

Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Sitagliptin phosphate (Januvia)

Notes:

- QL: 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 counter-regulation). 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%.

Initiation (new start) criteria: Non-formulary **Sitagliptin phosphate (Januvia)** will be covered on the prescription drug benefit when the following criteria are met:

- Diagnosis of diabetes mellitus type 2
- Documented allergic reaction to an inactive ingredient in sitagliptin base (Zituvio) not present in sitagliptin phosphate (Januvia)
- On maximally tolerated metformin dose or intolerance or contraindication to metformin (includes metformin XR)
- On pioglitazone for at least 3 months or intolerance or contraindication to pioglitazone
- On an SGLT2 inhibitor (e.g. Jardiance) or intolerance or contraindication to SGLT2 inhibitors
- 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
- 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
- Not currently using a GLP-1 receptor agonist (medications containing semaglutide, liraglutide, exenatide, lixisenatide, dulaglutide)

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Sitagliptin phosphate (Januvia)

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **sitagliptin phosphate (Januvia)** will be covered on the prescription drug benefit when the following criteria are met:

- Diagnosis of diabetes mellitus type 2
- Documented allergic reaction to an inactive ingredient in sitagliptin base (Zituvio) not present in sitagliptin phosphate (Januvia)
- On maximally tolerated metformin dose or intolerance* or contraindication to metformin (including metformin XR)
- On pioglitazone or intolerance or contraindication to pioglitazone
- On an SGLT2 inhibitor (e.g. Jardiance) or intolerance or contraindication to SGLT2 inhibitors
- Most recent HbA1c is less than 9% unless patient is on insulin at a total daily dose of ≥ 0.5 units/kg/day
- 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
- Not currently using a GLP-1 receptor agonist (medications containing semaglutide, liraglutide, exenatide, lixisenatide, dulaglutide, tirzepatide)

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