UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2027-17
Program	Prior Authorization/Medical Necessity
Medication/Therapeutic Class	Glumetza® (metformin extended-release modified release, brand and generic)* and metformin osmotic extended-release (generic Fortamet®)*
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, 2/2023, 2/2024, 4/2025
Effective Date	7/1/2025

1. Background:

According to the American Diabetes Association (ADA) metformin is the preferred initial pharmacological agent for type 2 diabetes if not contraindicated. Metformin osmotic extended-release (generic Fortamet), metformin extended-release (generic Glucophage XR) and Glumetza (metformin extended-release modified release) 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 osmotic extended-release (generic Fortamet)* and also requires an additional trial of metformin osmotic extended-release (generic Fortamet)* prior to receiving coverage for Glumetza*.

2. Coverage Criteria[a,b]:

A. Authorization

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

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

   -AND-

   b. **One** of the following:

      (1) 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:

         i. For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients' goal

-OR-

(2) 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-

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

-AND-

d. **One** of the following:

(1) Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release as evidenced by the following:

i. For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients' goal

-OR-

(2) 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).

2. **Glumetza*** will be approved based on **all** of the following criteria:

a. 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-

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

-AND-

c. **One** of the following:

(1) 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:

i. For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

-OR-

(2) 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-

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

-AND-

e. **One** of the following:

(1) Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin osmotic extended-release (generic Fortamet) as evidenced by the following:

i. For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

-OR-

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

-AND-

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

-AND-

g. **One** of the following:

(1) Submission of medical records (e.g. chart notes, laboratory values) documenting an inadequate response to metformin immediate-release as evidenced by the following:

i. For patients with diabetes diagnosis, the Hemoglobin A1c level is above patients goal

-OR-

(2) 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, medications prescribed for diabetes may be approved based on both of the following: 1) Provider attests use of this product is medically necessary for the treatment of diabetes; 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, Kentucky and Mississippi business, only a 30-day trial will be required.

*Typically excluded from coverage.

3. Additional Clinical Programs:

- 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 Glycemia Treatment: Standard of Medical Care in Diabetes - 2025. Diabetes Care 2025;48 (Supplement 1).
2. Glumetza [package insert]. Bridgewater, NJ: Bausch Health Companies Inc; March 2024.
3. Metformin Hydrochloride, extended release [package insert]. Fairfield, NJ: Leading Pharma, LLC; October 2024.

Program	Prior Authorization/Medical Necessity - Glumetza, Metformin extended-release (generic 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.
2/2023	Removed Fortamet brand from criteria as it is no longer available. Updated state mandate language for Mississippi. Updated references.
2/2024	Annual review. Updated references. Updated state mandate language and requirement for Connecticut.
4/2025	Annual review. Updated references.