

Washington State
Health Care Authority

Metformin ER
Medical Policy

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Presentation Objectives

- To provide **background information** relevant to metformin ER
- To present the proposed **medical policy** for **metformin ER**

Background Information

Metformin ER Products

Dosage Form	Name	Strength	Medicaid cost per tablet (before rebate)
Dual hydrophilic polymer-release	generic metformin ER	500 mg	\$0.06
		750 mg	\$0.15
	Glucophage XR®	500 mg	\$1.02
		750 mg	\$1.52
Osmotic-release	generic metformin ER	500 mg	\$4.83 – \$14.48
		1,000 mg	\$6.29
	Fortamet®	500 mg	\$30.43
		1,000 mg	\$30.43
Gastric retentive modified-release	generic metformin ER (available 2016)	500 mg	\$55.59
		1,000 mg	\$120.22
	Glumetza®	500 mg	\$51.90
		1,000 mg	\$112.22

Background: Metformin ER Utilization

Metformin ER Formulation	Unique Users
Dual hydrophilic polymer-release (generic of Glucophage XR®)	1276
Osmotic-release (generic of Fortamet®)	114
Gastric retentive modified-release (Glumetza®)	17

Background:

Diabetes Mellitus Guidelines

American Diabetes Association (in collaboration with the European Association for the Study of Diabetes [ADA/EASD]), in *Standards of Medical Care in Diabetes 2016*, recommends metformin as the preferred, initial pharmacotherapy for patients with type 2 diabetes mellitus who have failed lifestyle interventions (diet, physical activity, behavioral therapy) and who have no contraindications.

American College of Physicians (ACP) guidelines on pharmacotherapy for diabetes recommend immediate-release metformin therapy as the initial pharmacotherapy for patients with type 2 diabetes mellitus.

International Diabetes Foundation (IDF) guidelines recommend initiating metformin as first-line therapy and to titrate the dose according to patient response.

1.) American Diabetes Association. Approaches to glycemic treatment. Sec. 7. In *Standards of Medical Care in Diabetes – 2016*. Diabetes Care 2016;39(Suppl. 1):S52–S59.

2.) Devitt M. ACP Updates Guideline on Oral Pharmacologic Treatments for Type 2 Diabetes Mellitus. *Am Fam Physician*. 2013 Jan 15;87(2):140-144.

3.) International Diabetes Federation. *Global Guideline for Type 2 Diabetes*. Clinical Guidelines Task Force. 2012.

Background: Other Payor Policies

- **Group Health:** generic extended-release (Glucophage XR[®]) is Tier 1 whereas Fortamet[®], generic osmotic-release, and Glumetza[®] are Tier 3⁴.
- **Premera:** does not cover Glumetza[®]⁵.
- **Regence:** does not cover Glumetza[®], Fortamet[®] or their generics⁶.
- **Humana:** requires previous treatment or intolerance to metformin IR or metformin ER (generic Glucophage XR[®]) for at least 3 months⁷.
- **Uniform Medical Plan:** is not covering the generic formulations of Glumetza[®], brand is Tier 3 with 50% cost-share.

4.) Group Health Cooperative. Type 2 Diabetes Screening and Treatment Guideline. Jun 2015.

5.) Premera. Excessively High Cost Drug Products with Lower Cost Alternatives. Feb 2016.

6.) OmedaRx. Branded extended-release metformin. Oct 2015.

7.) Humana. Biguanide Agents. Pharmacy Coverage Policy. Feb 2016.

Medical Policy

Medical Policy:

Metformin ER

Metformin extended-release products with an osmotic-release or gastric retentive modified-release mechanism (e.g. Fortamet[®], Glumetza[®], and their generic equivalents) may be considered medically necessary for the treatment of FDA-approved indications when the patient meets criteria 1–3 of the **INCLUSION CRITERIA** and none of the **EXCLUSION CRITERIA**. Quantity and dispensing limits are listed on slide 11.

INCLUSION CRITERIA metformin extended-release products with a gastric retentive modified-release and osmotic-release (Fortamet[®], Glumetza[®], and their generic equivalents):

1. Patient has type 2 diabetes mellitus; **AND**
2. Patient has tried and is intolerant to at least five (5) different manufacturers of the generic metformin extended-release products that have a dual hydrophilic polymer-release mechanism (e.g. generic equivalent of Glucophage XR[®]); **AND**
3. Documentation of medical necessity for an extended-release metformin product with a gastric retentive modified-release or osmotic-release mechanism instead of a dual hydrophilic polymer-release mechanism.

Medicaid Medical Policy:

EXCLUSION CRITERIA

1. Patient has **ANY** of the following contraindications:
 - a. Renal disease or renal dysfunction (SCr ≥ 1.5 mg/dL in men; ≥ 1.4 mg/dL in women; CrCl < 30 mL/min/1.73m²) or abnormal creatinine clearance from any cause, including shock, acute myocardial infarction, or septicemia
 - b. acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
 - c. hypersensitivity to metformin

2. Metformin ER is being prescribed for any off-label indication other than the treatment of type 2 diabetes mellitus

Medical Policy:

Metformin ER Quantity Level Limits

PRIOR AUTHORIZATION APPROVAL DURATION AND LIMITS

Patients meeting the criteria above may receive osmotic-release metformin ER and gastric retentive modified-release metformin ER.

Table 1. Quantity Level Limits for metformin extended-release (ER) products

Name	Dosage Form	Strength	Quantity Level Limit
generic metformin ER [Fortamet®]	osmotic-release	500mg	30 tablets per 30 days
		1,000mg	60 tablets per 30 days
generic metformin ER [Glumetza®]	gastric retentive modified-release	500mg	30 tablets per 30 days
		1,000mg	60 tablets per 30 days

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Questions?

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Works Cited

- 1.) American Diabetes Association. Approaches to glycemic treatment. Sec. 7. In Standards of Medical Care in Diabetes – 2016. Diabetes Care 2016;39(Suppl. 1):S52–S59.
- 2.) Devitt M. ACP Updates Guideline on Oral Pharmacologic Treatments for Type 2 Diabetes Mellitus. Am Fam Physician. 2013 Jan 15;87(2):140-144.
- 3.) International Diabetes Federation. Global Guideline for Type 2 Diabetes. Clinical Guidelines Task Force. 2012.
- 4.) Group Health Cooperative. Type 2 Diabetes Screening and Treatment Guideline. Jun 2015.
- 5.) Premera. Excessively High Cost Drug Products with Lower Cost Alternatives. Feb 2016.
- 6.) OmedaRx. Branded extended-release metformin. Oct 2015.
- 7.) Humana. Biguanide Agents. Pharmacy Coverage Policy. Feb 2016.