Metformin ER Step Therapy with Quantity Limit Program Summary

This program applies to FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
05-01-2024	07-01-2018

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Glumetza® (metformin ER modified release)* Tablet	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	*- generic available	1
metformin HCL Tab ER Osmotic	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.		3

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Diabetes	The American Diabetes Association (ADA) state the following concerning metformin:(2) • First-line therapy depends on comorbidities, patient-centered treatment factors, and management needs and generally includes metformin and comprehensive lifestyle modifications. • Metformin should be continued upon initiation of insulin therapy (unless contraindicated or not tolerated) for ongoing glycemic and metabolic benefits.
Safety	Metformin products have the following black box warning: • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age greater than or equal to 65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment.

	• If lactic acidosis is suspected, discontinue metformin product and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. Metformin products carry the following contraindications: • Severe renal impairment: (eGFR below 30 mL/minute/1.73 m^2) • Known hypersensitivity to metformin • Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma

REFERENCES

Number	Reference
1	Glumetza prescribing information. Salix Pharmaceuticals. August 2019.
2	American Diabetes Association. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2022. Available at: https://diabetesjournals.org/care/issue/45/Supplement_1
3	Metformin ER Osmotic prescribing information. AiPing Pharmaceutical, Inc. February 2019.

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
	Metformin HCl Tab ER 24HR Osmotic 1000 MG	1000 MG	M ; N ; O ; Y	Y		
	Metformin HCl Tab ER 24HR Osmotic 500 MG	500 MG	M ; N ; O ; Y	Y		
Glumetza	Metformin HCl Tab ER 24HR Modified Release 1000 MG	1000 MG	M ; N ; O ; Y	O ; Y		
Glumetza	Metformin HCl Tab ER 24HR Modified Release 500 MG	500 MG	M ; N ; O ; Y	O ; Y		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
	Metformin HCl Tab ER 24HR 500 MG	500 MG	120	Tablets	30	DAYS			
	Metformin HCl Tab ER 24HR 750 MG	750 MG	60	Tablets	30	DAYS			
	Metformin HCl Tab ER 24HR Osmotic 1000 MG	1000 MG	60	Tablets	30	DAYS			
	Metformin HCl Tab ER 24HR Osmotic 500 MG	500 MG	90	Tablets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Glumetza	Metformin HCl Tab ER 24HR Modified Release 1000 MG	1000 MG	60	Tablets	30	DAYS			
Glumetza	Metformin HCl Tab ER 24HR Modified Release 500 MG	500 MG	90	Tablets	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Metformin HCl Tab ER 24HR Osmotic 1000 MG	1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Metformin HCl Tab ER 24HR Osmotic 500 MG	500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Glumetza	Metformin HCl Tab ER 24HR Modified Release 1000 MG	1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Glumetza	Metformin HCl Tab ER 24HR Modified Release 500 MG	500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Metformin HCl Tab ER 24HR 500 MG	500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Metformin HCl Tab ER 24HR 750 MG	750 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Metformin HCl Tab ER 24HR Osmotic 1000 MG	1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
	Metformin HCl Tab ER 24HR Osmotic 500 MG	500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Glumetza	Metformin HCl Tab ER 24HR Modified Release 1000 MG	1000 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx
Glumetza	Metformin HCl Tab ER 24HR Modified Release 500 MG	500 MG	FlexRx Closed ; FlexRx Open ; FocusRx ; GenRx Closed ; GenRx Open ; Health Insurance Marketplace/BasicRx ; KeyRx

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

TARGET AGENT(S)	PREREQUISITE AGENT(S)
Glumetza (metformin modified release)* **metformin osmotic ER** (generic Fortamet ER)	**metformin ER** (generic Glucophage XR)

*-generic available

Target Agent(s) will be approved when ONE of the following is met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   A. A statement by the prescriber that the patient is currently taking the requested agent **AND**
   B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
   C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
2. The patient's medication history includes use of a prerequisite agent **OR**
3. BOTH of the following:
   A. The prescriber has stated that the patient has tried a prerequisite agent **AND**
   B. The prerequisite agent was discontinued due to lack of effectiveness or an adverse event **OR**
4. The patient has a documented intolerance or hypersensitivity to an available prerequisite agent that is not expected to occur with the requested agent **OR**
5. The patient has an FDA labeled contraindication to ALL available prerequisite agents that is not expected to occur with the requested agent **OR**
6. The prescriber has provided documentation that ALL available prerequisite agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months