Insulin Degludec (TRESIBA)
Criteria for Use
April 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National Formulary Committee Monograph on this drug at the *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive insulin degludec.

☐ Hypersensitivity to insulin degludec

Inclusion Criteria – Insulin Degludec 100 u/mL Only

One of the following criteria must be met.

☐ Patient with instability of glucose levels (e.g., insulin-sensitive type 1 diabetes) resulting in hypoglycemia while receiving lower doses of insulin glargine 100 units/mL may consider use of insulin degludec 100 units/mL.

☐ Patient with wide fluctuation in glucose levels due to an inability to take basal insulin at a consistent time due to variability in shift work, dialysis, inconsistent routines, etc. and documented in the Federal EHR. ^1-3

1. Fluctuation in glucose levels is documented in a glucose diary or continuous glucose monitor (CGM) and included in the Federal electronic health record (EHR).
2. Patients who meet this criterion and are ALSO insulin resistant (e.g., require >1 unit/kg/day) may use the 200 u/mL.
3. There are two different concentrations of insulin degludec 200 u/mL and 100 u/mL. Concentrated degludec 200 u/mL can be given in 2-unit increments and deliver up to 160 units per single injection while degludec 100 u/mL can be given in 1-unit increments and deliver up to 80 u/mL per single injection. The concentrated product is preferred in patients who are insulin resistant receiving high doses of insulin.

Inclusion Criteria – Insulin Degludec 200 u/mL Only

One of the following criteria must be met.

☐ Patient is insulin resistant (e.g., requires >1 unit/kg/day) ^4

☐ Patient with recurrent episodes of hypoglycemia on insulin glargine 100 u/mL (e.g., ≥ three Level 2 or one Level 3 hypoglycemic event within a one-month period) despite use of CGM and adjustments made to current insulin regimen ^5-7

4. There are two different concentrations of insulin degludec 200 u/mL and 100 u/mL. Concentrated degludec 200 u/mL can be given in 2-unit increments and deliver up to 160 units per single injection while degludec 100 u/mL can be given in 1-unit increments and deliver up to 80 u/mL per single injection. The concentrated product is preferred in patients who are insulin resistant receiving high doses of insulin.
5. Level 2 hypoglycemia = glucose level <54 mg/dL; Level 3 hypoglycemia = severe event requiring assistance for management, regardless of glucose level.
6. CGM=Continuous glucose monitor.
7. Adjustment of insulin, other diabetes medications, timing and type of meals/snacks, exercise, etc.

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