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

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<th>☒ MassHealth (PUF)</th>
<th>☐ Commercial/Exchange</th>
<th>Program Type</th>
<th>☒ Prior Authorization</th>
<th>☐ Quantity Limit</th>
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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

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
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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 *

* 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
Fortamet (metformin extended-release, osmotic tablet)* and Glumetza (metformin extended-release, gastric tablet)*§
Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Fortamet or Glumetza, 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:

1. The 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 this 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 Over Generic Criteria)

§ Brand Preferred over generic equivalents. In general, A trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

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

Authorization may be reviewed on a case by case basis for members new to AllWays Health Partners who are currently receiving treatment with Riomet or Riomet ER solution 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:

1. Member has a diagnosis of type 2 Diabetes Mellitus
2. Member meets 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 BRAND NAME Riomet ER®, 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 Over Generic Criteria)

Continuation of Therapy
Reauthorization requires physician attestation of continuation of 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 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
2. Glumetza (metformin) [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; October 2019.
3. Glumetza (metformin) [product monograph]. Montreal, Quebec, Canada: Valeant Canada; June 2012.
5. Riomet (metformin) [prescribing information]. Cranbury, NJ: Sun Pharmaceuticals; November 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

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