

## STEP THERAPY POLICY

- POLICY:** Diabetes – Metformin Step Therapy Policy
- Fortamet® (metformin extended-release tablets – Shionogi, generics)
  - Glucophage® (metformin tablets – Bristol-Myers Squibb, generics)
  - Glucophage® XR (metformin extended-release tablets – Bristol-Myers Squibb, generics)
  - Glumetza® (metformin extended-release tablets – Salix, generics)
  - Riomet® (metformin oral solution – Sun Pharmaceuticals, generics)
  - Riomet ER™ (metformin extended-release oral suspension – Sun Pharmaceuticals)

**REVIEW DATE:** 10/14/2020

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### OVERVIEW

The extended-release metformin products, Glucophage XR (generics), Glumetza (generics), Fortamet (generics), and Riomet ER, are indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.<sup>1-4</sup> Riomet ER is also indicated in pediatric patients  $\geq 10$  years of age, but the prescribing information for Riomet ER notes efficacy relies upon data from metformin immediate-release tablets in adult and pediatric patients.<sup>4</sup>

The immediate-release metformin products, Glucophage tablets (generics) and Riomet oral solution (generics), are indicated for the treatment of type 2 diabetes in adjunct to diet and exercise in patients  $\geq 10$  years of age.<sup>1,5</sup>

### POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 drug prior to the use of a Step 2 drug (or the use of a Step 1 and a Step 2 drug prior to the use of a Step 3 drug, where applicable). If the Step Therapy rule is not met for the Step 2 or Step 3 drug 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 drugs, a patient with a history of one Step 1 immediate-release drug within the 130-day look-back period is excluded from Step Therapy. For extended-release drugs, there is no automation.

### Immediate-release drugs:

**Step 1:** metformin immediate-release tablets

**Step 2:** Glucophage, Riomet, metformin oral solution

### Extended-release drugs:

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

**Step 2:** Glucophage XR (brand), Fortamet (brand and generic), Riomet ER

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

## CRITERIA

### Immediate-Release Drugs

1. If the patient has tried one Step 1 immediate-release drug, approve a Step 2 immediate-release drug.
2. If the patient is unable to swallow or has difficulty swallowing tablets containing metformin, approve metformin oral solution (Riomet, generics).
3. No other exceptions are recommended.

### Extended-Release Drugs

1. If the patient has tried one Step 1 extended-release drug, approve a Step 2 extended-release drug.
2. If the patient has tried one Step 1 extended-release drug AND one Step 2 extended-release drug, approve a Step 3 extended-release drug.
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<sup>®</sup> tablets/Glucophage<sup>®</sup> XR extended-release tablets [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; May 2018.
2. Glumetza<sup>®</sup> extended release tablets [prescribing information]. Bridgewater, NJ: Salix/Valeant; November 2018.
3. Fortamet<sup>®</sup> 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.