

## **Clinical Policy: Metformin ER (Fortamet, Glumetza)**

Reference Number: CP.PMN.72

Effective Date: 12.01.15

Last Review Date: 02.20

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Metformin extended-release [ER] (Fortamet<sup>®</sup>, Glumetza<sup>®</sup>) is an oral biguanide antidiabetic agent.

### **FDA Approved Indication(s)**

Fortamet and Glumetza are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM).

Limitation(s) of use: Fortamet and Glumetza should not be used in patients with type 1 DM or for the treatment of diabetic ketoacidosis, as they would not be effective in these settings.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Fortamet and Glumetza are **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Type 2 Diabetes Mellitus (must meet all):**

1. Diagnosis of type 2 DM;
2. Member has experienced clinically significant adverse effects to immediate-release metformin or has contraindication(s) to its excipients;
3. Member has experienced clinically significant adverse effects to extended-release metformin (Glucophage<sup>®</sup> XR) or has contraindication(s) to its excipients;
4. If request is for brand Fortamet/Glumetza, member has experienced clinically significant adverse effects to generic Fortamet/Glumetza or has contraindication(s) to its excipients;
5. Dose does not exceed 2,000 mg (2 tablets) per day.

##### **Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Type 2 Diabetes Mellitus (must meet all):**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 2,000 mg (2 tablets) per day.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – Length of Benefit

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;

**B.** Type 1 DM;

**C.** Diabetic ketoacidosis.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

DM: diabetes mellitus

ER: extended-release

FDA: Food and Drug Administration

GPI: generic product identifier

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name                        | Dosing Regimen  | Dose Limit/<br>Maximum Dose |
|----------------------------------|---|-----------------------------|
| metformin<br>(Glucophage®)       | 500 mg PO BID or 850 mg PO QD, given with meals. Dosage increases should be made in increments of 500 mg weekly or 850 mg every 2 weeks, up to 2000 mg/day PO, given in divided doses | 2,550 mg/day                |
| metformin ER<br>(Glucophage® XR) | 500 mg PO QD with the evening meal; may increase daily dose by 500 mg/week as needed  | 2,000 mg/day                |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): severe renal impairment (eGFR < 30 mL/min/1.73 m<sup>2</sup>); known hypersensitivity to metformin; acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
- Boxed warning(s): lactic acidosis

*Appendix D: General Information*

- Generic Glucophage XR (GPI 27250050007520 or 27250050007530), generic Fortamet (GPI 27250050007560 or 27250050007570), and generic Glumetza (GPI 27250050007580 or 27250050007590) are identified with different GPI 14.
- Glucophage XR uses dual hydrophilic polymer matrix systems, Fortamet uses single-composition osmotic technology, and Glumetza uses gastric retention technology.

**V. Dosage and Administration**

| Indication                 | Dosing Regimen  | Maximum Dose |
|----------------------------|---|--------------|
| Metformin ER<br>(Fortamet) | 500 mg PO QD; may titrate in increments of no more than 500 mg/week<br><br>If glycemic control is not achieved with 2,000 mg PO QD, consider a trial of 1,000 mg PO BID | 2,000 mg/day |
| Metformin ER<br>(Glumetza) | 500 mg PO QD with the evening meal; may increase the dose in 500 mg increments every 1-2 weeks  | 2,000 mg/day |

**VI. Product Availability**

| Drug Name               | Product Availability                       |
|-------------------------|--|
| Metformin ER (Fortamet) | Extended-release tablets: 500 mg, 1,000 mg |
| Metformin ER (Glumetza) | Extended-release tablets: 500 mg, 1,000 mg |

**VII. References**

1. Glumetza Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; April 2017. Available at: <https://shared.salix.com/shared/pi/glumetza-pi.pdf>. Accessed September 24, 2019.

2. Fortamet Prescribing Information. Fort Lauderdale, FL: Actavis Laboratories TL, Inc.; November 2018. Available at: <https://www.shionogi.com/wp-content/themes/pdfs/fortamet.pdf>. Accessed September 24, 2019.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: <http://www.clinicalpharmacology-ip.com/>. Accessed September 24, 2019.

| Reviews, Revisions, and Approvals  | Date     | P&T Approval Date |
|--|----------|-------------------|
| New guideline created  | 11.15    | 11.15             |
| Converted to new integrated template.<br>Added requirement for PDL immediate release metformin.<br>Added FDA max recommended dose and health plan approved QL statement.<br>Updated continuation criteria.<br>Updated references to reflect current literature search.   | 08.16    | 11.16             |
| Converted to new template.<br>Initial: Added requirement related to contraindications per PI (severe renal impairment) in accordance with safety approach.<br>Continued approval: Added requirement that member is responding positively to therapy. Updated references.   | 08.14.17 | 11.17             |
| 2Q 2018 annual review: no significant changes from previously approved corporate policy, policies combined for Centene Medicaid and Commercial lines of business; added that members requesting brand Glumetza must have contraindication or intolerance to generic Glumetza; Medicaid: removed age limit and contraindication since other formulations of metformin are available freely on PDL without such restrictions; increased initial approval duration from 3 months to 12 months; Commercial: modified “failure” to allow only contraindication or clinically significant adverse effects; added requirement for positive response to therapy for continued therapy requests; references reviewed and updated. | 02.27.18 | 05.18             |
| Per SDC: added Fortamet to policy, removed redirection to generic Fortamet.  | 06.14.18 |                   |
| 1Q 2019 annual review: no significant changes; references reviewed and updated.  | 09.27.18 | 02.19             |
| 1Q 2020 annual review: added HIM line of business; no significant changes; modified max dose to 2,000 mg (2 tablets) per day for both products per prescribing information; references reviewed and updated.   | 09.24.19 | 02.20             |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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