Clinical Policy: Insulin degludec (Tresiba)

Reference Number: CP.PMN.285
Effective Date: 06.01.23
Last Review Date: 05.23
Line of Business: Medicaid

Coding Implications
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 the treatment of 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 ≥ 1 years;
3. If request is for brand Tresiba® or Tresiba FlexTouch Pen®, member must use unbranded insulin degludec or insulin degludec FlexTouch Pen, unless contraindicated or clinically significant adverse effects are experienced.*
   **Prior authorization may be required for insulin degludec and insulin degludec FlexTouch Pen*
4. If request is for unbranded insulin degludec or insulin degludec FlexTouch Pen, failure of two PDL insulin products, unless clinically significant adverse effects are experienced or all are contraindicated.

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 CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy CP.PMN.16 for Medicaid; 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 CP.PMN.53 for Medicaid.

II. Continued Therapy

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

1. 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)*;
2. 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 PDL (Medicaid), the no coverage criteria policy CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy CP.PMN.16 for Medicaid; 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 CP.PMN.53 for Medicaid.

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 – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list

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 (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

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 degludec or any of the excipients in Tresiba
- Boxed warning(s): None reported

Appendix D: General Information

- If switching to Tresiba from other insulin therapies:
  - Dose adjustments are recommended to lower the risk of hypoglycemia when switching patients to insulin degludec from another insulin therapy.
    - Adults with type 1 or type 2 diabetes mellitus: Start Tresiba at the same unit dose as the total daily long or intermediate-acting insulin unit dose.
    - Pediatric patients 1 year of age and older with type 1 or type 2 diabetes mellitus: Start Tresiba at 80% of the total daily long or intermediate-acting insulin unit dose to minimize the risk of hypoglycemia.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Type 1 diabetes mellitus	Initiation: One-third to one-half of the total daily insulin dose SC QD	Not applicable
Type 2 diabetes mellitus	Initiation: 10 units SC QD	Not applicable

VI. Product Availability

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

VII. References

1. Tresiba Prescribing Information. Plainsboro, NJ. Novo Nordisk Inc. July 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/203314s018s020lbl.pdf. Accessed February 24, 2023.

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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.21.23	05.23

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.