UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Fortamet, Glumetza

Program	Prior Authorization
Medications	Fortamet (metformin extended-release), Glumetza (metformin extended-release)
Markets in Scope	California, Florida- CHIP, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Ohio, Pennsylvania Medicaid, Pennsylvania- CHIP, Rhode Island
Issue Date	3/2016
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

1. Background:

According to the American Diabetes Association (ADA) metformin is the preferred initial pharmacological agent for type 2 diabetes if not contraindicated. Fortamet, Glucophage XR and Glumetza only differ in their extended-release formulation technology and excipient content. Treatment guidelines do not specify which metformin formulation should be selected for diabetes management.

This program requires a member to try metformin immediate-release (generic Glucophage) and metformin extended-release (generic Glucophage XR) prior to receiving coverage for metformin extended-release (generic Fortamet) and also requires an additional trial of metformin extended-release (generic Fortamet) prior to receiving coverage for metformin extended-release (generic Glumetza).

2. Coverage Criteria:

A. **Metformin extended-release (generic Fortamet)** will be approved based on **all** of the following criteria:

1. History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR).

-AND-

2. **One** of the following:

   a. Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

-OR-

b. Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

-AND-

3. History of greater than or equal to 12 week trial of metformin immediate-release

-AND-

4. **One** of the following:

a. Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release as evidenced by the hemoglobin A1c level being above the patient's goal

-OR-

b. Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

B. **Metformin extended-release (generic Glumetza)** will be approved based on **all** of the following criteria:

1. History of greater than or equal to 12 week trial of metformin extended-release (generic Glucophage XR).

-AND-

2. **One** of the following:

a. Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Glucophage XR) as evidenced by the hemoglobin A1c level being above the patient's goal

-OR-

b. Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Glucophage XR) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

-AND-

3. History of greater than or equal to 12 week trial of metformin extended-release (generic Fortamet).

-AND-

4. **One** of the following:

   a. Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin extended-release (generic Fortamet) as evidenced by the hemoglobin A1c level being above the patient's goal

   -OR-

   b. Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin extended-release (generic Fortamet) which is unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

-AND-

5. History of greater than or equal to 12 week trial of metformin immediate-release

-AND-

6. **One** of the following:

   a. Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release as evidenced by the hemoglobin A1c level being above the patient's goal

   -OR-

   b. Submission of medical records (e.g. chart notes, laboratory values) documenting an intolerance to metformin immediate-release which is

unable to be resolved with attempts to minimize the adverse effects where appropriate (e.g. dose reduction).

-AND-

7. Submission of article(s) published in the peer-reviewed medical literature showing that the requested drug is likely to be more efficacious to this patient than metformin extended-release (generic Glucophage XR AND generic Fortamet)

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2019. Diabetes Care 2019: Jan; 42 (Supplement 1)
2. Glumetza [package insert]. Bridgewater, NJ: Bausch Health Companies Inc; August 2019.
3. Glucophage/Glucophage XR [package insert]. Princeton, NJ: Bristol- Myers Squibb; May 2018.
4. Fortamet [package insert]. Ft. Lauderdale, FL: Actavis Laboratories FL, Inc; November 2018.

Program	Prior Authorization - Glumetza, Glucophage XR, Fortamet
Change Control	
Date	Change
3/2016	New program.
4/2017	Annual review. References updated.
6/2017	Updated Hemoglobin A1c level requirements to be specific to the diagnosis of diabetes.
8/2018	Annual review. Updated references.
5/2019	Moved generic Glumetza to non-preferred section. Updated references.
6/2019	Removed language regarding requests for the brand products.
9/2019	Updated references.
10/2020	Annual review, updated references. Added Additional Clinical Rules.