

## Metformin and Metformin Containing Products

**Policy # 00255**

Original Effective Date: 04/24/2013

Current Effective Date: 12/09/2024

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member’s contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

#### **For Patients With “Step Therapy” (generic before brand) ONLY:**

Based on review of available data, the Company may consider brand name metformin products (including, but not limited to Glumetza<sup>®</sup>, Fortamet<sup>®</sup>, Riomet<sup>®</sup>, and branded Metformin 625 mg)<sup>‡</sup> to be **eligible for coverage\*\*** when one of the below patient selection criteria is met:

#### **Patient Selection Criteria**

Coverage eligibility will be considered for brand name metformin products when one of the following criteria is met:

- Requested drug is a brand name metformin product: patient has tried and failed generic metformin immediate release OR generic metformin extended-release therapy (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin); OR
- Requested drug is Riomet: patient has tried and failed generic immediate release metformin oral solution; OR
- There is clinical evidence or patient history that suggests the generically available products required in this policy will be ineffective or cause an adverse reaction to the patient.

*(Note: All of the above specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

### When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name metformin products when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.\*\***

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## When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

### **For Patients With "Prior Authorization" ONLY:**

Based on review of the available data, the Company may consider Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), Riomet, and branded Metformin 625 mg to be **eligible for coverage\*\*** when the below patient selection criteria are met:

#### Patient Selection Criteria

Coverage eligibility will be considered for Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), Riomet, and branded Metformin 625 mg when the following criteria are met for the requested drug:

- For Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), and branded Metformin 625 mg requests:
  - Patient has tried and failed a 12 week trial of generic metformin extended-release therapy (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin), unless there is clinical evidence or patient history that suggests the use of generic metformin extended-release therapy (EXCEPT the generic osmotic release and generic gastric retention extended release versions of metformin) will be ineffective or cause an adverse reaction to the patient; AND
  - Medical records document intolerance to generic metformin extended-release therapy (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin) which is unresolved with attempts to minimize adverse events (e.g., taking with largest meal, dose reduction, proper dose up titration).

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

- For Riomet requests:
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic metformin oral solution unless there is clinical evidence or patient history that suggests the use of generic metformin oral solution will be ineffective or cause an adverse reaction to the member.

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*



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## When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), and branded Metformin 625 mg when the patient selection criteria are not met to be **not medically necessary**.\*\*

Based on review of available data, the Company considers the use of Riomet when there is no documentation that the patient has tried and failed (e.g. intolerance or inadequate response) generic metformin oral solution to be **not medically necessary**.\*\*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

### **For Patients With BOTH "Prior Authorization" AND "Step Therapy":**

Based on review of available data, the Company may consider brand name metformin products (including, but not limited to Glumetza, Fortamet, Riomet, and branded Metformin 625 mg) as well as generic osmotic release and generic gastric retention versions of extended release metformin to be **eligible for coverage**\*\* when the patient selection criteria are met:

#### Patient Selection Criteria

Coverage eligibility will be considered for the requested products when the drug's specific patient selection criteria are met:

- For Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), and branded Metformin 625 mg requests:
  - Member has tried and failed a 12 week trial of generic metformin extended-release therapy (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin), unless there is clinical evidence or patient history that suggests the use of generic metformin extended-release therapy (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin) will be ineffective or cause an adverse reaction to the patient; AND
  - Medical records document intolerance to generic metformin extended-release therapy (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin) which is unresolved with attempts to minimize adverse events (e.g., taking with largest meal, dose reduction, proper dose up titration).

