Select Long-Acting Insulin Products

Policy # 00728
Original Effective Date: 02/08/2021
Current Effective Date: 11/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select insulin glargine products including, but not limited to branded insulin glargine-yfgn, branded insulin glargine, Semglee™‡ (insulin glargine-yfgn), Rezvoglar™‡ (insulin glargine-aglr) and branded insulin degludec to be **eligible for coverage**** when the below patient selection criterion is met.

Patient Selection Criteria

Coverage eligibility will be considered for select insulin glargine-products, including but not limited to branded insulin glargine-yfgn, branded insulin glargine, Semglee (insulin glargine-yfgn), Rezvoglar (insulin glargine-aglr), and branded insulin degludec when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of Lantus®‡ (insulin glargine), Levemir®‡ (insulin detemir), Toujeo®‡ (insulin glargine), or Tresiba®‡ (insulin degludec) will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select insulin glargine products, including but not limited to branded insulin glargine-yfgn, branded insulin glargine, Semglee (insulin glargine-yfgn), Rezvoglar (insulin glargine-aglr), and branded insulin degludec when the patient selection criterion is not met to be **not medically necessary.****

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Background/Overview

The long acting products mentioned in this policy are approved for both Type 1 and Type 2 diabetes mellitus. Branded insulin glargine-yfgn, Semglee (insulin glargine-yfgn), Rezvoglar (insulin glargine-aglr), branded insulin glargine, and Lantus all contain 100 units per mL of insulin glargine. Levemir contains 100 units per mL of insulin detemir. Toujeo contains 300 units per mL of insulin glargine. Tresiba and branded insulin degludec contain either 100 or 200 units per mL of insulin degludec.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The patient selection criterion presented in this policy takes into consideration clinical evidence or patient history that suggests the use of Lantus, Levemir, Toujeo, or Tresiba will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above-mentioned caveat, there is no advantage of using branded insulin glargine-yfgn, branded insulin glargine, Semglee (insulin glargine-yfgn), Rezvoglar (insulin glargine-aglr), or branded insulin degludec over Lantus, Levemir, Toujeo, or Tresiba.

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References

1. Semglee [package insert]. Mylan Pharmaceuticals. Morgantown, West Virginia. Updated June 2020.
2. Lantus [package insert]. Sanofi-Aventis. Bridgewater, New Jersey. Updated November 2019.
3. Levemir [package insert]. Novo Nordisk. Plainsboro, New Jersey. Updated April 2020.
4. Toujeo [package insert]. Sanofi-Aventis. Bridgewater, New Jersey. Updated November 2019.
5. Tresiba [package insert]. Novo Nordisk. Plainsboro, New Jersey. Updated December 2019.
6. insulin glargine-yfgn [package insert]. Mylan Pharmaceuticals. Morgantown, West Virginia. Updated July 2021.
7. Insulin glargine [package insert]. Winthrop U.S. Bridgewater, New Jersey. Updated January 2021.
8. Insulin degludec [package insert]. Novo Nordisk. Plainsboro, New Jersey. Updated July 2022.
9. Rezvoglar [package insert]. Eli Lilly and Company. Indianapolis, Indiana. Updated November 2022.

Policy History

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01/07/2021	Medical Policy Committee review
01/13/2021	Medical Policy Implementation Committee approval. New policy.
01/06/2022	Medical Policy Committee review
01/12/2022	Medical Policy Implementation Committee approval. No change to coverage.
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Added insulin glargine-yfgn to the policy. Changed the title of the policy from Semglee (insulin glargine) to insulin glargine-yfgn (Semglee, biosimilar).
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Changed title of policy from insulin glargine-yfgn (Semglee, biosimilar) to Select insulin glargine Products. Updated product list to read as branded insulin glargine-yfgn, branded insulin glargine, and branded Semglee-yfgn.
03/02/2023	Medical Policy Committee review

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03/08/2023	Medical Policy Implementation Committee approval. Change title from "Select insulin glargine Products" to "Select Long-Acting Insulin Products." Added branded insulin degludec to policy.
10/05/2023	Medical Policy Committee review
10/11/2023	Medical Policy Implementation Committee approval. Edited policy to delete "branded" from Semglee (insulin glargine-yfgn). Added new drug, Rezvoglar, to the policy.
10/03/2024	Medical Policy Committee review
10/08/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2025

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.