

Commercial/Healthcare Exchange PA Criteria Effective: February 2013

Prior Authorization: Insulins

<u>Products Affected</u>: Admelog, Apidra, Apidra Solostar, Fiasp/Fiasp FlexTouch, Fiasp PenFill, Fiasp Pumpcart, Novolin and Novolog insulins (pens and vials), Insulin lispro kwikpen, Insulin lispro, Insulin lispro junior kwikpen, insulin lispro protamine mix, Insulin Lispro Mix 75-25 Kwikpen

Medication Description: Insulin lowers blood glucose levels by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis in the adipocyte, inhibits proteolysis, and enhances protein synthesis. Insulin, secreted by the beta cells of the pancreas, is the principal hormone required for proper glucose use in normal metabolic processes. Insulin analogues can be described as rapid acting (insulin lispro, insulin aspart, and insulin glulisine), short acting (regular insulin), intermediate acting (insulin isophane), or long acting (insulin glargine, insulin detemir, insulin degludec). The rapid-acting insulin analogues act faster than regular insulin and have a lower risk of hypoglycemia. Both insulin lispro and insulin aspart are available in mixtures with protamine. The addition of protamine increases the duration of insulin action. However, these mixtures do not mimic normal physiologic processes and are less effective than a regimen that involves a rapid-acting insulin plus a long-acting insulin analogue.

Covered Uses: Treatment of type 1 diabetes mellitus and type 2 diabetes mellitus to improve glycemic control

Exclusion Criteria:

- 1. Episodes of hypoglycemia
- 2. Hypersensitivity to insulin lispro, insulin aspart, Insulin Glulisine, or any component of the formulation

Required Medical Information:

- 1. Fasting blood glucose levels
- 2. History of previous insulin therapy tried/failed
- 3. Hgb A1C value(s)

Age Restrictions: N/A

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

1. Patient has had a trial and failure of Humulin or Humalog

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- a. Failure to control Hgb A1c and fasting blood glucose levels; OR
- 2. Patient has an intolerance or contraindication to a Humulin or Humalog, defined as (but not limited to):
 - a. Allergic reaction; OR
 - b. Adverse drug reactions.

References:

- 1. Product Information: Humalog® subcutaneous injection, intravenous injection, insulin lispro rDNA origin subcutaneous injection, intravenous injection. Lilly USA, LLC (per FDA), Indianapolis, IN, 2015.
- 2. Product Information: HUMULIN® 70/30 subcutaneous injection suspension, human insulin isophane 70% human insulin 30% rDNA origin subcutaneous injection suspension. Lilly USA, LLC (per FDA), Indianapolis, IN, 2015.
- 3. Product Information: NovoLog® subcutaneous injection solution, insulin aspart rDNA origin subcutaneous injection solution. Novo Nordisk Inc. (per FDA), Plainsboro, NJ, 2015.
- 4. Product Information: APIDRA® subcutaneous injection solution, intravenous injection solution, insulin glulisine rDNA origin subcutaneous injection solution, intravenous injection solution. Sanofi-Aventis U.S. LLC (per FDA), Bridgewater, NJ, 2015.
- 5. FIASP® subcutaneous, intravenous injection, insulin aspart subcutaneous, intravenous injection. Novo Nordisk Inc (per manufacturer), Plainsboro, NJ, 2017.
- 6. Lyumjev [®] subcutaneous injection, intravenous injection, insulin lispro-aabc subcutaneous injection, intravenous injection. Eli Lilly and Company (per manufacturer), Indianapolis, IN, 2020.

Policy Revision history

Rev#	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/2013





		Moved to new template	Added Products affected: Insulin lispro kwikpen, Insulin	
		Added products affected	lispro, Insulin lispro junior kwikpen, insulin lispro	
2	Update	Added medication description	protamine mix, Insulin Lispro Mix 75-25 Kwikpen	04/22/2020
		Exclusion criteria added		
		Added Covered uses	Exclusion criteria: Added	
		Added Covered uses	Ezpisodes of hypoglycemia, and	
			Hypersensitivity to insulin lispro.	
3	Update	Added products affected	Added Products affected:	09/02/2020
			Lyumjev (vial, KwikPen Junior	
			KwikPen, Tempo Pen,	
4	Update	Removed product	Lyumjev (vial, KwikPen Junior	01/01/2022
			KwikPen, Tempo Pen,	
5	Update	Added products affected	Added Fiasp PenFill, Fiasp	10/17/2023
			Pumpcart	