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
- ^ 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 counterregulation). Severe hypoglycemia is defined as hypoglycemia that leads to seizures or loss of consciousness or that requires help from others.
- 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>

<u>Initiation (new start) criteria</u>: Non-formulary <u>empagliflozin/linagliptin/metformin XR</u> (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
- Documented allergy/intolerance* to sitagliptin
- On maximally tolerated metformin dose
- On pioglitazone for at least 3 months or contraindication or intolerance^{*}
- On an SGLT2 inhibitor (e.g. Jardiance)
- Most recent HbA1c is less than 1% above patient's designated goal[#] unless on insulin at a total daily dose of > 0.5 units/kg/day
- Not currently using a GLP-1 receptor agonist (medications containing semaglutide, liraglutide, exenatide, lixisenatide, dulaglutide)
- Meets 1 of the following:
 - On maximum dose sulfonylurea or intolerance* or contraindication to sulfonylureas^
 - On insulin at a total daily dose of > 0.5 units/kg/day
- 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

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Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Empagliflozin/linagliptin/metformin XR (Trijardy XR)

<u>Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously</u>: 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
- Documented allergy/intolerance* to sitagliptin
- On pioglitazone for at least 3 months or contraindication or intolerance*
- Most recent HbA1c is less than 9% unless on insulin at a total daily dose of ≥ 0.5 units/kg/day
- Not currently using a GLP-1 receptor agonist (medications containing semaglutide, liraglutide, exenatide, lixisenatide, dulaglutide)
- Meets 1 of the following:
 - On maximum dose sulfonylurea or intolerance* or contraindication to sulfonylureas^
 - o On insulin at a total daily dose of ≥ 0.5 units/kg/day
- 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

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