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5.30.020

Section:	Prescription Drugs	**Effective Date:**	October 1, 2024
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	October 18, 2015
Subject:	Metformin	**Page:**	1 of 7

Last Review Date: September 6, 2024

Metformin

Description

Glumetza* (extended-release metformin, modified release)

Riomet (metformin oral solution)

Riomet ER* (extended-release metformin oral suspension)

Metformin extended-release (modified release)

Metformin extended-release (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 Metformin ER osmotic 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
GLP-1 Agonists, Insulin GLP-1 Combinations, SGLT2 Inhibitors, SGLT2 Step Policy, Trijardy XR

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** if the conditions indicated below are met.

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

Prior-Approval Requirements

Age **Glumetza and Metformin ER osmotic 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 Metformin ER osmotic 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** 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 Metformin ER osmotic 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% **OR** HbA1c has decreased by at least 1.0% from baseline
2. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/minute/1.73 m^2
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.

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
Metformin ER osmotic 500 mg	360 tablets per 90 days **OR**
Metformin ER osmotic 1000 mg	180 tablets per 90 days

***Maximum daily limit of any Metformin ER osmotic 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 Metformin ER osmotic 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.; March 2024.
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 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
June 2023	Annual review. Changed policy number to 5.30.020
September 2023	Annual review. Per SME, removed requirement of no hepatic impairment
June 2024	Annual review and reference update. Per SME, allowed option for renewal for patient to meet a 1.0% reduction in A1c from baseline

September 2024	Annual editorial review. Removed brand name Fortamet due to being discontinued

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 6, 2024 and is effective on October 1, 2024.