SmartPA Criteria Proposal

Drug/Drug Class:	Niacin Derivatives PDL Edit
First Implementation Date:	January 8, 2009
Proposed Date:	September 17, 2020
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: Niacin (nicotinic acid) lowers serum levels of total cholesterol, low-density lipoprotein cholesterol (LDL-C), very low-density lipoprotein (VLDL), and triglycerides. High-dose nicotinic acid also increases serum levels of high-density lipoprotein cholesterol (HDL-C). Though the true mechanism of antihyperlipidemic action of nicotinic acid is not well understood, it is believed to inhibit lipolysis in adipocytes and possibly inhibits hepatic triglyceride production resulting in a reduction of VLDL levels that are available for conversion LDL-C. High dose niacin, both as monotherapy and in combination with statins, has been found to significantly decrease cardiovascular and cerebrovascular events in those with coronary heart disease (CHD). It is thought that this effect is due, at least in part, to niacin's antihyperlipidemic activity.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Niacor® • Niacin ER • Niacin IR	• Niaspan®

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

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

Setting & Population

- Drug class for review: Niacin Derivatives
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for preferred agents **OR**
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

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

Disposition of Edit

Denial: Exception Code “0160” (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Evidence-Based Medicine and Fiscal Analysis: “Lipotropic Agents: Niacin and Combination Preparations – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; July 2020.
2. Evidence-Based Medicine Analysis: “Lipotropics: Statins, Niacin Preparations, CAIs, and Combinations”, UMKC-DIC; July 2020.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
4. USPDI, Micromedex; 2020.
5. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.