UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Fortamet, Glucophage XR, Glumetza

Program	Prior Authorization
Medications	Fortamet (metformin extended-release, brand and generic), Glucophage XR (metformin extended-release, brand only) and Glumetza (metformin extended-release, brand and generic)
Issue Date	3/2016
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

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 Glucophage XR (brand only) and metformin extended-release (generic Fortamet) and also requires an additional trial of metformin extended-release (generic Fortamet) prior to receiving coverage for Glumetza or Fortamet (brand only).

2. **Coverage Criteria:**

A. **Glucophage XR (brand only)** or **metformin extended-release (generic Fortamet and 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 following:

      (1) For patients with diabetes diagnosis, the hemoglobin A1c level is above patients 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 following:

(1) For patients with diabetes diagnosis, the hemoglobin A1c level is above patients 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. **Glumetza (brand only)** or **Fortamet (brand only)** 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 following:

(1) For patients with diabetes diagnosis, the hemoglobin A1c level is above patients 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 following:

(1) For patients with diabetes diagnosis, the hemoglobin A1c level is above patients 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 following:

(1) For patients with diabetes diagnosis, the hemoglobin A1c level is above patients 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)

Authorization will be issued for 12 months.

3. References:

1. Glumetza Prescribing Information. Valeant Pharmaceutical North America LLC, Bridgewater, NJ. April 2016.
2. Glucophage Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. February 2017.
3. Glucophage XR Prescribing Information. Bristol-Myers Squibb. Princeton, NJ. February 2017.
4. Fortamet Prescribing Information. Watson Laboratories. Ft. Lauderdale, FL. April 2012.
5. American Diabetes Association; Standard of Medical Care in Diabetes- 2016. Diabetes Care 2016: Jan; 39 (Supplment 1): S39-S46.

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.