Pharmacy Benefit Coverage Criteria

Effective Date .............................................. 7/1/2020
Next Review Date ............................................ 7/1/2021
Coverage Policy Number ................................. P0023

Insulin glargine

Table of Contents

Medical Necessity Criteria ................................. 1
FDA Summary .................................................. 2
Background ..................................................... 2
References ....................................................... 3

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, 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.

Medical Necessity Criteria

Coverage for insulin glargine (Lantus® and Toujeo®) varies across plans. Refer to the customer’s benefit plan document for coverage details.

Where coverage requires the use of preferred products, the following criteria apply:

For Employer Group Plans:

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<th>Standard Drug List Plan</th>
<th>Value Drug List Plan</th>
<th>Legacy Drug List Plan</th>
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<td>Performance Drug List Plan</td>
<td>Advantage Drug List Plan</td>
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| Lantus®, Lantus SoloStar® (insulin glargine U-100) | • Documented contraindication per FDA label, intolerance, or inability to use ALL of the following:  
  o Basaglar (insulin glargine)  
  o Levemir (insulin detemir)  
  o Tresiba (insulin degludec) |                      |                        |
| Toujeo SoloStar®, Toujeo Max | • Documented contraindication per FDA label, intolerance, or inability to use ALL of the following:  
  o Basaglar (insulin glargine) |                      |                        |
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<td>SoloStar® (insulin glargine U-300)</td>
<td>o Levemir (insulin detemir) o Tresiba (insulin degludec)</td>
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Initial and reauthorization is up to 12 months.

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.

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

*If you’re a Cigna provider, please log in to the Cigna for Health Care Professionals website and search for specific patients to view their covered medications.

**FDA Summary**

Basaglar, Lantus, Levemir, Tresiba, and Toujeo are long-acting (basal) insulin analogs, indicated to improve glycemic control in patients with type 1 or type 2 diabetes.

- In type 1 diabetes, Basaglar, Lantus, and Toujeo are indicated down to 6 years of age, Levemir is indicated down to 2 years of age, and Tresiba is indicated down to 1 year of age.
- In type 2 diabetes, Basaglar, Lantus, and Levemir are indicated in adults. Toujeo is indicated down to 6 years of age and Tresiba is indicated down to 1 year of age (although efficacy studies in pediatric patients were limited to type 1 diabetes for both Toujeo and Tresiba).
- Basaglar, a follow-on insulin glargine product, was filed as a New Drug Application under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act.

Basaglar, Lantus, and Toujeo contain the same active ingredient, insulin glargine. However, the concentration is higher with Toujeo (300 units/mL [U-300]) vs. Lantus and Basaglar (U-100). Levemir contains insulin detemir U-100. Tresiba contains insulin degludec U-100 or U-200.

The basal insulins are administered by subcutaneous (SC) injection. Levemir is indicated for once daily (QD) or twice daily (BID) dosing while Basaglar, Lantus, Toujeo, and Tresiba are indicated for QD dosing.

- Basaglar, Lantus, Toujeo, and Tresiba may be given at any time during the day; Levemir (QD dose schedule) should be administered with the evening meal or at bedtime.
- For patients transitioning from Lantus to Toujeo, expect that a higher dose of Toujeo will be needed. If transitioning from Toujeo to Lantus or Basaglar, give 80% of the previous Toujeo dose.
- All of the products are available as pen devices; Lantus, Levemir, and Tresiba are also available in vials.

**Background**

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. (AACE/ACE, 2020, 2015; ADA 2020)

References

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