



## STEP THERAPY POLICY

- POLICY:** Diabetes – Metformin Step Therapy Policy
- Immediate-release products
- metformin tablets (generic only)
  - 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

### **INSTRUCTIONS FOR USE**

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

### **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>1-4</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>1</sup> Generic metformin immediate-release tablets are available in strengths of 500 mg, 625 mg, 850 mg, and 1,000 mg. 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. 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

#### **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.

## 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

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