

Clinical Policy: Insulin Degludec (Tresiba)

Reference Number: HIM.PA.09

Effective Date: 03.01.19

Last Review Date: 02.20

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[®]) is a long-acting human insulin analog.

FDA Approved Indication(s)

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

Limitation(s) of use: 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 is **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 \geq 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.PHAR.21 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.PHAR.21 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.PHAR.21 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 Tresiba or one of its excipients
- Boxed warning(s): none reported

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|--------------------------|--|---|
| Type 1 diabetes mellitus | Initiation: <ul style="list-style-type: none"> Insulin-naïve: 1/3 to 1/2 of total daily insulin dose SC QD Already on insulin: SC QD: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Insulin-naïve: 10 units SC QD Already on insulin: SC QD: <ul style="list-style-type: none"> 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 |

VI. Product Availability

- Single-patient-use 3 mL FlexTouch[®] pen: 100 units/mL (U-100), 200 units/mL (U-200)
- Multiple-dose 10 mL vial: 100 units/mL (U-100)

VII. References

- Tresiba Prescribing Information. Plainsboro, NJ: Novo Nordisk Inc.; November 2018. Available at: www.tresiba.com. Accessed September 24, 2019.

| 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 |

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.

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