Criteria-Based Consultation (CBC) Criteria for Coverage

Insulin glargine injection (Basaglar Flexpen and Basaglar TempoPen)

Non-formulary insulin glargine (Basaglar) requires a clinical review. Appropriateness of therapy will be based on the following criteria:

- The member has a documented allergic reaction to an inactive ingredient in Lantus not present in Basaglar

-AND-

- Meet clinical criteria to use insulin glargine*

-AND-

- Meet Insulin Pen Criteria:
    - Unable to draw up insulin accurately from a vial with a syringe due to young age, visual impairment, physical disabilities (i.e., amputations, tremors/Parkinson's disease, rheumatoid arthritis), or history of IV drug use

    - OR –

    - Pediatric patient who is required to use such devices by school

    - OR –

    - Type 1 DM

<u>*Glargine Insulin Criteria:</u>

- Use in patients with type 1 diabetes mellitus as basal insulin

  -OR-
- Use in patients with any type of diabetes age 19 or younger

  -OR-
- Patients with Type 2 diabetes mellitus AND insulinopenia
    - Insulinopenia is defined as a fasting C-peptide level of less than or equal to 0.88 ng/mL with a concurrent glucose of 70-225 mg/dL
    - In those with renal insufficiency with a creatinine clearance less than or equal to 50 ml/minute, insulinopenia is defined as a C-peptide level of less than or equal to 1.6 ng/mL with a concurrent glucose of 70-225 mg/dL

  -OR-
- 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

  -OR-
- 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)

  -OR-
- Use in patient with type 2 diabetes mellitus that require ultra-long acting insulin due to work (night shift work where hours of sleep are significantly and repeatedly varied over time, frequent time-zone traveler)