

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Dapagliflozin/ Metformin XR (Xigduo 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

Initiation (new start) criteria: Non-formulary **Dapagliflozin/ Metformin XR (Xigduo XR)** will be covered on the prescription drug benefit when the following criteria are met:

- Intolerance* to preferred SGLT-2 inhibitor empagliflozin (Jardiance)
-AND-
- Patient has a diagnosis of Type 2 Diabetes Mellitus and one of the following conditions:
 - 1) 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
 - 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 dapagliflozin and metformin XR

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Criteria for members already taking the medication who have not been reviewed previously (e.g., new members): Non-formulary **dapagliflozin /metformin XR (Xigduo XR)** will be covered on the prescription drug benefit for when the following criteria are met:

- Intolerance* to preferred SGLT-2 inhibitor empagliflozin (Jardiance)
-AND-
- Patient has a diagnosis of Type 2 Diabetes Mellitus and one of the following conditions:
 - 1) 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
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- Documentation has been provided for the reason why the combination is clinically necessary and not for convenience over the individual components of dapagliflozin and metformin XR