RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	insulin glargine
Policy Number:	RxA.355
Drug(s) Applied:	Basaglar®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
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 SC once daily	Not applicable
	Type 2 diabetes mellitus	Initiation: 0.2 units/kg SC once daily or 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.

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. 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

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
Lantus® (insulin glargine)	**Type 1 diabetes mellitus:** Approximately one-third of the total daily insulin requirement SC QD **Type 2 diabetes mellitus:** 0.2 units/kg SC QD or 10 units/day initially. Adjust dosage according to patient response	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):
  - o Use during episodes of hypoglycemia
  - o Hypersensitivity to Basaglar® or one of its excipients
- Boxed warning(s):
  - None

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 June 11, 2020 .
2. Lantus Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; May 2019. Available at: www.lantus.com. Accessed . June 13, 2019.

3. Insulin glargine, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed June 13, 2020.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed June 13, 2020.

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