## Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

# **Empagliflozin (Jardiance)**

#### 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
- <sup>#</sup> 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%</p>

**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 <u>all</u> of the following:
  - On maximally tolerated metformin dose or intolerance\* or contraindication to metformin (includes both metformin IR and XR)
  - On pioglitazone for at least 3 months or contraindication or intolerance\*
  - Most recent HbA1c is above patient's designated goal<sup>#</sup> but less than 8.6%
  - eGFR is 45 mL/min or greater
  - And meets one of the following:
    - Has contraindication/intolerance to or is currently taking maximum dose sulfonylurea
    - Patient is on insulin at a total daily dose of ≥ 0.5 units/kg/day

### -OR-

- Patient has a diagnosis of Type 2 Diabetes Mellitus and <u>one</u> of the following conditions:
  - Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)\*\* AND

     On metformin or allergy or intolerance\* to metformin
  - 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

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Revised: 01/11/24 Effective: 03/07/24 All plans offered and underwritten by Kaiser Foundation Health Plan of the Northwest



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# **Empagliflozin (Jardiance)**

- 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

-OR-

- Patient does not have a diagnosis of Type 2 Diabetes Mellitus but has one of the following conditions:
  - 1) 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
  - 2) 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 <u>all</u> of the following:
  - On maximally tolerated metformin dose or intolerance\* or contraindication to metformin (includes both metformin IR and XR)
  - Currently taking or contraindication/intolerance to pioglitazone
  - eGFR is 45 mL/min or greater
  - And meets one of the following:
    - Has contraindication/intolerance to or is currently taking maximum dose sulfonylurea
    - Patient is on insulin at a total daily dose of ≥ 0.5 units/kg/day

### -OR-

- Patient has a diagnosis of Type 2 Diabetes Mellitus and <u>one</u> of the following conditions:
  - Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD)\*\* AND

     On metformin or allergy or intolerance\* to metformin

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# **Empagliflozin (Jardiance)**

- 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

### -OR-

- Patient does not have a diagnosis of Type 2 Diabetes Mellitus but has one of the following conditions:
  - 1) 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
  - 2) Diagnosis of heart failure

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