Dipeptidyl Peptidase-4 Inhibitor (DPP-4) PA Criteria

1. Does the patient have a diagnosis of diabetes mellitus, type 2?
    a. If Yes, Go to question #2.
    b. If No, Category 3 denial.
    Category 3: Not a covered benefit. DPP-4s are only FDA approved for the treatment of type 2 diabetes.

2. Is the patient newly diagnosed?
    a. If Yes, Forward to Medical Director for medical appropriateness.
    Category 5: Not medically appropriate. An appropriate trial period of lifestyle modifications and traditional anti-diabetic agents (metformin, pioglitazone, and sulfonylureas) required for newly diagnosed patients prior to consideration of DPP-4s.
    b. If No, Go to question #3.

3. Is the patient currently taking metformin, pioglitazone, and a sulfonylurea?
    a. If Yes, Go to question #5.
    b. If No, Go to question #4.

4. Has the patient tried and failed, metformin, pioglitazone, and a sulfonylurea, or does the patient have contraindications to these treatments*?
    a. If Yes, move to question #5.
    b. If No, Forward to Medical Director for medical appropriateness.
    Category 5: Not medically appropriate. Provider submitted documentation does not indicate that patient has tried and failed, or has a contraindication to, treatment option metformin plus pioglitazone plus a sulfonylurea.

5. Review fill history for patient. Has patient shown compliance to current diabetes medications (80% or greater adherence)?
    a. If Yes, Go to question #6.
    b. If No, Forward to Medical Director for medical appropriateness.
    Category 5: Not medically appropriate. Approval requires patient compliance.

6. Is the request for a formulary DPP-4 agent? Formulary DPP-4 agents are the alogliptin (Nesina) and sitagliptin (Januvia).
    a. If Yes, Go to question #8.
    b. If No, Go to questions #7.

7. Has the patient tried and failed formulary DPP-4 agents? Formulary DPP-4 agents are the alogliptin (Nesina) and sitagliptin (Januvia).
    a. If Yes, Go to question #8.
    b. If No, Category 15 denial.
    Category 15: Not a covered benefit. Provider submitted documentation does not indicate that the patient has tried and failed formulary alternatives alogliptin (Nesina) and sitagliptin (Januvia).

8. Is the medication dosing within the FDA approved dosing parameters for the medication?* Dosing adjustment due to renal or hepatic impairment may be necessary.
    a. If Yes, **Approve**.
    b. If No, Category 3 denial.

Category 3: Not a covered benefit. The requested medication dosing is outside the approved dosing established in the FDA approved medication package insert, and therefore safety and efficacy cannot be established.

*** Contraindications to traditional anti-diabetic medications:**

- Metformin contraindications: hypersensitivity to metformin, renal disease or renal dysfunction, acute or chronic metabolic acidosis, and increased risk of lactic acidosis (e.g. CHF, advanced age, impaired hepatic function).
- Pioglitazone contraindications: hypersensitivity to pioglitazone, CHF, bladder cancer, edema, high risk of fractures, impaired hepatic function, and anemia.
- Sulfonylurea contraindications: hypersensitivity to sulfonylureas, high risk of hypoglycemia, and diabetic ketoacidosis.

*** FDA approved medication dosing:**

- Alogliptin (Nesina): 25 mg once daily
- Linagliptin (Tradjenta): 5 mg once daily
- Saxagliptin (Onglyza): 2.5 mg to 5 mg once daily
- Sitagliptin (Januvia): 100 mg once daily

Guide to Denial Categories	Reason for Denial
Category 1	The condition is not on a funded line
Category 3	The use of the medication is considered experimental/ investigational (usually applies to off-label use of a medication)
Category 5	Not medically appropriate
Category 15	Formulary medications have not been exhausted