UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2022 P 2027-14
Program	Prior Authorization/Medical Necessity
Medication/Therapeutic Class	Fortamet (metformin extended-release, brand and generic)*, and Glumetza (metformin extended-release, brand and generic)*
P&T Approval Date	5/2014, 11/2014, 7/2015, 10/2015, 3/2016, 4/2017, 6/2017, 8/2018, 9/2019, 10/2020, 11/2021, 2/2022
Effective Date	5/1/2022; Oxford only: 5/1/2022

1. **Background:**
   According to the American Diabetes Association (ADA) metformin is the preferred initial pharmacological agent for type 2 diabetes if not contraindicated[1]. 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[1].

   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 Glumetza * or Fortamet (brand only)*.

2. **Coverage Criteria[a,b]:**

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[c] 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[c] 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*** or **Fortamet (brand only)*** will be approved based on **all** of the following criteria:

1. 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-

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

-AND-

3. **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-

4. History of greater than or equal to 12 week trial[c] of metformin extended-release (generic Fortamet).

-AND-

5. **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-

6. History of greater than or equal to 12 week trial[c] of metformin immediate- release

-AND-

7. **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).

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

[b] In Florida, Maine, and Tennessee only, diabetes medications may be approved based on both of the following: 1) Provider attests use of this product is medically necessary; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

[c] For Connecticut business, only a 60-day trial will be required. For Kentucky business, only a 30-day trial will be required.

3. Additional Clinical Programs:

*Typically excluded from coverage.

- 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.

4. References:

1. American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes—2021. Diabetes Care 2021: Jan; 44 (Supplement 1):S111-124.
2. Glumetza [package insert]. Bridgewater, NJ: Bausch Health Companies Inc; August 2019.
3. Fortamet [package insert]. Ft. Lauderdale, FL: Actavis Laboratories FL, Inc; March 2021.

Program	Prior Authorization/Medical Necessity - Glumetza, Glucophage XR, Fortamet
Change Control	
Date	Change
5/2014	New program.
11/2014	Updated to clarify trial period for Connecticut and Kentucky to comply with state regulations.
7/2015	Updated criteria to clarify submission of medical records is required.
10/2015	Updated background information and references. Updated criteria for Glumetza (brand) and Fortamet (brand) to also require the trial of metformin extended-release (generic Fortamet). Added criteria for submission of literature to support request.
3/2016	Updated criteria to include newly launched generic Glumetza.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Administrative change. Added California coverage information.
4/2017	Annual review. References updated. State mandate reference language updated.
6/2017	Updated Hemoglobin A1c level requirements to be specific to the diagnosis of diabetes.
8/2018	Annual review. References updated.
9/2019	Annual review. References updated, added automation language.
10/2020	Annual review. References updated.
11/2021	Removed Glucophage XR from criteria as brand is no longer available.
2/2022	Added Florida, Maine, and Tennessee mandate language. Updated state mandate language for CT and KY.