

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Biguanides & Combination Agents PDL Edit
<b>First Implementation Date:</b>	April 13, 2005
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" 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:** Type 2 diabetes mellitus is a significant health problem associated with excessive morbidity and mortality. As the prevalence of this metabolic disorder is rapidly increasing and as older treatments fail to stabilize the disease in many participants, prevention and control are considered key objectives. Metformin monotherapy and combination therapy are generally well tolerated and improve glycemic control and lipid concentrations in patients with non-insulin-dependent diabetes mellitus, whose diabetes is poorly controlled with diet or sulfonylurea therapy alone. Metformin decreases hepatic glucose output by inhibiting gluconeogenesis by reducing glucose substrate availability through its antilipolytic effect which decreases serum free fatty acid concentrations. It also increases insulin-mediated glucose use in peripheral tissues such as in the muscle and liver, typically after meals. In addition, metformin also activates the AMP-activated protein kinase (AMPK) enzyme in hepatocytes which contributes to decreases serum lipid concentrations. The most common adverse effects are gastrointestinal related, metallic taste, vitamin B12 deficiency, and lactic acidosis. It is recommended to take these agents with meals to reduce gastrointestinal adverse effects.

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>• Glipizide/Metformin</li> <li>• Glyburide/Metformin</li> <li>• Metformin HCl</li> <li>• Metformin ER (gen Glucophage® XR)</li> </ul>	<ul style="list-style-type: none"> <li>• Fortamet®</li> <li>• Glucophage®</li> <li>• Glucophage® XR</li> <li>• Glumetza®</li> <li>• Metformin ER (gen Fortamet®)</li> <li>• Metformin ER (gen Glumetza®)</li> <li>• Metformin Soln</li> <li>• Repaglinide/Metformin</li> <li>• Riomet®</li> <li>• Riomet ER™</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: Biguanides & Combination Agents
- 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 of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- For Glumetza and Fortamet: adequate therapeutic trial on generic Glucophage and/or Glucophage XR (90/120 days) **OR**
- For Riomet ER: Clinical Consultant Review

## Denial Criteria

- Lack of adequate trial on required preferred agents
- 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
FORTAMET ER 1,000 MG	METFORMIN ER	2 tablets per day
FORTAMET ER 500 MG	METFORMIN ER	5 tablets per day
GLUCOPHAGE XR 500 MG	METFORMIN ER	4 tablets per day
GLUCOPHAGE XR 750 MG	METFORMIN ER	2 tablets per day
GLUCOVANCE 1.25 MG/250 MG	GLYBURIDE/METFORMIN	1 tablet per day
GLUCOVANCE 2.5 MG/500 MG	GLYBURIDE/METFORMIN	2 tablets per day
GLUCOVANCE 5 MG/500 MG	GLYBURIDE/METFORMIN	4 tablets per day
GLUMETZA ER 1,000 MG	METFORMIN ER	2 tablets per day
GLUMETZA ER 500 MG	METFORMIN ER	4 tablets per day
METAGLIP 2.5 MG/250 MG	GLIPIZIDE/METFORMIN	1 tablet per day
METAGLIP 2.5 MG/500 MG	GLIPIZIDE/METFORMIN	4 tablets per day
METAGLIP 5 MG/500 MG	GLIPIZIDE/METFORMIN	4 tablets per day
<b>RIOMET ER 500 MG/5 ML SUSP</b>	<b>METFORMIN HCL</b>	<b>20 mL per day</b>

## 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

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Wexler, D., (2019). Metformin in the treatment of adults with type 2 diabetes mellitus. In J.E. Mulder (Ed.), *UpToDate*.
4. American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. *Diabetes Care*. 2021;44(suppl 1): S1-S232.
5. Evidence-Based Medicine and Fiscal Analysis: “Oral Antidiabetics: Biguanide and Combination Agents – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
6. Evidence-Based Medicine Analysis: “Biguanides”, UMKC-DIC; May 2021.
7. Evidence-Based Medicine Analysis: “Antidiabetic Combination Agents – Oral and Injectable”, UMKC-DIC; March 2020.
8. Fortamet [package insert]. Florham Park, NK: Shionogi; March 2021.
9. Glucophage [package insert]. Princeton, NJ; Bristol-Myers Squibb; December 2019.
10. Glumetza [package insert]. Bridgewater, NJ; Salix Pharmaceuticals; August 2019.
11. Riomet [package insert]. Cranbury, NJ: Sun Pharmaceuticals; December 2018.