Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

insulin degludec U-100 multi-dose vial, U-100 pen, U-200 pen (Tresiba, Tresiba Flextouch U-100, Tresiba Flextouch U-200)

Non-formulary **insulin degludec U-100 multi-dose vial, U-100 pen, U-200 pen** (Tresiba, Tresiba Flextouch U-100, Tresiba Flextouch U-200) will be covered on the prescription drug benefit when the following criteria are met:

• Documented allergy or intolerance* to insulin glargine

-AND-

Meets one of the following criteria:

- 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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