Clinical Policy: Insulin Glargine (Semglee, Toujeo)

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

Revision Log

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

Description

Insulin glargine (Semglee™, Toujeo®) is a long-acting human insulin analogs.

FDA Approved Indication(s)

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.

Toujeo is indicated to improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus.

Limitation(s) of use: Semglee and Toujeo 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 Semglee and Toujeo 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 ≥ 6 years;
3. Failure of Basaglar®, Levemir®, and Tresiba® unless clinically significant adverse effects are experienced or all are contraindicated.

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum 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	

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 glargine (Toujeo)	Type 1 diabetes mellitus	Initiation:
		• Insulin-naïve: 1/3 to 1/2 of total daily insulin dose SC QD
		• Already on insulin: SC QD:
		  ○ Once-daily long or intermediate insulin: same unit dose as total daily long acting insulin unit dose. Expect higher daily dose of Toujeo will be needed to maintain the same level of glycemic control in patients on Lantus.
		  ○ Twice-daily long or intermediate insulin: 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: 0.2 units/kg SC QD • Already on insulin: SC QD: ○ Once-daily long or intermediate insulin: same unit dose as total daily long acting insulin unit dose. Expect higher daily dose of Toujeo will be needed to maintain the same level of	Not applicable; dose is individualized and titrated based on metabolic needs, blood glucose monitoring results, and glycemic control goal

Drug Name	Indication	Dosing Regimen	Maximum Dose
		glycemic control in patients on Lantus. ○ Twice-daily long or intermediate insulin: 80% of total daily long or intermediate-acting insulin unit dose	
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 glargine (Toujeo)	Single-patient-use prefilled pen 300 units/mL: 1.5 mL (Toujeo SoloStar), 3 mL (Toujeo Max SoloStar)
Insulin glargine (Semglee)	• Multiple-dose vial: 10 mL containing 100 units/mL • Prefilled pen: 3 mL containing 100 units/mL

VII. References

1. Semglee Prescribing Information. Morgantown, WV: Mylan Specialty L.P.; June 2020. Available at: https://www.semgleehcp.com/. Accessed January 19, 2021.
2. Toujeo Prescribing Information. Bridgewater, NJ: Sanofi_Aventis U.S. LLC; December 2020. Available at: www.toujeo.com. Accessed October 28, 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
Per October SDC and prior clinical guidance, removed Tresiba from policy as PA is no longer required; add Toujeo to policy and revise redirection to require use of Basaglar, Levemir, and Tresiba; revised required age to 6 years or older consistent with Semglee and Toujeo prescribing information.	10.27.21	

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.

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