## Criteria Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

## Alogliptin/pioglitazone (Oseni)

## 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

<u>Initiation (new start) criteria</u>: Non-formulary <u>alogliptin/pioglitazone</u> (Oseni) will be covered on the prescription drug benefit when the following criteria are met:

- Diagnosis of diabetes mellitus type 2
- Documented intolerance\* to linagliptin
- On maximally tolerated metformin dose or intolerance or contraindication to metformin (includes both metformin IR and XR)
- On maximally tolerated pioglitazone dose
- Recent HbA1c less than 9%
- Not currently using a GLP-1 receptor agonist (medications containing semaglutide, liraglutide, exenatide, lixisenatide, dulaglutide)
- Meets 1 of the following:
  - Intolerance or contraindication to sulfonylurea<sup>^</sup>
  - Inadequate glycemic response to insulin despite high dose requirements (total daily insulin dose of 1.5 units per kilogram of body weight or higher OR total daily insulin dose 200 units or more)
  - Recurrent nocturnal hypoglycemia with basal insulin defined as: 3 or more episodes of blood glucose less than 70 mg/dL over the preceding 30 days that persists despite basal insulin dose reduction (including decrease in NPH insulin dose and subsequent switch to and dose adjustment of insulin glargine)
  - History of severe hypoglycemia<sup>#</sup> on basal insulin

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