



## STEP THERAPY POLICY

- POLICY:** Diabetes – Metformin Step Therapy Policy
- Immediate-release products
- metformin tablets (generic only)
  - metformin 625 mg tablets (branded generic)
  - metformin 750 mg tablets (branded generic)
  - metformin 750 mg tablets (generic)
  - Riomet® (metformin oral solution – Sun Pharmaceuticals, generic)
- Extended-release products
- metformin extended-release tablets (generic to obsolete brand Fortamet – generic only)
  - Glumetza® (metformin extended-release tablets – Salix, generic)
  - metformin extended-release tablets (generic to obsolete brand Glucophage XR – generic only)

**REVIEW DATE:** 10/09/2024; selected revision 01/29/2025 and 03/12/2025

### INSTRUCTIONS FOR USE

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## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

The extended-release metformin products, generic metformin extended-release tablets (generic to the obsolete brand Glucophage XR and generic to the obsolete brand Fortamet XR), and Glumetza (generic) are indicated as adjuncts to diet and exercise to **improve glycemic control** in adults with type 2 diabetes mellitus.<sup>1-3</sup>

The immediate-release metformin products, metformin tablets and Riomet oral solution (generic), are indicated for the **treatment of type 2 diabetes mellitus** in conjunction with diet and exercise in patients  $\geq 10$  years of age.<sup>4,5</sup> Generic metformin immediate-release tablets are available in strengths of 500 mg, 850 mg,

and 1,000 mg, metformin 625 mg and 750 mg tablets available as branded generics, and metformin 750 mg is available as a generic product. In the prescribing information for immediate-release metformin, it is noted that the recommended starting dose is 500 mg twice daily or 850 mg once daily.<sup>5</sup> Increase the dose in increments of 500 mg weekly or 850 mg once every 2 weeks on the basis of glycemic control and tolerability, up to a maximum dose of 2,550 mg per day, given in divided doses.

## **POLICY STATEMENT**

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product (or the use of a Step 1 and a Step 2 Product prior to the use of a Step 3 Product, where applicable). If the Step Therapy rule is not met for the Step 2 or Step 3 Product at the point of service, coverage will be determined by Step Therapy criteria below. All approvals are provided for 1 year in duration.

### **Immediate-Release Products:**

**Step 1:** generic metformin immediate-release tablets (500 mg, 850 mg, and 1,000 mg strengths)

**Step 2:** Riomet (brand and generic), metformin 625 mg tablets, metformin 750 mg tablets (branded generic and generic)

### **Extended-Release Products:**

**Step 1:** metformin extended-release tablets (generic to obsolete brand Glucophage XR only)

**Step 2:** metformin extended-release tablets (generic to obsolete brand Fortamet only)

**Step 3:** Glumetza (brand and generic)

**Diabetes – Metformin Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.**

## **CRITERIA**

### **Immediate-Release Products**

1. If the patient has tried one Step 1 immediate-release product, approve a Step 2 immediate-release product.

2. If the patient is unable to swallow or has difficulty swallowing tablets containing metformin, approve metformin oral solution (Riomet, generic).

### Extended-Release Products

1. If the patient has tried one Step 1 extended-release product, approve a Step 2 extended-release product.
2. If the patient has tried one Step 1 extended-release product AND one Step 2 extended-release product, approve a Step 3 extended-release product.

### REFERENCES

1. Metformin ER 500 and 750 mg tablet [prescribing information]. Hyderabad, India: Granules India Limited; November 2022.
2. Glumetza® extended-release tablets [prescribing information]. Bridgewater, NJ: Salix/Valeant; March 2024.
3. Fortamet® extended-release tablets [prescribing information]. Florham Park, NJ: Shionogi; November 2018.
4. Riomet® oral solution [prescribing information]. Jacksonville, FL: Sun Pharmaceuticals; November 2018.
5. metformin tablets [prescribing information]. Madisonville, LA: Solubiomix; January 2025.

### HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	<b>Extended-Release Products</b> <b>Riomet ER:</b> This product was removed from Step 2 of the extended-release products step (inactive/discontinued). The criterion allowing for approval of Riomet ER in patients unable to swallow or with difficulty swallowing tablets containing metformin, was removed.	10/18/2023
Annual Revision	<b>Immediate-Release Products</b> <b>Metformin 625 mg tablets:</b> The term “generic” was removed from this Step 2 immediate-release product. Metformin 625 mg tablet is coded as a brand.  <b>Extended-Release Products</b> <b>Fortamet (brand):</b> This product was removed from Step 2 of the extended-release products step (obsolete > 3 years). The generic to Fortamet remains in Step 2 of the extended-release products step.	10/09/2024
Selected Revision	<b>Immediate-Release Products</b> <b>Metformin 750 mg tablets (branded generic):</b> This product was added to the policy and to Step 2 of the immediate-release products step.	01/29/2025
Selected Revision	<b>Immediate-Release Products</b> <b>Metformin 750 mg tablets (generic):</b> This product was added to the policy and to Step 2 of the immediate-release products step.	03/12/2025

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