Criteria Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

insulin glargine U-300 (Toujeo Solostar, Toujeo Max Solostar)

Non-formulary **insulin glargine U-300 (Toujeo Solostar, Toujeo Max Solostar)** will be covered on the prescriptiondrug benefit when the following criteria are met:

- The member has a documented allergic reaction to an inactive ingredient in Lantus, or its unbranded biologic, and Semglee, or its unbranded biologic, not present in Toujeo

-AND-

- The member has a documented allergy to insulin degludec

-AND-

<u>Meets one of the following criteria:</u>

- Use in patients with type 1 diabetes mellitus as basal insulin
- Use in patients with any type of diabetes age 19 or younger
- Use in patients with type 2 diabetes mellitus AND insulinopenia^
- Use in patients with type 2 diabetes mellitus AND documented allergy or intolerance* to NPH insulin
- Use in patients with type 2 diabetes mellitus that experience recurrent nocturnal hypoglycemia (low blood sugar at night) with bedtime NPH insulin dosing defined as: 3 or more episodes of nocturnal CBG (capillary blood glucose at night) less than 70 over the preceding 30 days that persists despite NPH insulin dose reduction
    - For patients on 70/30 insulin, trial of NPH insulin (dosed am and bedtime) and Regular insulin (dosed breakfast and dinner) where the bedtime dose of NPH insulin resulted in recurrent hypoglycemia as defined above
- Use in patients with type 2 diabetes mellitus on NPH insulin that experience any episode of severe hypoglycemia defined as: hypoglycemia resulting in seizures, loss of consciousness, episode necessitating assistance from someone else, EMT (emergency medical technician), and/or use of glucagon (medication used to raise the concentration of glucose in the blood)
- Use in patient with type 2 diabetes mellitus that require long-acting insulin due to work (night shift work where hours of sleep are significantly and repeatedly varied over time, frequent time-zone traveler)

* Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

^ Insulinopenia is defined fasting c-peptide less than or equal to 0.88 ng/mL (or 1.6 ng/mL in patients with creatinine clearance less than 50 mL/min) with a concurrent blood glucose of 70-225 mg/dL

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