

SmartPA Criteria Proposal

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| Drug/Drug Class: | Niacin Derivatives PDL Edit |
| First Implementation Date: | January 8, 2009 |
| Proposed Date: | September 15, 2022 |
| Prepared For: | MO HealthNet |
| Prepared By: | MO HealthNet/Conduent |
| Criteria Status: | <input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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 |
|-------------------------------|---|---|
| | <ul style="list-style-type: none"> Niacin ER | <ul style="list-style-type: none"> Niacin IR Niaspan® |

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: Niacin Derivatives
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 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:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

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

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Lipotropics: Statins, Niacin Preparations, Cholesterol Absorption Inhibitors", UMKC-DIC; July 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Lipotropic Agents: Niacin and Combination Preparations – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; July 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.