SmartPA Criteria Proposal

Drug/Drug Class:	Biosimilar vs Reference Products Fiscal Edit
First Implementation Date:	January 30, 2020
Revised Date:	October 14, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐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

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

Disposition of Edit

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

Default Approval Period

1 year

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.