BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.30.20

| | | | |
|---|---|---|---|
| **Section:** | Prescription Drugs | **Effective Date:** | July 1, 2022 |
| **Subsection:** | Endocrine and Metabolic Drugs | **Original Policy Date:** | October 18, 2015 |
| **Subject:** | Metformin | **Page:** | 1 of 7 |

***Last Review Date:*** June 16, 2022

# Metformin

## Description

Fortamet (extended-release metformin osmotic), Glumetza* (extended-release metformin), Riomet (metformin oral solution), Riomet ER* (extended-release metformin oral suspension), Metformin ER (modified & osmotic)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

**Background**
Metformin is an oral antidiabetic medication used to improve glycemic control in adults with type 2 diabetes mellitus. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, and loss of limbs. Proper control of diabetes may also lessen the risk of a heart attack or stroke. Metformin works by helping to restore the body's proper response to the insulin it naturally produces. It also decreases the amount of sugar that the liver makes and that the stomach/intestines absorb (1-4).

**Regulatory status**
FDA-approved indication: Metformin is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (1-4).

Limitations of Use:
Metformin is not used for the treatment of type 1 diabetes or ketoacidosis (1-4).

Metformin carries a boxed warning regarding the risk of lactic acidosis, which may be fatal. Increased risk is associated with hypotensive states such as acute congestive heart failure and acute myocardial infarction. Metformin is contraindicated in patients with renal impairment, metabolic acidosis, or hypersensitivity to metformin hydrochloride. Before initiating therapy with Metformin, evaluate the patient's renal function (1-4).

Patients should be warned against excessive alcohol intake while taking Metformin (1-4).

The American Diabetes Association notes that metformin can be used for the prevention of diabetes (especially in those with a Body Mass Index (BMI) ≥ 35, > 60 years of age and women with prior gestational diabetes) and for polycystic ovary syndrome (PCOS) (5).

The safety and effectiveness of Glumetza and Fortamet in pediatric patients less than 18 years of age have not been established (1-2). The safety and effectiveness of Riomet and Riomet ER in pediatric patients less than 10 years of age have not been established (3-4).

**Related policies**
SGLT2 Inhibitors, SGLT2 Step Policy

## Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Metformin may be considered **medically necessary** in patients with type 2 diabetes mellitus and if the conditions indicated below are met.

Metformin may be considered **investigational** for all other indications.

## Prior-Approval Requirements

**Age**
**Glumetza and Fortamet only:** 18 years of age or older
**Riomet and Riomet ER only:** 10 years of age or older

**Diagnosis**

Patient must have the following:

Diabetes mellitus Type 2

**AND ONE** of the following for **Glumetza and Fortamet only**:

1. Inadequate response
    a. Submission of medical records (e.g., chart notes, laboratory values) documenting a history of a minimum of 3 month trial with **each** of the following:
        i. Immediate release metformin
        ii. Extended-release metformin (generic Glucophage XR)
    b. Patient must have a HbA1c greater than 7.0%

2. Intolerance
    a. Submission of medical records (e.g., chart notes, laboratory values) documenting an intolerance which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction) with a history of minimum of a 1 month trial with **each** of the following:
        i. Immediate release metformin
        ii. Extended-release metformin (generic Glucophage XR)
    b. Patient must have a documented HbA1c

**Riomet and Riomet ER only:**

1. Documentation that the patient is unable to swallow or has difficulty swallowing metformin tablets
2. Patient must have a HbA1c greater than 7.0%, unless patient has been established on metformin therapy for at least 3 months

**AND** documentation of the following for **ALL** formulations:

1. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/minute/1.73 $m^2$
2. **NO** hepatic impairment
3. **NO** metabolic acidosis, including diabetic ketoacidosis

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

## Prior – Approval *Renewal* Requirements

**Age** **Glumetza and Fortamet only:** 18 years of age or older

**Riomet and Riomet ER only:** 10 years of age or older

**Diagnosis**

Patient must have the following:

