
9/20/2021	Development of initial document
03/16/2023	Incorporated guidance for resuming previous biologic therapy after a biologic interchange
10/15/2023	Updated insulin glargine and ranibizumab preferred products
12/22/2023	Added new biosimilar, adalimumab-afzb (Abrilada)
4/2/2024	Added biosimilars, bevacizumab-adcd (Vegzelma) and insulin glargine-aglr (Rezvoglar)
4/4/2024	Added new biosimilar, adalimumab-ryvk (Simlandi)
6/26/2024	Added new biosimilar, tocilizumab-aazg (Tyenne) and tocilizumab-bavi (Tofidence)
9/10/2024	Updated language to clarify reference product versus biosimilar
9/23/2024	Updated filgrastim preferred product
4/3/2025	Addition of ustekinumab biosimilars, preferred product, and guidance for resuming previous biologic therapy after a biologic interchange.

Reference: [Biosimilars | FDA](#)

Helpful Resources

- [Non-Medicare Injectable Drugs Requiring Prior Authorization](#)
- [Medicare Injectable Drugs Requiring Prior Authorization](#)
- [Medicare Part B Step Therapy](#)
- [Infusion Site of Care Policy](#)
- [Infusion Site of Service Policy](#)