Clinical Policy: Insulin Detemir (Levemir)

Reference Number: HIM.PA.171
Effective Date: 01.01.24
Last Review Date: 12.25
Line of Business: HIM

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Insulin detemir (Levemir®) is long-acting human insulin analog.

FDA Approved Indication(s)*

Levemir is indicated to improve glycemic control in adult and pediatric patients with diabetes mellitus.

Limitation(s) of use: Levemir is not recommended for the treatment of diabetic ketoacidosis.

***Novo Nordisk, manufacturer of Levemir, has discontinued Levemir® FlexPen®, Levemir® FlexTouch®, and Levemir® vials (see *Appendix E*).**

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results, or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Levemir is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Diabetes Mellitus (must meet all)**:**

1. Provider attestation acknowledging the discontinuation of Levemir products (e.g., FlexPen, FlexTouch, vials; *see Appendix E*);
2. Diagnosis of type 1 or type 2 diabetes mellitus;
3. Failure of insulin glargine-yfgn (unbranded Semglee®) and branded Tresiba® (insulin degludec), unless clinically significant adverse effects are experienced or both are contraindicated.*
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or

b. For drugs NOT on the formulary (health insurance marketplace), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. Diabetes Mellitus (must meet all)**:**

1. Provider attestation acknowledging the discontinuation of Levemir products (e.g., FlexPen, FlexTouch, vials; *see Appendix E*);
2. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
3. Failure of insulin glargine-yfgn (unbranded Semglee) and branded Tresiba (insulin degludec), unless clinically significant adverse effects are experienced or both are contraindicated;*^
   **For Illinois HIM requests, the step therapy requirements above do not apply as of 1/1/2026 per IL HB 5395*
   ^For New York requests, the step therapy requirements above do not apply
4. Member is responding positively to therapy.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (health insurance marketplace), the no coverage criteria policy for the relevant line of business: HIM.PA.33 for health insurance marketplace; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: HIM.PA.103 for health insurance marketplace; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PA.154 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose

insulin degludec (branded Tresiba)	**Type 1 diabetes mellitus:** Initiation:
	• Insulin-naïve: 1/3 to 1/2 of total daily insulin dose SC QD
	• Already on insulin: SC QD:
	  ○ Adults: same unit dose as total daily long or intermediate-acting insulin unit dose
	  ○ Pediatrics: 80% of total daily long or intermediate-acting insulin unit dose
	
	Type 2 diabetes mellitus: Initiation:
	• Insulin-naïve: 10 units SC QD
	• Already on insulin: SC QD:
	  ○ Adults: same unit dose as total daily long or intermediate-acting insulin unit dose
	  ○ Pediatrics: 80% of total daily long or intermediate-acting insulin unit dose
		Not applicable

insulin glargine-yfgn (Semglee)	**Type 1 diabetes mellitus:** Initiation: • Approximately one-third of the total daily insulin requirement administered SC QD **Type 2 diabetes mellitus:** Initiation: • Insulin-naïve: 0.2 units/kg SC QD or up to 10 units/day. Adjust dosage according to patient response	Not applicable

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): during episodes of hypoglycemia, hypersensitivity to insulin detemir or any of the excipients
- Boxed warning(s): none reported

Appendix D: General Information
- If switching to Levemir from other insulin therapies:
  - If converting from insulin glargine to Levemir, the change can be done on a unit-to-unit basis.

- If converting from NPH insulin, the change can be done on a unit-to-unit basis. However, some patients with type 2 diabetes mellitus may require more Levemir than NPH insulin.

Appendix E: Discontinuation of Levemir Products

- Novo Nordisk, manufacturer of Levemir, is no longer manufacturing Levemir due to manufacturing issues and availability of alternative treatments. Levemir FlexPen and vial were discontinued in December 2024, and Levemir FlexTouch was discontinued in February 2023.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Diabetes mellitus	**Type 1 diabetes mellitus:** • Initiation for insulin-naïve: Approximately one-third to one-half of the total daily insulin SC QD or divided BID. • Individualize starting dose based on type of diabetes and whether patient is insulin-naïve. Administer SC QD (with evening meal or at bedtime) or BID. **Type 2 diabetes mellitus:** • Initiation: 0.2 units/kg up to 10 units/day SC QD (with evening meal or at bedtime) or BID • Individualize starting dose based on type of diabetes and whether patient is insulin-naïve.	Not applicable

VI. Product Availability

- Single-patient-use FlexPen® prefilled pen: 3 mL containing 100 units/mL
- Multiple-dose vial: 10 mL containing 100 units/mL

VII. References

1. Levemir Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; December 2022. Available at: https://www.novo-pi.com/levemir.pdf. Accessed July 16, 2025.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed July 17, 2025.
3. What is Levemir. Novo Nordisk. Available at: https://www.levemir.com/. Accessed July 17, 2025.
4. ASHP Drug Shortages List. Available at: https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=907&loginreturnUrl=SSOCheckOnly. Accessed July 17, 2025.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3590	Unclassified biologics
C9399	Unclassified drugs or biologicals
S5553	Insulin, long acting; 5 units
S5571	Insulin delivery device, disposable pen (including insulin); 3 mL size

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per August SDC.	08.22.23	12.23
4Q 2024 annual review: no significant changes; references reviewed and updated.	07.30.24	11.24
Per August SDC, removed Basaglar redirection and added redirection to branded Semglee; added Semglee to Appendix B; for continued therapy requests, added redirection to preferred products.	08.22.24	12.24
Added disclaimer that Novo Nordisk discontinued Levemir products; added requirement for provider attestation acknowledging the discontinuation of Levemir products; added Appendix E regarding discontinuation of Levemir products.	01.30.25	
4Q 2025 annual review: added step therapy bypass for IL HIM per IL HB 5395; references reviewed and updated.	07.16.25	11.25
Per August SDC, removed redirection to branded Semglee and unbranded Tresiba from policy; added redirection to insulin glargine-yfgn (unbranded Semglee) and branded Tresiba.	08.20.25	12.25

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering

benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.