

## Commercial PA Criteria

Effective: October 8, 2020

**Prior Authorization:** Long-Acting Insulin

**Products Affected:** Semglee (insulin glargine) Pen, Semglee (insulin glargine) vial, Semglee-yfng Pen, Semglee-yfng vial, Insulin glargine-yfng Pen, Insulin glargine-yfng vial, Insulin glargine 100 units/mL vial and Insulin glargine 100 units/mL pen, Insulin Glargine Solostar, Insulin Glargine Max Solo, Insulin Degludec, Rezvoglar (insulin glargine-aglr)

**Medication Description:** The primary activity of insulin, including insulin glargine, is regulation of glucose metabolism. Insulin and its analogs lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis and enhances protein synthesis.

Insulin degludec is a long-acting basal human insulin analog for subcutaneous injection produced by a process that includes expression of recombinant DNA in *Saccharomyces cerevisiae* followed by chemical modification.

**Covered Uses:** Improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

**Exclusion Criteria:**

1. Patients with hypersensitivity to insulin glargine (for Semglee, Semglee-yfng, insulin glargine-yfng, insulin glargine)
2. Patients with hypersensitivity to insulin degludec (for insulin degludec)
3. Use during episodes of hypoglycemia

**Required Medical Information:**

1. Diagnosis
2. Previous therapies tried and failed

**Age Restrictions:**

1. Semglee, Semglee-yfng, insulin glargine-yfng, insulin glargine:  
Type 1 diabetes mellitus: 6 years of age or older  
Type 2 diabetes mellitus: 18 years of age or older
2. Insulin degludec: 1 year of age or older

**Prescriber Restrictions:** None

**Coverage Duration:** 12 months

**Other Criteria:**

1. **Diabetes mellitus (type 1 or type 2)**
  - A. Patient has a diagnosis of type 1 or type 2 diabetes mellitus; **AND**
  - B. Patient has a documented intolerance to, contraindication, or treatment failure to **ALL** the following long-acting insulins:



- i. Lantus (Solostar, vial)
- ii. Levemir (Flextouch, vial)
- iii. Toujeo (Max Solostar, Solostar)
- iv. Tresiba (Flextouch, vial)

**References:**

- 1. Semglee (insulin glargine) [prescribing information]. Morgantown, WV: Mylan; June 2020.
- 2. Insulin degludec [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2022.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/08/2020
2	Update	Updated policy to include new Semglee products (Semglee- yfgn and Insulin glargine-yfgn) vial and pen	Products Affected	11/12/2021
3	Update	Added Insulin glargine	Products Affected	6/27/2022
4	Update	Added Insulin degludec, changed name from "Semglee" to "Long-Acting Insulin"	Prior Authorization, Products Affected, Medication Description, Exclusion Criteria and Age Restrictions	10/31/2022
5	Update	Added Rezvoglar to Products Affected, Changed name to add Rezvoglar in Title	Products Affected, Policy Name	05/11/2023
6	Update	Added Insulin Glargine Solostar, Insulin Glargine Max Solo	Products Affected	1/23/2024