# SmartPA Criteria Proposal

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|---|---|
| **Drug/Drug Class:** | Biosimilar vs Reference Products Fiscal Edit |
| **First Implementation Date:** | January 30, 2020 |
| **Proposed Date:** | December 16, 2021 |
| **Prepared for:** | MO HealthNet |
| **Prepared by:** | MO HealthNet/Conduent |
| **Criteria Status:** | ☐Existing Criteria<br>☒Revision of Existing Criteria<br>☐New Criteria |

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of biosimilar agents and their reference products

**Why Issue Selected:** A biosimilar is a biological product that is very similar to an FDA approved reference biologic and for which there are no clinically meaningful differences in terms of safety, purity, and potency. The Biologics Price Competition and Innovation Act (BPCI Act) of 2009 created the abbreviated licensure pathway for biological products to provide more treatment options, increase access to lifesaving mediations, and potentially lower health care costs through competition. The FDA applies rigorous approval standards to all biosimilar products, so patients and health care professionals are able to rely on the safety and effectiveness of a biosimilar just as they would the reference product. An interchangeable biosimilar meets additional FDA requirements and may be substituted for the reference product without the intervention of the prescriber, subject to state laws. In July 2021, the FDA approved the first interchangeable biosimilar product Semglee®, which is both biosimilar to and interchangeable with the reference product Lantus®. In certain situations, it is fiscally advantageous for MO HealthNet to establish a preference for either the reference or biosimilar product.

**Type of Criteria:**
- ☐ **Increased risk of ADE**
- ☐ **Appropriate Indications**
- ☐ **Preferred Drug List**
- ☒ **Fiscal Edit**

**Data Sources:**
- ☒ **Only Administrative Databases**
- ☐ **Databases + Prescriber-Supplied**

## Setting & Population

- Drug class for review: Biosimilar agents and their reference products
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Claim is for a preferred biologic agent (see Appendix A)

## Denial Criteria

- Therapy will be denied if all approval criteria are not met

## Required Documentation

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|---|---|---|---|
| Laboratory Results: | | Progress Notes: | |
| MedWatch Form: | | Other: | X |

## Disposition of Edit

Denial: Exception code "0683" (Fiscal Edit)
Rule Type: CE

## Default Approval Period

**1 month**

## Appendix A – Preferred and non-preferred biologic agents

| Biologic Agent | Preferred Agents | Non-Preferred Agents |
|---|---|---|
| RITUXIMAB | RITUXAN 100 MG/10 ML VIAL | **RIABNI 100 MG/10 ML VIAL** |
| | | RUXIENCE 100 MG/10 ML VIAL |
| | | TRUXIMA 100 MG/10 ML VIAL |
| RITUXIMAB | RITUXAN 500 MG/50 ML VIAL | **RIABNI 500 MG/50 ML VIAL** |
| | | RUXIENCE 500 MG/50 ML VIAL |
| | | TRUXIMA 500 MG/50 ML VIAL |
| **INSULIN GLARGINE** | **LANTUS 100 UNIT/ML VIAL** | **SEMGLEE 100 UNIT/ML VIAL** |
| | | **SEMGLEE (YFGN) 100 UNIT/ML VL** |
| **INSULIN GLARGINE** | **LANTUS SOLOSTAR 100 UNIT/ML** | **BASAGLAR 100 UNIT/ML KWIKPEN** |
| | | **SEMGLEE 100 UNIT/ML PEN** |
| | | **SEMGLEE (YFGN) 100 UNIT/ML PEN** |

## References


- US Food and Drug Administration. Biosimilars. Biosimilars | FDA. Accessed October 4, 2021.
- US Food and Drug Administration. Biosimilar and Interchangeable Products. Biosimilar and Interchangeable Products | FDA. Accessed October 4, 2021.
- US Food and Drug Administration. Purple Book: Database of Licensed Biological Products. Purple Book: Licensed Biological Products (fda.gov). Accessed October 4, 2021.