

Insulin Glargine 300 Units/mL (TOUJEO AND TOUJEO MAX)

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 glargine 300 units/mL.

- Hypersensitivity to insulin glargine or glargine biosimilar

Inclusion Criteria

One of the following criteria must be met.

- Patient is insulin resistant (e.g., requires >1 unit/kg/day) ^{^1}
- Patient with recurrent episodes of hypoglycemia on insulin glargine 100 u/mL (e.g., \geq 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 ^{^2-^4}
1. There are two concentrated insulin glargine 300 u/mL products available (TOUJEO Solostar and TOUJEO Solostar MAX). TOUJEO delivers in 1-unit increments and can deliver up to 80 units in a single injection while TOUJEO MAX delivers in 2-unit increments and can deliver up to 160 units in a single injection. TOUJEO MAX is preferred in patients with insulin resistance receiving high doses of insulin. Note: Insulin glargine (LANTUS) also provides 80 units as the maximum dose per single injection.
 2. Level 2 hypoglycemia = glucose level <54 mg/dL; Level 3 hypoglycemia = severe event requiring assistance for management, regardless of glucose level.
 3. CGM=Continuous glucose monitor
 4. Adjustment of insulin, other diabetes medications, timing and type of meals/snacks, exercise, etc.

Additional information:

- Clinical need for concentrated, smaller volume insulin injections, such as insulin glargine 300 u/mL, should be demonstrated. Patients doing well on glargine 100 u/mL should not be switched to concentrated insulin for the sole purpose of achieving smaller volume injections.
- If not already receiving, consider insulin sensitizing agents such as metformin, empagliflozin or semaglutide unless contraindicated.