

DRUG QUANTITY MANAGEMENT POLICY - PER RX

Policy: Diabetes – Metformin Extended-Release Drug Quantity Management

Policy – Per Rx

 metformin extended-release tablets (generic only [to discontinued Fortamet])

- metformin HCl extended-release tablets (generic only [to discontinued Glucophage XR])
- Glumetza® (metformin extended-release tablets Salix, generic)

REVIEW DATE: 07/02/2025

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The extended-release metformin products are indicated as adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**.¹⁻³

Dosing

Recommended dosing is similar for all of the extended-release metformin products.¹⁻³ The recommended starting dose is 500 mg once daily (QD) with the evening meal. The dose may be increased in increments of 500 mg weekly depending on glycemic control and tolerability, up to a maximum recommended

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dose of 2,000 mg QD. If this dose does not provide adequate glycemic control, consider a dose of 1,000 mg twice daily (BID). According to Glucophage XR (discontinued product) labeling, if higher doses are required, the patient should switch to metformin immediate-release at total daily doses of up to 2,550 mg.²

Availability

Generic metformin extended-release tablets (generic to discontinued Fortamet) are available as 500 mg and 1,000 mg tablets.¹ Generic metformin extended-release tablets (generic to discontinued Glucophage XR) are available as 500 mg and 750 mg tablets.² Glumetza (generic) is available as 500 mg and 1,000 mg tablets.³

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of extended-release metformin. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

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Product	Strength/Dosage Form	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx	
metformin extended-release tablets	500 mg tablets	30 tablets	90 tablets	
(generic to discontinued Fortamet)	1,000 mg tablets	60 tablets	180 tablets	
metformin HCl extended-release	500 mg tablets	120 tablets	360 tablets	
tablets, (generic to discontinued Glucophage XR)	750 mg tablets	60 tablets	180 tablets	
Glumetza [®]	500 mg tablets	120 tablets	360 tablets	
(metformin extended-release tablets, generic)	1,000 mg tablets	60 tablets	180 tablets	

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Metformin 500 mg extended-release tablets (generic to discontinued Fortamet)

- 1. If the patient is taking 1,500 mg per day, approve 90 tablets per dispensing at retail or 270 tablets per dispensing at home delivery.
 - <u>Note</u>: At a dose of 1,500 mg per day, 90 of the 500 mg tablets is a quantity sufficient to allow for a 30-day supply per dispensing at retail or 270 tablets is a quantity sufficient to allow for a 90-day supply per dispensing at home delivery.

³ Pages - Cigna National Formulary Coverage - Policy: Diabetes - Metformin Extended-Release Drug Quantity Management Policy - Per Rx

If the patient is taking a dose of 1,000 mg or 2,000 mg daily, they should be referred to the 1,000 mg tablet. If a higher dose of metformin is required, metformin immediate-release tablets should be used.

Metformin 1,000 mg extended-release tablets (generic to discontinued Fortamet)
No overrides recommended.

Metformin 500 mg and 750 mg extended-release tablets (generic to formerly available Glucophage XR)

No overrides recommended.

Metformin 500 mg and 1,000 mg extended-release tablets (Glumetza, generic) No overrides recommended.

REFERENCES

- 1. Metformin ER 500 and 750 mg tablet [prescribing information]. Hyderabad, India: Granules India Limited; November 2022.
- Glumetza® extended-release tablets [prescribing information]. Bridgewater, NJ: Salix/Valeant; March 2024.
- 3. Fortamet® extended-release tablets [prescribing information]. Florham Park, NJ: Shionogi; November 2018.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No criteria changes.	07/05/2023
Annual Revision	Brand Fortamet removed from policy (obsolete).	07/08/2024
Annual Revision	No criteria changes.	07/02/2025

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