

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

- Fortamet[®] (metformin extended-release tablets – Shionogi [brand obsolete 07/01/2021], generic)
- Glumetza[®] (metformin extended-release tablets – Salix, generic)
- metformin extended-release tablets (generic to obsolete brand Glucophage XR – generic only)
- Riomet ER[™] (metformin extended-release oral suspension – Sun Pharmaceuticals)

REVIEW DATE: 11/09/2022

OVERVIEW

The extended-release metformin products, Fortamet (generic), generic metformin extended-release tablets (generic to the obsolete brand Glucophage XR), Glumetza (generic), and Riomet ER, are indicated as adjuncts to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.¹⁻⁴ Riomet ER is also indicated in pediatric patients ≥ 10 years of age; however, the prescribing information for Riomet ER notes efficacy relies upon data from metformin immediate-release tablets in adult and pediatric patients.⁴

The immediate-release metformin products, metformin tablets and Riomet oral solution (generics), are indicated for the treatment of type 2 diabetes mellitus in conjunction with diet and exercise in patients ≥ 10 years of age.^{1,5} 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 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.

Automation: For immediate-release products, a patient with a of one Step 1 immediate-release product within the 130-day look-back period is excluded from Step Therapy. For extended-release products, there is no automation.

Immediate-Release Products:

Step 1: 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: Fortamet (brand and generic), Riomet ER

Step 3: Glumetza (brand and generic)

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).
3. No other exceptions are recommended.

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.
3. If the patient is unable to swallow or has difficulty swallowing tablets containing metformin, approve Riomet ER (metformin extended-release suspension).
4. No other exceptions are recommended.

REFERENCES

1. Glucophage® tablets/Glucophage® XR extended-release tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2018.
2. Glumetza® extended-release tablets [prescribing information]. Bridgewater, NJ: Salix/Valeant; November 2018.
3. Fortamet® extended-release tablets [prescribing information]. Florham Park, NJ: Shionogi; November 2018.
4. Riomet™ ER oral suspension [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals; August 2019.
5. Riomet® oral solution [prescribing information]. Jacksonville, FL: Sun Pharmaceuticals; November 2018.

