Clinical Policy: Insulin Degludec (Tresiba), Insulin Glargine (Semglee)

Reference Number: HIM.PA.09
Effective Date: 03.01.19
Last Review Date: 02.21
Line of Business: HIM

Revision Log

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

Description

Insulin degludec (Tresiba®) and insulin glargine (Semglee™) are long-acting human insulin analogs.

FDA Approved Indication(s)

Tresiba is indicated to improve glycemic control in patients 1 year of age and older with diabetes mellitus.

Semglee is indicated to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.

Limitation(s) of use: Tresiba and Semglee are not recommended for treating diabetic ketoacidosis.

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 Tresiba and Semglee are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of type 1 or type 2 diabetes mellitus;
2. Age ≥ 1 year;
3. Failure of Basaglar® and Levemir®, unless contraindicated or clinically significant adverse effects are experienced.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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.

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
Basaglar® (insulin glargine)	**Type 1 diabetes mellitus:** Initiation: Approximately one-third of the total daily insulin requirement administered SC QD **Type 2 diabetes mellitus:** Initiation: 0.2 units/kg SC QD up to 10 units/day. Adjust dosage according to patient response	Not applicable
Levemir® (insulin detemir)	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.	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): use during episodes of hypoglycemia, hypersensitivity to the requested product or one of its excipients
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Insulin degludec (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	Not applicable; dose is individualized and titrated based on metabolic needs, blood glucose monitoring results, and glycemic control goal
	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; dose is individualized and titrated based on metabolic needs, blood glucose monitoring results, and glycemic control goal
Insulin glargine (Semglee)	Type 1 diabetes mellitus	Initiation: Approximately one-third of the total daily insulin requirement administered SC QD	Not applicable
	Type 2 diabetes mellitus	Initiation: 0.2 units/kg SC QD or 10 units/day. Adjust dosage according to patient response	Not applicable

VI. Product Availability

Drug Name	Availability
Insulin degludec (Tresiba)	• Single-patient-use 3 mL FlexTouch® pens: 100 units/mL (U-100), 200 units/mL (U-200) • Multiple-dose 10 mL vial: 100 units/mL (U-100)
Insulin glargine (Semglee)	• Multiple-dose vial: 10 mL containing 100 units/mL • Prefilled pen: 3 mL containing 100 units/mL

VII. References

1. Tresiba Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; November 2019. Available at: www.tresiba.com. Accessed October 26, 2020.
2. Semglee Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; June 2020. Available at: https://www.semgleehcp.com/. Accessed January 19, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2019 Policy created	12.05.18	02.19
Per SDC and prior clinical guidance, added additional requirement for redirection to Levemir.	10.23.19	
1Q 2020 annual review: added requirement for trial of Levemir per SDC; references reviewed and updated.	10.24.19	02.20
Added Semglee to policy per October SDC and prior clinical guidance	10.08.20	
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.26.20	02.21

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.