Clinical Policy Title:	insulin glargine
Policy Number:	RxA.355
Drug(s) Applied:	Basaglar®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
Line of Business Policy Applies to:	All lines of business

Background

Insulin glargine (Basaglar®) is a long-acting human insulin analog. It 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: It is not recommended for the treatment of diabetic ketoacidosis.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
insulin glargine (Basaglar®)	Type 1 diabetes mellitus	Initiation: Approximately one-third of the total daily insulin requirement administered subcutaneously once daily	Not applicable
	Type 2 diabetes mellitus	Initiation: 0.2 units/kg subcutaneously once daily or up to 10 units/day. Adjust dosage according to patient response	Not applicable

Dosage Forms

- KwikPen prefilled delivery device: 3 mL containing 100 units/mL
- Tempo Pen prefilled delivery device: 3 mL containing 100 units/mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

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

1. Diagnosis of type 1 or type 2 diabetes mellitus;
2. Member has contraindication to Lantus®, such as an allergy to a non-active ingredient.

Approval duration:

Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy.

Approval duration:
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Lantus® (insulin glargine)	**Type 1 diabetes mellitus:** Approximately one-third of the total daily insulin requirement subcutaneously once daily **Type 2 diabetes mellitus:** 0.2 units/kg subcutaneously once daily or 10 units/day initially. Adjust dosage according to patient response	Not applicable

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - During episodes of hypoglycemia;
  - Hypersensitivity to Basaglar® or one of its excipients;

- Boxed warning(s):
  - None reported.

APPENDIX D: General Information

- If changing patients from another insulin glargine 100 units/mL product (e.g., Lantus®) to Basaglar®, the dose of Basaglar® should be the same as the other insulin glargine product.
- If changing patients from a once-daily insulin glargine 300 units/mL product (e.g., Toujeo®) to once-daily Basaglar®, the recommended initial Basaglar® dosage is 80% of the insulin glargine product dose that is being discontinued.

References

1. Basaglar® Prescribing Information. Indianapolis, IN: Lilly USA, LLC. November 2019. Available at: www.Basaglar®.com Accessed May 29, 2021.

2. Lantus Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; January 2021. Available at: www.lantus.com. Accessed May 29, 2021.
3. Insulin glargine, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed May 29, 2021.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2021. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed May 29, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was updated to "All lines of business". 3. Dosage Forms was updated: "Tempo Pen" added. 4. Clinical policy was updated: Approval duration was updated from length of benefit to 12 months for both Initial and Continued Approval Criteria; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy…"; changed requirement of Lantus failure to contraindication 5. References were updated	06/13/2020	09/14/2020
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…’’ was added to Clinical Policy. 2. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has	05/29/2021	09/14/2021

been authorized by RxAdvance...". 3. Therapeutic Alternatives verbiage was rephrased to "Below are suggested therapeutic alternatives based on clinical guidance..". 4. Statement about drug listing format in Appendix B is rephrased to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand; Brand name® when the drug is available by brand only and generic name when the drug is available by generic only". 5. References were reviewed and updated.		