



Louisiana

Metformin and Metformin Containing Products

Policy # 00255

Original Effective Date: 04/24/2013

Current Effective Date: 07/13/2020

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 Glucophage XR[®], Glumetza[®], Fortamet[®], Riomet[®], Riomet ER, and Glucophage[®])[‡] 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/ER: 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 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

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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**.**

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), brand Glucophage XR, and Riomet ER 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), brand Glucophage XR, and Riomet ER when the following criteria are met for the requested drug:

- For Fortamet (and its osmotic release generic), Glumetza (and its gastric retention generic), and brand Glucophage XR 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).

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

- For Riomet ER requests:
 - Patient has a diagnosis of type 2 diabetes mellitus; AND
 - Patient is NOT able to swallow tablets and/or capsules (e.g., has dysphagia or a gastrostomy tube [G-tube]); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient is NOT taking any other medications in tablet and/or capsule form; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - 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 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 brand Glucophage XR 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 ER when there is no documentation that the patient is NOT able to swallow tablets and/or capsules (e.g., has dysphagia or a gastrostomy tube [G-tube]) OR when there is no documentation that the patient is NOT taking any other medications in tablet and/or capsule form to be **not medically necessary.****

Based on review of available data, the Company considers the use of Riomet ER 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.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Riomet ER for a diagnosis other than type 2 diabetes mellitus to be **investigational**.*

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 Glucophage XR, Glumetza, Fortamet, Riomet, Riomet ER, and Glucophage) 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 brand Glucophage XR 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

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

- For Riomet ER requests:
 - Patient has a diagnosis of type 2 diabetes mellitus; AND
 - Patient is NOT able to swallow tablets and/or capsules (e.g., has dysphagia or a gastrostomy tube [G-tube]); AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - Patient is NOT taking any other medications in tablet and/or capsule form; AND
*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
 - 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 criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- For ALL other brand name metformin requests:
 - 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 (immediate release): 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 criteria are additional Company requirements 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 brand Glucophage XR 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 ER when there is no documentation that the patient is NOT able to swallow tablets and/or capsules (e.g., has dysphagia or a gastrostomy tube [G-tube]) OR when there is no documentation that the patient is NOT taking any other medications in tablet and/or capsule form to be **not medically necessary**.**

Based on review of available data, the Company considers the use of Riomet ER 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**.**

Based on review of available data, the Company considers the use of all other branded metformin products (e.g. Glucophage, Riomet [immediate release]) when the patient selection criteria are not met to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Riomet ER for a diagnosis other than type 2 diabetes mellitus to be **investigational**.*

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

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release metformin versions is the generic to Glucophage XR. All extended release products have the same clinical efficacy. There are also both immediate release and extended release versions of metformin oral solution available. The immediate release oral metformin is available in generic form.

Rationale/Source

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 requests for Fortamet (and its generic osmotic release version), Glumetza (and its gastric retention version), and brand Glucophage XR, there is no advantage of using these products over the other extended release generic metformin products. There is also no advantage of using Riomet ER 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. Riomet ER oral solution [package insert]. Sun Pharmaceuticals. Cranbury, New Jersey. Updated November 2019.

Policy History

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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.

06/04/2020 Medical Policy Committee review

06/10/2020 Medical Policy Implementation Committee approval. Added a new drug, Riomet ER, to the policy.

Next Scheduled Review Date: 06/2021

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****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.

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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.

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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.

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