

Drug and Biologic Coverage Policy



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Coverage Policy Number P0023

Insulin Glargine

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Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following insulin glargine products:

- **Basaglar**[®] (insulin glargine subcutaneous injection)
- **Basaglar Tempo Pen** (insulin glargine subcutaneous injection)
- **insulin glargine** subcutaneous injection
- **insulin glargine-yfgn** subcutaneous injection
- **Lantus**[®] (insulin glargine subcutaneous injection)
- **Rezvoglar**[™] (insulin glargine-AGLR subcutaneous injection)
- **SEMGLEE-YFGN**[™] (insulin glargine-YFGN subcutaneous injection)
- **Toujeo**[®] (insulin glargine subcutaneous injection)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

When coverage requires the use of preferred products, there is documentation of **ONE** of the following (A or B):

- A. The individual has had inadequate efficacy to the number of covered alternatives according to the table below

OR

- B. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for the covered alternatives according to the table below

**Note: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation)*

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Standard/Performance	Cigna Total Savings Legacy Value/Advantage
Basaglar (insulin glargine)	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	Preferred Brand
Basaglar Tempo Pen (insulin glargine)	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	Preferred Brand
Insulin Glargine, Insulin Glargine SoloStar 100 units/mL	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	ALL of the following: <ul style="list-style-type: none"> Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR) Tresiba (insulin degludec)
insulin glargine-yfgn 100 units/mL (SEMGLEE-YFGN authorized generic)	Preferred Brand	ALL of the following: <ul style="list-style-type: none"> Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR) Tresiba (insulin degludec)
Lantus, Lantus SoloStar (insulin glargine U-100)	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	ALL of the following: <ul style="list-style-type: none"> Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR) Tresiba (insulin degludec)
Levemir (insulin detemir U-100)	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	ALL of the following: <ul style="list-style-type: none"> Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR) Tresiba (insulin degludec)
Rezvoglar (insulin glargine-AGLR subcutaneous injection)	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	Preferred Brand
SEMGLEE-YFGN	Preferred Brand	ALL of the following:

Non-Covered Product	Standard/Performance	Cigna Total Savings Legacy Value/Advantage
(insulin glargine U-100)		<ul style="list-style-type: none"> Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR) Tresiba (insulin degludec)
Toujeo SoloStar, Toujeo Max SoloStar (insulin glargine U-300)	BOTH of the following: <ul style="list-style-type: none"> insulin glargine-yfgn (SEMGLEE-YFGN authorized generic) -OR- SEMGLEE-YFGN (insulin glargine) Tresiba (insulin degludec) 	ALL of the following: <ul style="list-style-type: none"> Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR) Tresiba (insulin degludec)

[^]Coverage for Authorized Generic Drugs and their associated Reference Brand Drugs varies across benefit plans/formularies and therapeutic classes/categories. Coverage for any non-covered alternative is allowed only when the covered formulary alternative is not available in the market.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Insulin glargine products are considered medically necessary for continued use when initial criteria are met **AND** there is documentation of beneficial response.

Authorization Duration

Initial and reauthorization approval duration: up to 12 months

Conditions Not Covered

Insulin glargine products are considered experimental, investigational, or unproven for **ANY** other use.

Background

OVERVIEW

Employer group plans may adopt a Prescription Drug List that does not cover certain drugs or biologics unless those products are approved based on a medical necessity review as there are generally covered therapeutic alternatives available. Covered therapeutic alternatives are products usually in the same therapeutic class that can be expected to have equivalent clinical efficacy and safety when administered to patients under the conditions specified in the FDA-approved product information (Label). The number of Covered Alternative Drugs may vary by employer group plan and Prescription Drug Lists (e.g. “closed” versus “open” formulary plan designs).

Professional Societies/Organizations

The American Diabetes Association, European Association for the Study of Diabetes, and American Academy of Clinical Endocrinologists

Clinical practice guidelines do not advocate the use of one long-acting insulin analog product over another. However, guidelines do recommend long-acting basal analogs over neutral protamine Hagedorn (NPH) insulin as analogs have been shown to be equally effective in reducing A1C with significantly less symptomatic and nocturnal hypoglycemia. Additionally, the ADA states that longer-acting basal analogs (U-300 glargine or degludec) may convey a lower hypoglycemia risk compared with U-100 glargine. (ACE/ACE, 2020, 2015; ADA 2020)

References

1. Basaglar, Lantus, Levemir, Toujeo, Tresiba. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. Available from Wolters Kluwer Health, Inc. Accessed April 2020.
2. AACE/ACE Garber AJ, Handelsman Y, Grunberger G, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary. Endocr Pract. 2020 Jan. Available at: <https://www.aace.com/publications/algorithm>
3. ADA Standards of Medical Care in Diabetes, Diabetes Care January 2020; 43(Suppl. 1):S90–S102. Available at: https://care.diabetesjournals.org/content/43/Supplement_1/S1
4. Lantus [prescribing information], Bridgewater, NJ: Sanofi-Aventis, November 2019. Accessed April 2020.
5. Semglee [prescribing information]. Morgantown, WV: Mylan; June 2020.
6. Toujeo [prescribing information], Bridgewater, NJ: Sanofi-Aventis, November 2019. Accessed April 2020.
7. Rezvoglar [prescribing information], Indianapolis, IN: Eli Lilly and Company, November 2022.

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