

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Brand Biologic with Biosimilar or Unbranded Biologic Available

Initiation (new start) criteria and criteria for new or current Kaiser Permanente members already taking brand product: A brand biologic^a will be covered on the prescription drug benefit for 12 months or less, if new interchangeable biologic products become available, when the following criteria are met:

- An unbranded biologic^b is not available. **-AND-**
- The member has a documented allergic reaction to an inactive ingredient in the biosimilar^c product (e.g., dye) not present in the brand biologic. **-AND-**
- Other biosimilars to the brand are not available without the inactive ingredient **-AND-**
 - The member has tried and failed at least one preferred therapeutic alternative without the inactive ingredient (if available).

^a Brand biologic = a drug that has a brand (proprietary) name and is listed as a reference product in the FDA Purple Book.

^b Unbranded biologic = a drug that is the same exact product as the brand biologic and made by the brand manufacturer except it is marketed without the brand name. Since it is equivalent to the brand biologic (reference product) because it is the same drug, it is not listed separately in the FDA Purple Book.

^c Biosimilar = a drug that is highly similar to the brand biologic (reference product) and listed as a biosimilar in the FDA Purple Book. There are no clinically meaningful differences between the biosimilar and the brand biologic in terms of the safety, purity and potency of the product.