

## Commercial/Healthcare Exchange PA Criteria

Effective: January 22, 2016

**Prior Authorization:** Extended Release Metformin (Osmotic & Gastric Retention)

**Products Affected:** metformin extended release (osmotic) oral tablet, metformin extended release (gastric retention) oral tablet, Glumetza ER oral tablet, Fortamet ER oral tablet

**Medication Description:**

Metformin hydrochloride is an oral antihyperglycemic agent. It lowers both basal and postprandial glucose levels in type 2 diabetes patients through several mechanisms. Metformin decreases hepatic glucose production, decreases intestinal absorption and increases peripheral glucose uptake and utilization by improving insulin sensitivity.

**Covered Uses:** Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**Exclusion Criteria:**

1. **Hypersensitivity to metformin.**
2. Severe renal impairment (eGFR below 30 mL/min/1.73 m<sup>2</sup>)
3. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma

**Required Medical Information:**

1. Diagnosis
2. Previous therapies tried/failed
3. Hemoglobin A1c (HbA1c) [**documentation required**]

**Age Restrictions:** N/A

**Prescriber Restrictions:** N/A

**Coverage Duration:** 12 months

**Other Criteria:**

- A. Patient has a confirmed diagnosis of Type 2 Diabetes; **AND**
- B. Patient has had an adequate trial and therapeutic failure of metformin ER, (generic Glucophage XR ONLY) defined as a trial of at least 30 days in the past 6 months with either:
  - a. Failure to lower Hemoglobin A1c (HbA1c) [**documentation required**]; OR
  - b. Intolerance which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g., dose reduction) [**documentation required**].

**References:**

1. Product Information: GLUMETZA(R) oral extended-release tablets, metformin HCl oral extended-release tablets. Santarus, Inc. (per Manufacturer), San Diego, CA, 2013.
2. Product Information: GLUCOPHAGE(R) XR oral extended-release tablets, metformin HCl oral extended-release tablets. Bristol-Myers Squibb Company (per manufacturer), Princeton, NJ, 2015.
3. Product Information: FORTAMET(R) oral extended-release tablets, metformin HCl oral extended-release tablets. Shionogi Pharma, Inc. (per manufacturer), Atlanta, GA, 2010.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/22/2016
2	Policy Update	<p>Revised Policy name from Glumetza/Fortamet to Extended Release Metformin (Osmotic &amp; Gastric Retention)</p> <p>Updated clinical criteria to reflect FDA label – metformin allergy</p>	<p>Prior Authorization</p> <p>Products Affected</p> <p>Exclusion Criteria</p> <p>Other Criteria</p>	1/24/2020

