Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 27, 2024

Toujeo® SoloStar/Max SoloStar (insulin glargine)

LENGTH OF AUTHORIZATION: One year

REVIEW CRITERIA:

- Patient must be ≥ 6 years of age; **AND**
- Patient must have a diagnosis of diabetes mellitus; **AND**
- Patient had an inadequate response or intolerance to no less than a 6-month trial on Lantus® (insulin glargine) demonstrated by, but not limited to the following - *clinical documentation (e.g., progress notes, lab results, etc.) detailing treatment response must be provided*:
  - Recurrent episodes of hypoglycemia despite adjustments to dose/dosage frequency.
  - **For Toujeo Max SoloStar –** failure to achieve glycemic control goals on Lantus® (insulin glargine) **AND** high dose insulin glargine therapy is medically necessary.

Note: Toujeo is not recommended for the treatment of diabetic ketoacidosis.

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response (e.g., reduction in hypoglycemic episodes, HbA1c, and fasting blood glucose); **AND**
- Patient has not experienced any treatment-restricting adverse effects; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 300 units/mL (U-300) insulin glargine for injection:
  - 1.5 mL SoloStar single-use prefilled pen
  - 3 mL Max SoloStar single-use prefilled pen