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# 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)<br>adalimumab-aacf (Idacio)<br>adalimumab-adaz (Hyrimoz, Adalimumab-adaz)<br>adalimumab-adbm (Cyltezo)<br>adalimumab-aaty (Yuflyma)<br>adalimumab-aqvh (Yusimry)<br>adalimumab-bwwd (Hadlima)<br>adalimumab-fkjp (Hulio, Adalimumab-fkjp) | Pharmacy | Amjevita |

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| | | | | |
|---|---|---|---|---|
| | | adalimumab-afzb (Abrilada)<br>adalimumab-ryvk (Simlandi) | | |
| Insulin glargine | Lantus | insulin glargine-yfgn (Semglee)<br>insulin glargine-yfgn (Unbranded Semglee)<br>Insulin glargine-aglr (Rezvoglar) | Pharmacy | Insulin glargine-yfgn (Unbranded Semglee |
| Rituximab | Rituxan | rituximab-arrx (Riabni)<br>rituximab-pvvr (Ruxience)<br>rituximab-abbs (Truxima) | Medical | Riabni |
| Pegfilgrastim | Neulasta | pegfilgrastim-apgf (Nyvepria)<br>pegfilgrastim-bmez (Ziextenzo)<br>pegfilgrastim-cbqv (Udenyca)<br>pegfilgrastim-jmdb (Fulphila)<br>pegfilgrastim-pbbk (Fylnetra)<br>pegfilgrastim-fpgk (Stimufend) | Pharmacy & Medical | Fulphila |
| Infliximab | Remicade | infliximab-axxq (Avsola)<br>infliximab-qbtx (Ixifi)<br>infliximab-abda (Renflexis)<br>infliximab-dyyb (Inflectra) | Medical | Inflectra |
| Bevacizumab | Avastin | bevacizumab-bvzr (Zirabev)<br>bevacizumab-awwb (Mvasi)<br>bevacizumab-maly (Alymsys)<br>bevacizumab-adcd (Vegzelma) | Medical | Mvasi |
| Trastuzumab | Herceptin | trastuzumab-anns (Kanjinti)<br>trastuzumab-qyyp (Trazimera)<br>trastuzumab-dttb (Ontruzant)<br>trastuzumab-pkrb (Herzuma)<br>trastuzumab-dkst (Ogivri) | Medical | Kanjinti |
| Filgrastim | Neupogen | filgrastim-aafi (Nivestym)<br>filgrastim-sndz (Zarxio)<br>filgrastim-ayow (Releuko) | Pharmacy & Medical | Zarxio |
| Epoetin-alfa | Epogen | epoetin alfa-epbx (Retracrit) | Pharmacy & Medical | Epogen/Procrit |
| Ranibizumab | Lucentis | ranibizumab-nuna (Byooviz)<br>ranibizumab-eqrn (Cimerli) | Medical | Byooviz |

**Guidance for resuming previous biologic therapy after a biologic interchange**

Patients who have switched from a biologic to the preferred biologic may resume the previous biologic if deemed clinically appropriate by the prescriber AND specific criteria below are met.

**Criteria**

- Patient was established on a previous biologic for at least 3 administrations (injections or infusions), OR as specified in the drug-specific table below [Table 2].
- Patient has received at least 2 administrations based on route and frequency of the preferred biologic, OR as specified in the table below, with one of the following:

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1. Increased side effects or development of a new side effect not experienced with the previous biologic.
   - 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 biologic 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** | Mild, asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated |
| | **2** | Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.) |
| | **3** | Severe or medically significant but not immediately life-threatening; 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** | Clinical or diagnostic observations only; Tenderness with or without associated symptoms (e.g., warmth, erythema, itching) |
| | **2** | Moderate; minimal, local or noninvasive intervention indicated; Pain (local or noninvasive intervention indicated); lipodystrophy, edema; phlebitis |
| | **3** | Severe or medically significant but not immediately life-threatening; 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

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**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)<br>Adalimumab-xxxx* | 6 administrations or 3 months, whichever duration is longer | [Non- GI specialty] 3 administrations or 1.5 months of preferred biologic, whichever duration is longer<br><br>[GI specialty] lack of response or flare<br>• Obtain CRP and fecal calprotectin prior to resuming prior biologic |
| Infliximab (Remicade)<br>Infliximab-xxxx* | 4 administrations or 4 months, whichever duration is longer | [Non- GI specialty] 2 administrations or 2 months of preferred biologic, whichever duration is longer<br><br>[GI specialty] lack of response or flare<br>• 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) |

Reference: Biosimilars | FDA

**Helpful Resources**

- Non-Medicare Injectable Drugs Requiring Prior Authorization

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- Medicare Injectable Drugs Requiring Prior Authorization
- Medicare Part B Step Therapy
- Infusion Site of Care Policy
- Infusion Site of Service Policy

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