

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Niacin Derivatives PDL Edit
<b>First Implementation Date:</b>	January 8, 2009
<b>Proposed Date:</b>	October 17, 2023
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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"> <li>Niacin ER</li> </ul>	<ul style="list-style-type: none"> <li>Niacin IR</li> </ul>

**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 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; April 2023.
- 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; 2023.
- Facts and Comparisons eAnswers (online); 2023 Clinical Drug Information, LLC.