SmartPA Criteria Proposal

Drug/Drug Class:	Homozygous Familial Hypercholesterolemia (HFHC) Products PDL Edit
First Implementation Date:	January 29, 2014
Revised Date:	January 21, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Juxtapid™ is a branded drug product indicated as an adjunct to lipid-lowering medications, treatments, and diet to reduce low-density lipoprotein-cholesterol (LDL-C), apolipoprotein B, total cholesterol (TC) and non-high density lipoprotein-cholesterol (non HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). Familial Hypercholesterol (FH) is a genetic disorder characterized by high cholesterol levels, specifically very high levels of low-density lipoprotein (LDL) in the blood. Patients who have one abnormal copy of the LDLR gene have the heterozygous form while those patients who have two abnormal copies of the LDLR gene have the homozygous form. Heterozygous FH is a common genetic disorder occurring in 1:500 people while Homozygous FH is much rarer, occurring in 1 in a million births.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
	• Juxtapid®

Type of Criteria:

☐ **Increased risk of ADE**	☒ **Preferred Drug List**
☒ **Appropriate Indications**	☐ **Clinical Edit**

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

Setting & Population

- Drug class for review: Homozygous Familial Hypercholesterolemia (HFHC) Products
- Age range: All appropriate MO HealthNet participants 18 years and older

Approval Criteria

- Participants 18 years of age and older **AND**
- Documented diagnosis of homozygous familial hypercholesterolemia **AND**
- Adequate therapeutic trial of high potency statin (atorvastatin 80mg/day, rosuvastatin 40mg/day, atorvastatin/amlodipine 80mg-5mg/day, or atorvastatin/amlodipine 80mg-10mg/day) **OR**
    - Documented ADE/ADR to high potency statin therapy **AND**
- LDL-C remains >175mg/dL

Denial Criteria

- Participant is currently pregnant **OR**
- Documented diagonsis of moderate or severe hepatic impairement
- Therapy will be denied if all approval criteria are not met
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
JUXTAPID 5 MG CAPSULE	LOMITAPIDE	60 mg/day
JUXTAPID 10 MG CAPSULE	LOMITAPIDE	60 mg/day
JUXTAPID 20 MG CAPSULE	LOMITAPIDE	60 mg/day
JUXTAPID 30 MG CAPSULE	LOMITAPIDE	60 mg/day
JUXTAPID 40 MG CAPSULE	LOMITAPIDE	60 mg/day
JUXTAPID 60 MG CAPSULE	LOMITAPIDE	60 mg/day

Required Documentation

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

Disposition of Edit

Denial: Exception Code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

1. Evidence-Based Medicine and Fiscal Analysis: “Homozygous Familial Hypercholesterolemia Products – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
2. Evidence-Based Medicine Analysis: “Homozygous Familial Hypercholesterolemia Products”, UMKC-DIC; July 2020.
3. Package Insert for Kynamro, Kastle Therapeutics, Chicago, IL 60602; May 2016.
4. Package Insert for Juxtapid, Aegerion Pharmaceuticals, Inc., Cambridge, MA 02142; August 2017.
5. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
6. USPDI, Micromedex; 2020.
7. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.