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary\*\* if not met).*



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- For Riomet requests:
  - Patient has tried and failed (e.g., intolerance or inadequate response) generic metformin oral solution unless there is clinical evidence or patient history that suggests the use of generic metformin oral solution will be ineffective or cause an adverse reaction to the member.  
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary\*\* if not met).*

### **When Services Are Considered Not Medically Necessary**

Based on review of available data, the Company considers the use of Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), and branded Metformin 625 mg when the patient selection criteria for those particular drugs are not met to be **not medically necessary.\*\***

Based on review of available data, the Company considers the use of Riomet when there is no documentation that the patient has tried and failed (e.g. intolerance or inadequate response) generic metformin oral solution to be **not medically necessary.\*\***

### **Background/Overview**

Metformin is an oral biguanide antihyperglycemic agent that is indicated for patients with Type 2 Diabetes Mellitus. Over the past few years, there have been extreme price hikes of the gastric retention and osmotic release extended release metformin products (both in the brand and generic category). The extended release metformin products can be tricky to differentiate, however the pricier versions are the gastric retention and osmotic release versions of metformin. Those particular products are the generics for Glumetza and Fortamet, respectively. The cheaper of the extended release metformin versions is the generic to Glucophage XR. All extended release products have the same clinical efficacy. Metformin is also available as brand Riomet 500 mg/5 mL immediate release solution and generic 500 mg/5 mL immediate release solution.

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the generically available drugs (EXCLUDING the generic osmotic release and generic gastric retention extended release versions of metformin) will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name metformin product over the available generic metformin products for step therapy. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs. In regards to prior authorization



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requests for Fortamet (and its generic osmotic release version), Glumetza (and its gastric retention version), and branded Metformin 625 mg, there is no advantage of using these products over the other extended release generic metformin products. There is also no advantage of using Riomet over the generic metformin oral solution.

## **References**

1. Glucophage tablets/Glucophage XR extended-release tablets [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2013/March 2014.
2. Glumetza extended release tablets [package insert]. Menlo Park, CA: Depomed, Inc.; April 2011.
3. Fortamet extended release tablets [package insert]. Ft. Lauderdale, FL: Watson Pharmaceuticals, Inc.; July 2008.
4. Riomet oral solution [package insert]. Jacksonville, FL: Ranbaxy Pharmaceuticals; September 2013.
5. Metformin Hydrochloride [package insert]. LifSa Drugs, LLC. New Brunswick, New Jersey. Updated April 2022.

## **Policy History**

Original Effective Date: 04/24/2013

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|            |   |
|------------|---|
| 04/04/2013 | Medical Policy Committee review   |
| 04/24/2013 | Medical Policy Implementation Committee approval. New policy.   |
| 08/07/2014 | Medical Policy Committee review   |
| 08/20/2014 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 10/08/2015 | Medical Policy Committee review   |
| 10/21/2015 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 10/06/2016 | Medical Policy Committee review   |
| 10/19/2016 | Medical Policy Implementation Committee approval. Changed to exclude the gastric release and osmotic release products from the step 1 option. Added prior authorization to Fortamet (its generic), Glumetza (its generic), and Glucophage XR. Split into step, PA, and step/PA. (Branded) removed from title. |
| 10/05/2017 | Medical Policy Committee review   |
| 10/18/2017 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 10/04/2018 | Medical Policy Committee review   |
| 10/17/2018 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |
| 10/03/2019 | Medical Policy Committee review   |
| 10/09/2019 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.   |



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06/04/2020 Medical Policy Committee review  
06/10/2020 Medical Policy Implementation Committee approval. Added a new drug, Riomet ER, to the policy.  
06/03/2021 Medical Policy Committee review  
06/09/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
06/02/2022 Medical Policy Committee review  
06/08/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.  
11/03/2022 Medical Policy Committee review  
11/09/2022 Medical Policy Implementation Committee approval. Added branded Metformin 625 mg to the policy.  
11/02/2023 Medical Policy Committee review  
11/08/2023 Medical Policy Implementation Committee approval. Removed Glucophage and Glucophage XR from policy because these products have been discontinued.  
11/07/2024 Medical Policy Committee review  
11/13/2024 Medical Policy Implementation Committee approval. Removed Riomet ER from the policy due to its discontinuation.

Next Scheduled Review Date: 11/2025

\*\*Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.



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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

