



Louisiana

Metformin and Metformin Containing Products

Policy # 00255

Original Effective Date: 04/24/2013

Current Effective Date: 10/17/2018

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[®], 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: patient is unable to swallow or has difficulty swallowing; 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.

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**.**

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), and brand Glucophage XR 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), and brand Glucophage XR when the following criteria are met:

- 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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Metformin and Metformin Containing Products

Policy # 00255

Original Effective Date: 04/24/2013

Current Effective Date: 10/17/2018

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)

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**.**

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, 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:
 - o 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
 - o 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)
- For ALL other brand name metformin requests:
 - o 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
 - o Requested drug is Riomet: patient is unable to swallow or has difficulty swallowing; or
 - o 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.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Metformin and Metformin Containing Products

Policy # 00255

Original Effective Date: 04/24/2013

Current Effective Date: 10/17/2018

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of brand name metformin products (including, but not limited to Glucophage XR, Glumetza, Fortamet, Riomet, and Glucophage) as well as generic osmotic release and generic gastric retention versions of extended release metformin when patient selection criteria are not met to be **not medically necessary**.**

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.

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. This policy also takes into account whether or not the patient is unable to swallow or has difficulty swallowing. 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.

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.

Policy History

Original Effective Date: 04/24/2013

Current Effective Date: 10/17/2018

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

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.



Louisiana

Metformin and Metformin Containing Products

Policy # 00255

Original Effective Date: 04/24/2013

Current Effective Date: 10/17/2018

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.

Next Scheduled Review Date: 10/2019

**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.

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.

©2018 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.