Clinical Policy Title:	metformin ER
Policy Number:	RxA.122
Drug(s) Applied:	Fortamet®, Glumetza®
Original Policy Date:	03/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Metformin extended release [ER] (Fortamet®, Glumetza®) is an oral biguanide antidiabetic agent. These products 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: These products 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Metformin ER (Fortamet®)	Type 2 Diabetes mellitus (DM)	500 mg PO once daily with the evening meal; may increase the dose in 500 mg increments weekly	2,000 mg/day
Metformin ER (Glumetza®)	Type 2 Diabetes mellitus (DM)		2,000 mg/day

Dosage Forms

- Metformin ER (Fortamet®) - Extended-release tablets: 500 mg, 1,000 mg
- Metformin ER (Glumetza®) - Extended-release tablets: 500 mg, 1,000 mg

Clinical Policy

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

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® XR) or has contraindication(s) to its excipients;
4. If request is for brand Fortamet®/Glumetza®, member has experienced clinically significant adverse effects to the corresponding generic product or has contraindication(s) to its excipients;

5. Dose does not exceed 2,000 mg (2 tablets) per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
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
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
DM: diabetes mellitus
ER: extended-release
FDA: Food and Drug Administration
GPI: generic product identifier

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Maximum Dose
metformin (Glucophage®)	500 mg PO twice daily or 850 mg PO once daily, 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 (Glucophage® XR)	500 mg PO once daily 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^2); 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.

References

1. Glumetza® Prescribing Information. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; August 2019. Available at: https://shared.salix.com/shared/pi/glumetza-pi.pdf. Accessed January 20, 2021.
2. Fortamet® Prescribing Information. Fort Lauderdale, FL: Actavis Laboratories TL, Inc.; November 2018. Accessed January 20, 2021.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/. Accessed January 20, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy was established.	02/2020	03/07/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance". 2. References were reviewed and updated.	05/2020	05/21/2020
Policy was reviewed: 1. Policy title table was updated. 2. Dosing information section for indication and regimen were updated for clarity. 3. Approval duration was updated to include Medicaid with same approval duration as commerical. 4. Appendix B standard text was updated. 5. Initial approval criteria I.A.2 and 3 updated to change wording from "inactive ingredients" to "excipients". 6. Initial approval criteria I.A.5 and continued therapy criteria II.A.3 for maximum dosing updated to be more concise. 7. Continued therapy criteria	01/20/2021	03/09/2021

II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 8. Added continued therapy criteria II.A.2 to ensure response is therapy is considered. 9. References were updated.		