

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Empagliflozin (Jardiance)

Notes:

- Quantity limits: Yes
- GMI - Glucose Management Indicator, an estimated A1c level based on continuous glucose monitoring data
- * 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
- # For patients aged 18-64, recommend goal A1c of < 7.0% unless significant co-morbidities (history of dementia, blindness, lower extremity amputation, CKD 4/5, ESRD, cardiomyopathy/HF, or ASCVD). For patients aged 65 or older, consider goal A1c of < 8.0%

Initiation (new start) criteria Formulary **empagliflozin (Jardiance)** will be covered on the prescription drug benefit when the following criteria are met:

Patient has a diagnosis of Type 2 Diabetes Mellitus AND meets the following:

- Not on insulin or on insulin at a total daily dose less than 0.5 units/kg/day, meets ALL of the following criteria:
 - On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR
 - On maximally tolerated sulfonylurea or has contraindication/intolerance to sulfonylureas
 - On pioglitazone or has contraindication/intolerance to pioglitazone
 - HbA1c or GMI remains above, but within 2% of, patient's designated goal# after adequate trial^ of the therapies mentioned above

-OR-

- On insulin at a total daily dose of ≥ 0.5 units/kg/day, meets ALL of the following criteria:
 - On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR
 - HbA1c or GMI is above patient's designated goal

-OR-

Patients aged 10-19 years with diagnosis of Type 2 Diabetes Mellitus:

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Revised: 2/13/25
Effective: 4/3/25

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- On maximally tolerated metformin dose or has contraindication/intolerance to metformin XR
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- HbA1c or GMI is above, but within 2% of, patient's designated goal[#] OR
 - If patient on insulin, A1c only needs to be above patient's designated goal

-OR-

Patient has a diagnosis of Type 2 Diabetes Mellitus and one of the following conditions:

- Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)** AND
 - On metformin or allergy or intolerance* to metformin XR
- 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
- 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
- Diagnosis of heart failure

-OR-

Patient does not have a diagnosis of Type 1 or Type 2 Diabetes Mellitus but has one of the following conditions:

- 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
- Diagnosis of heart failure

Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Formulary **empagliflozin (Jardiance)** will be covered on the prescription drug benefit for when the following criteria are met:

Patient has a diagnosis of Type 2 Diabetes Mellitus AND all of the following:

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- Not on insulin or on insulin at a total daily dose less than 0.5 units/kg/day, meets ALL of the following criteria:
 - On maximally tolerated metformin dose or intolerance or contraindication to metformin XR
 - On maximally tolerated sulfonylurea or has contraindication/intolerance to sulfonylureas
 - On pioglitazone or has contraindication/intolerance to pioglitazone
 - Most recent HbA1c or GMI is at, or within 2% of, patient's designated goal[#]

-OR-

- Patient is on (or history of) insulin at a total daily dose of ≥ 0.5 units/kg/day, meets the following criteria:
 - On maximally tolerated metformin dose or intolerance* or contraindication to metformin XR

-OR-

Patient aged 10-19 years with a diagnosis of Type 2 Diabetes Mellitus:

- On maximally tolerated metformin dose or has contraindication/intolerance to metformin XR
- HbA1c or GMI at or within 2% of patient's designated goal[#] if not on insulin

-OR-

Patient has a diagnosis of Type 2 Diabetes Mellitus and one of the following conditions:

- Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)** AND
 - On metformin or allergy or intolerance* to metformin
- 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
- 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
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-OR-

Patient does not have a diagnosis of Type 1 or Type 2 Diabetes Mellitus but has one of the following conditions:

- 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
- Diagnosis of heart failure

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