METFORMIN

Fortamet (extended-release metformin osmotic), Glumetza* (extended-release metformin), Riomet (metformin oral solution), Metformin ER (modified & osmotic)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Metformin is an oral antidiabetic medication used to improve glycemic control in adults with type 2 diabetes mellitus. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, and loss of limbs. Proper control of diabetes may also lessen the risk of a heart attack or stroke. Metformin works by helping to restore the body’s proper response to the insulin it naturally produces. It also decreases the amount of sugar that the liver makes and that the stomach/intestines absorb (1-3).

Regulatory status
FDA Approved Indications: Metformin is a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes (1-3).

Limitations of Use:
Metformin is not used for the treatment of type 1 diabetes or ketoacidosis (1-3).

Metformin carries a boxed warning regarding the risk of lactic acidosis, which may be fatal. Increased risk is associated with hypotensive states such as acute congestive heart failure and acute myocardial infarction. Metformin is contraindicated in patients with renal impairment, metabolic acidosis or hypersensitivity to metformin hydrochloride. Before initiating therapy with Metformin, evaluate the patient’s renal function (1-3).

Patients should be warned against excessive alcohol intake while taking Metformin (1-3).

The safety and effectiveness of Glumetza and Fortamet in pediatric patients less than 18 years of age have not been established (2). The safety and effectiveness of Riomet in pediatric patients less than 10 years of age have not been established (1, 3).

Summary
Metformin is indicated to improve glycemic control in adult patients with type 2 diabetes mellitus. Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, and loss of limbs. Proper control of diabetes may also lessen the risk of a heart attack or stroke. Metformin works by helping to restore the body’s proper response to the insulin it naturally produces. It also decreases the amount of sugar that the liver makes and that the stomach/intestines absorb. The safety and effectiveness of Glumetza and Fortamet in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of Riomet in pediatric patients less than 10 years of age have not been established (1-3).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Metformin while maintaining optimal therapeutic outcomes.

References