A Public Entity

Inland Empire Health Plan

| IEHP UM Subcommittee Approved Authorization Guideline | | | |
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| **Guideline** | Biosimilar Products | **Guideline #** | UM_OTH 22 |
| | | **Original Effective Date** | 5/13/2020 |
| **Section** | Other | **Revised Date** | 12/15/2021 |

## COVERAGE POLICY

1. Biosimilar drugs are preferred when there is a lack of data demonstrating clinical superiority of reference products over the US Food and Drug Administration (FDA)-approved biosimilar drugs.
2. A reference product may be approved under the following conditions:
    a. Treatment with at least two (2) associated biosimilar drug(s) has been ineffective, not tolerated, or is contraindicated;
    b. Prescribing physician attests that failure, intolerance, or contraindication would not be expected to occur with reference product;
    c. Requested dosage is consistent with FDA approved labeling;
    d. Prescribed for an FDA approved indication; or
    e. Prescribed for a non-FDA approved indication recognized by Micromedex Information System as recommended regimen of category 2B or above (Recommended, In Some Cases).
3. Reauthorization requires the following:
    a. Documentation supporting patient stability and positive clinical response, i.e. chart notes, relevant lab values
    b. Dosages and duration of therapy must not exceed standard of care, package insert information, or established clinical practice guidelines

## COVERAGE LIMITATION AND EXCLUSIONS

1. Biosimilar coverage does not include the following:
    a. Requests for investigational use
    b. Requests that exceed standard of care, package insert information, or established clinical practice guidelines and are not considered medically necessary or appropriate
    c. Requests for patients with history of failure, intolerance, or contraindications to the requested drugs

## CLINICAL/REGULATORY RESOURCE

1. Congress, through the Biologics Price Competition and Innovation Act (BPCI Act) of 2009, created an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biological product. This pathway was established as a way to provide more treatment options, increase access to lifesaving medications, and potentially lower health care costs through competition.

2. The FDA states that a proposed biosimilar demonstrate close similarity to the reference product through extensive analysis of purity, chemical identity and bioactivity of both the reference product and the proposed biosimilar. The proposed biosimilar product must also show no clinically meaningful differences from the reference product in terms of safety and potency. This is generally demonstrated through human pharmacokinetic (exposure) and pharmacodynamic (response) studies, an assessment of clinical immunogenicity, and, if needed, additional clinical studies.

## DEFINITION OF TERMS

1. Reference product – A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data.
2. Biosimilar – A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.

## REFERENCES

1. U.S. Food and Drug Administration. Biosimilar and Interchangeable Products. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products. Accessed November 28, 2022.

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