

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Empagliflozin/linagliptin/metformin XR (Trijardy XR)

Notes:

- Quantity Limits: Yes
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- ** Per Kaiser National Clinical Practice Guideline, clinical ASCVD (secondary prevention) includes acute coronary syndrome (ACS), history of myocardial infarction (MI), stable or unstable angina, coronary or other arterial revascularization, ischemic stroke, transient ischemic attack (TIA), or symptomatic peripheral artery disease (PAD), all of atherosclerotic origin
 - Subclinical atherosclerosis, such as elevated coronary artery calcium or aortic atherosclerosis, or patients at high risk for ASCVD (primary prevention) are NOT included in the definition of clinical ASCVD
- ^ Sulfonylurea is contraindicated if high risk for severe hypoglycemia. Risk factors for severe hypoglycemia include history of severe hypoglycemia, alcoholism, erratic timing of meals, and autonomic failure (causing impaired awareness of hypoglycemia and defective glucose counter-regulation).
- # Severe hypoglycemia is defined as hypoglycemia that leads to seizures or loss of consciousness or that requires help from others

Initiation (new start) criteria: Non-formulary **empagliflozin/linagliptin/metformin XR (Trijardy XR)** will be covered on the prescription drug benefit when the following criteria are met:

- Patient has a diagnosis of Type 2 Diabetes Mellitus
- On maximally tolerated metformin dose
- On maximally tolerated pioglitazone dose or intolerance or contraindication to pioglitazone
- Recent HbA1c less than 9%
- Not currently using a GLP-1 receptor agonist (medications containing semaglutide, liraglutide, exenatide, lixisenatide, dulaglutide)
- Meets one of the following criteria:
 - Intolerance or contraindication to sulfonylurea[^]
 - Inadequate glycemic response to insulin despite high dose requirements (total daily insulin dose of 1.5 units per kilogram of body weight or higher OR total daily insulin dose 200 units or more)
 - Recurrent nocturnal hypoglycemia with basal insulin defined as: 3 or more episodes of blood glucose less than 70 mg/dL over the preceding 30 days that persists despite basal insulin dose reduction (including decrease in NPH insulin dose and subsequent switch to and dose adjustment of insulin glargine)
 - History of severe hypoglycemia[#] on basal insulin

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- And meets one of the following conditions:
 - 1) Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)** AND
 - 2) Chronic Kidney Disease with estimated glomerular filtration rate (eGFR) less than 60 mL/min AND
 - On maximally tolerated dose or allergy or intolerance* to ACE inhibitor or ARB
 - 3) Proteinuria defined as urine albumin/creatinine ratio (ACR) greater than 300 mg/gm or protein creatinine ratio (PCR) greater than 0.5 AND
 - On maximally tolerated dose or allergy or intolerance* to ACE inhibitor or ARB
 - 4) Diagnosis of heart failure

-AND-

- Documentation has been provided for the reason why the combination is clinically necessary and not for convenience over the individual components of empagliflozin, linagliptin and metformin XR