Diabetes mellitus Type 2

**AND** documentation of **ALL** of the following**:**

1. Submission of medical records (e.g., chart notes, laboratory values) documenting a HbA1c level ≤ 7.0%
2. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/minute/1.73 $m^2$
3. **NO** hepatic impairment
4. **NO** metabolic acidosis, including diabetic ketoacidosis

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

## Policy Guidelines

### Pre - PA Allowance

None

### Prior - Approval Limits

**Quantity**

| Medication (BRAND with approved Formulary Exception only) | Quantity |
|---|---|
| Glumetza 500 mg | 360 tablets per 90 days **OR** |
| Glumetza 1000 mg | 180 tablets per 90 days |

***Maximum daily limit of any Glumetza combination: 2000mg**

| Medication | Quantity |
|---|---|
| Fortamet 500 mg | 360 tablets per 90 days **OR** |
| Fortamet 1000 mg | 180 tablets per 90 days |

***Maximum daily limit of any Fortamet combination: 2500mg**

| Medication | Quantity |
|---|---|
| Riomet 500 mg/5 mL | 2365 mL per 90 days |
| Riomet ER 500 mg/5 mL (**with approved Formulary Exception only**) | 1892 mL per 90 days |

**Duration** 12 months

## Prior – Approval *Renewal* Limits

Same as above

## Rationale

**Summary**

Metformin is indicated to improve glycemic control in adult patients with type 2 diabetes mellitus. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, and loss of limbs. Proper control of diabetes may also lessen the risk of a heart attack or stroke. Metformin works by helping to restore the body's proper response to the insulin it naturally produces. It also decreases the amount of sugar that the liver makes and that the stomach/intestines absorb. The safety and effectiveness of Glumetza and Fortamet in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Riomet and Riomet ER in pediatric patients less than 10 years of age have not been established (1-4).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of metformin while maintaining optimal therapeutic outcomes.

**References**

1. Glumetza [package insert]. Raleigh, NC: Salix Pharmaceuticals, Inc.; August 2019.
2. Fortamet [package insert]. Fort Lauderdale, FL: Actavis Laboratories FL, Inc.; November 2018.
3. Riomet [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2018.
4. Riomet ER [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; November 2019.

5. Prevention or Delay of Type 2 Diabetes: Standards of Medical Care in Diabetes—2020 American Diabetes Association. Diabetes Care Jan 2020, 43 (Supplement 1) S32-S36; DOI: 10.2337/dc20-S003.

## Policy History

| Date | Action |
|---|---|
| October 2015 | Addition to PA |
| December 2015 | Annual review |
| February 2016 | Addition of inadequate response, intolerance to all of the following: generic form of Glumetza, generic form of Glucophage ER. Also, addition of the requirement of inadequate response, intolerance to the generic form of Glumetza in the renewal section |
| March 2016 | Annual editorial review<br>Policy number change from 5.07.20 to 5.30.20 |
| June 2016 | Addition of Managed PA documentation and generic Glumetza |
| September 2016 | Annual review and reference update |
| July 2017 | Annual review |
| December 2018 | Removal of Brand Glumetza |
| March 2018 | Annual review |
| February 2019 | Addition of statement: *Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication. |
| March 2019 | Annual review. Merged with Policy 5.30.50 Fortamet Riomet and renamed policy Metformin. Increased Fortamet age requirement to 18 and older and added HbA1c requirements to Riomet |
| February 2020 | Addition of Riomet ER. Changed SCr requirement to eGFR > 30 |
| March 2020 | Annual review. Revised intolerance trial to one month. Revised Riomet requirement for HbA1c to be greater than 7, unless the patient has been established on metformin therapy for at least 3 months |
| June 2020 | Annual review and reference update. Revised regulatory status to mention that metformin can be used for prevention of diabetes and for PCOS per SME |
| December 2020 | Annual review and reference update. MFE + PA required for Riomet ER |
| June 2021 | Annual review |
| March 2022 | Added Fortamet/Glumetza initiation requirement for metformin intolerance to have a documented HbA1c. Also revised continuation requirement to remove the word “reduction” in HbA1c |
| June 2022 | Annual review |

## Keywords

**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.**