Biguanides
Fortamet, Glumetza, Riomet and Riomet ER solution (metformin)
Effective 11/01/2022

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Metformin is an antihyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes mellitus, lowering both basal and postprandial plasma glucose. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and day-long plasma insulin response may decrease.

No PA	PA required
Metformin immediate release	Fortamet® (metformin extended release osmotic tablet) *
Metformin extended release, XR tablet	Glumetza® (metformin extended release gastric release) *§
Riomet® # (metformin immediate release solution) < 13 years old	Riomet® (metformin immediate release solution) ≥ 13 years old *
	Riomet ER® (metformin solution extended release suspension)

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*A-rated generic available. Both brand and A-rated generic require PA.
§ Brand Preferred over generic equivalents. A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members new to the plan who are currently receiving treatment with requested medication, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted if the member meets ALL following criteria and documentation has been submitted:

Biguanides: extended-release formulations

Fortamet (metformin extended-release, osmotic tablet)*
Glumetza (metformin extended-release, gastric tablet)*§

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of Type 2 Diabetes Mellitus
2. Medical records documenting an inadequate response or adverse reaction, at the requested dose, to the metformin extended-release, XR tablet formulation available without prior authorization within the last 90 days
3. For requests for metformin extended-release, gastric tablet clinical rationale for the use of the requested product instead of other available metformin formulations.
4. If request is for BRAND NAME Fortamet® the member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to generic metformin extended release (as per the Brand Name and Non-Preferred Generic Drugs Guideline)

*A-rated generic available. Both brand and A-rated generic require PA.
§ Brand Preferred over generic equivalents. In general, A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Biguanides: solution formulations

Riomet® (metformin immediate-release solution) ≥ 13 years old *
Riomet ER® (metformin extended-release suspension)

Prescriber provides documentation of **ALL** of the following:

1. Member has a diagnosis of Type 2 Diabetes Mellitus
2. **ONE** of the following:
    a. Medical necessity for a liquid formulation (inability to swallow oral medications)
    b. Medical records documenting an inadequate response despite 90 days of therapy with the metformin tablet formulation, or an allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e. nausea, diarrhea)
3. If the request is for Riomet ER®, medical records documenting an inadequate response despite 90 days of therapy with the immediate release metformin solution formulation
4. If the request is for BRAND NAME Riomet®, the member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to generic metformin solution (as per the Brand Name and Non-Preferred Generic Drugs Guideline)

*A-rated generic available. Both brand and A-rated generic require PA.

Continuation of Therapy

Reauthorization requires physician attestation of continuation of therapy and a positive response to therapy.

Limitations
Initial approvals and reauthorizations will be granted for 12 months

Appendix
Appendix A: § Brand preferred over generic equivalent
In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are Brand Preferred Over Generic.

- metformin extended-release, gastric tablet

Appendix B: Off-Label Indications
Gestational diabetes:
Prescriber provides documentation of the following:

- Diagnosis of gestational diabetes AND documents inadequate response, adverse reaction, or contraindication to insulin **AND** all other criteria for the requested formulation are met.

Polycystic ovarian syndrome:
Prescriber provides documentation of the following:

- Member meets ONE of the following:
    - Diagnosis of oligomenorrhea related to PCOS AND inadequate response, adverse reaction, or contraindication to combined oral contraceptives **AND** all other criteria for the requested formulation are met.
    - If the provider documents prevention of diabetes related to PCOS **AND** all other criteria for the requested formulation are met.

Prediabetes:
Prescriber provides documentation of the following:

- Diagnosis of prediabetes, **AND** all other criteria for the requested formulation are met.

References

1. Fortamet (metformin) [prescribing information]. Florham Park, NJ: Shionogi; March 2021.
2. Glumetza (metformin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; October 2019.
3. Glumetza (metformin) [product monograph]. Montreal, Quebec, Canada: Valeant Canada; June 2012.
4. Riomet ER (metformin) suspension [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals; September 2019.
5. Riomet (metformin) [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals; December 2018.

Review History
07/01/2017 – Effective
04/24/2018 – Reviewed
04/17/2019 – Reviewed in P&T Meeting
05/20/2020 – Added Riomet ER solution formulation. Effective 7/1/2020
11/05/2020 – Updated; Changed criteria name to Biguanide and combination products; Updated criteria to be in compliance with MassHealth partial unified formulary requirements for implementation on 1/1/2021
11/17/2021 -Updated and Reviewed for Nov P&T; matched MH UPPL; appendix was added for off-label metformin requests for the following indications: gestational diabetes, PCOS, and prediabetes. Multiple

metformin formulation listings updated to reflect obsolete brand Glucophage XR, as well as verbiage updates to Fortamet/Glumetza criteria. Lastly, Glumetza is now brand preferred. Effective 1/1/2022
11/16/2022 – Reviewed and updated for Nov P&T; matched MH UPPL. Changes reflected in brand preferred over generic verbiage. Formatting changes. Effective 11/01/2022

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.