RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	insulin glulisine
Policy Number:	RxA.589
Drug(s) Applied:	Apidra®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Insulin glulisine (Apidra®) is a rapid-acting human insulin analog. Apidra® is indicated to improve glycemic control in adults and children with diabetes mellitus.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Insulin glulisine (Apidra®)	Diabetes mellitus	Individualized dose based on route of administration, individual's metabolic needs, blood glucose monitoring results, and glycemic control goal. SC or IV*: Inject within 15 minutes before a meal or within 20 minutes after starting a meal. Continuous SC Infusion: Administer using insulin pump in region recommended by pump manufacturer.	Not applicable

*If IV: use at concentrations of 0.05 units/mL to 1 unit/mL in 0.9% NaCl; administer under medical supervision in a clinical setting for glycemic control.

Dosage Forms

100 units/mL (U-100) injection available as:

- 10 mL multi-dose vial
- SoloStar® prefilled pen: 3 mL/pen (5 pens/package)

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 had inappropriate treatment response or intolerance to Humalog or a Humalog Mix insulin;
3. Prescribed in combination with a longer-acting basal insulin analog (e.g., insulin NPH, insulin glargine).

Approval Duration
Commercial: 6 months
Medicaid: 6 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
Humalog®
Humalog® KwikPen
Humalog® Junior KwikPen

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Use during episodes of hypoglycemia.
  - Hypersensitivity to Apidra® or any of its excipients.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- There are no studies to support the use of Apidra® for treatment of obesity.
- Apidra® may be infused by external insulin infusion pumps.
- Changes in an insulin regimen (e.g., insulin, insulin strength, manufacturer, type, injection site or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; a sudden change in the injection site (to unaffected area) has been reported to result in hypoglycemia.
- Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. For patients with type 2 diabetes, dosage adjustments in concomitant oral antidiabetic treatment may be needed.

References

1. Apidra® Prescribing Information. Bridgewater, NJ: Sanofi-Aventis; November 2019. Available at: www.apidra.com.

Accessed October 30, 2020.
2. American Diabetes Association. Standards of medical care in diabetes—2020. Diabetes Care. 2020; 43(Suppl 1): S1-S212. Accessed October 30, 2020.
3. Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2019 executive summary. Endocr Pract. 2019; 25(1): 69-204. Accessed October 30, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. Line of business policy applies to was updated to “all lines of business”. 2. Dosing information section updated to include more specific information for routes of administration. 3. Dosage forms section updated for clarity. 4. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. Approval duration for Medicaid was added to initial and continued therapy approval criteria. 6. Appendix D was updated to include details about administration and monitoring. 7. References were updated.	10/30/2020	12/07/2020