



Prior Authorization Protocol

NESINA™ (alogliptin)

NATL

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

I. FDA Approved Indications:

- As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

II. Health Net Approved Indications and Usage Guidelines:

- Diagnosis of diabetes mellitus type 2
AND
- Failure to achieve Hemoglobin A1c (HgbA1C) less than or equal to 6.5% on at least 1,500 mg per day of metformin, unless contraindicated

III. Coverage is Not Authorized For:

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature

IV. General Information:

- Both the American Diabetes Association guideline and the American Association of Clinical Endocrinologist/American College of Endocrinology algorithm recommend metformin as an initial first line agent due to its safety and efficacy profile.
- Warning of acute pancreatitis, hepatic failure (fatal), and severe and disabling arthralgia in postmarketing reports.

V. Therapeutic Alternatives:

Drug	Dosing Regimen	Dose Limit/Maximum Dose
acarbose (Precose®)	25 -100 mg PO TID	300 mg/day
glimepiride (Amaryl®)	1-2 mg PO QD	8 mg/day
glipizide (Glucotrol®)	5-40 mg PO QD	40 mg/day
glipizide ER (Glucotrol XL®)	5-20 mg PO QD	20 mg/day
glyburide (Micronase®, Diabeta®)	2.5-5 mg PO QD	20 mg/day
glyburide, micronized (Glynase®Pres Tab)	1.5 to 3 mg PO QD	12 mg/day
Glyset® (miglitol)	25 – 100 mg PO TID	300 mg/day
Invokana™ (canagliflozin)	100 mg PO QD	300 mg/day
Januvia® (sitagliptin)	100 mg PO QD	100 mg/day
metformin (Glucophage®)	500 mg PO BID or 850 mg PO QD	2,550 mg/day

Prior Authorization Protocol

NESINA™ (alogliptin)

NATL

Drug	Dosing Regimen	Dose Limit/Maximum Dose
pioglitazone (Actos®)	15-45 mg PO QD	45 mg/day
Onglyza™ (saxagliptin)	2.5-5 mg PO QD	5 mg/day
Tradjenta™ (linagliptin)	5 mg PO QD	5 mg/day

*Prior authorization required

VI. Recommended Dosing Regimen and Authorization Limit:

Drug	Dosing Regimen	Authorization Limit
Nesina	25 mg PO QD CrCL 30-60: 12.5 mg PO QD CrCL <30: 6.25 mg PO QD	Length of Benefit

VII. Product Availability:

Nesina Tablets: 25 mg, 12.5 mg, 6.25 mg

VIII. References:

1. Nesina [Prescribing Information] Deerfield, IL: Takeda Pharmaceuticals America, Inc.; August 2015.
2. Rodbard HW, Jellinger PS, Davidson JA, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An Algorithm for Glycemic Control. *Endocr Pract* 2009;15:540-559.
3. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of Hyperglycemia in Type 2 Diabetes: A Patient-Centered Approach. *Diabetes Care* 2012;35:1364-1379.
4. Alogliptin. American Hospital Formulary Service Drug Information. Available at: <http://www.medicinescomplete.com/mc/ahfs.current/>. Accessed February 25, 2016.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed February 25, 2016.
6. Clinical Pharmacology Web site. Available at <http://cpip.gsm.com/>. Accessed February 25, 2016.

The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.