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Medication Policy Manual

Policy No: dru372

Topic: Non-Preferred Injectable Insulins

- Apidra®
- Apidra SoloStar®
- Fiasp®
- Novolin N®
- Novolin R®
- Novolin® Mix 70/30
- NovoLog®
- NovoLog® FlexPen
- NovoLog® Mix 70/30
- NovoLog® Mix 70/30 FlexPen

Date of Origin: November 13, 2014

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Next Review Date: July 2018

Effective Date: October 12, 2017

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Injectable insulins are used to improve glycemic control in patients with type 1 or type 2 diabetes mellitus. They help stimulate peripheral glucose uptake by skeletal muscle and fat, and inhibit the production of glucose from the liver. This policy does not apply to Levemir®.

Policy/Criteria

I. Most contracts require prior authorization approval of non-preferred injectable insulins prior to coverage (*See Appendix 1*). Non-preferred injectable insulins may be considered medically necessary in patients with type 1 or type 2 diabetes mellitus when treatment with a preferred injectable insulin manufactured by Eli Lilly (*See Appendix 1*) is contraindicated, not tolerated, or ineffective in reducing A1C to goal of 7% or less after 90 days of therapy.

II. Administration, Quantity Limitations, and Authorization Period

A. Regence Pharmacy Services considers non-preferred injectable insulins to be self-administered medications.

B. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement [1,2]

Summary

- There are no clinical differences between one brand of injectable insulin over another within each formulation. Preferred insulin products manufactured by Eli Lilly provide the best value.
  * There is no evidence that any injectable insulin is safer or more effective than another for reducing A1C or the risk of long-term complications.[3-5]
  * All insulin products have an extensive track record of clinical safety experience, having been on the market for over 10 years.
  * Insulin products manufactured by Eli Lilly have a similar pharmacokinetic profile to that of non-preferred insulin products (*See Appendix 2*).
- Insulin therapy is the mainstay of treatment in type 1 diabetes mellitus (T1DM), and is a second line treatment option in type 2 diabetes mellitus (T2DM) when metformin and lifestyle interventions are ineffective in maintaining glycemic control.
- Current national and international treatment guidelines do not recommend one brand of injectable insulin over another within each formulation.

Goals of Treatment

The American Diabetes Association has set an A1C treatment goal for patients with diabetes to not exceed 7% [1,3] .

- Lowering A1C to below or around 7% has been shown to reduce microvascular and neuropathic complications of T1DM and T2DM [3].
- Large-scale, randomized controlled trials have failed to find a significant long-term benefit of intensive glycemic control (A1C goal of less than 6.5%) for lowering cardiovascular (macrovascular) risk [4-6].
- Intensive glycemic control (A1C goals less than 6.5%) may increase mortality in some patients.

- The American Association of Clinical Endocrinologists (AACE) treatment guidelines suggest an A1C treatment target for patients with diabetes of 6.5%. However, this goal must be customized for the individual patient in consideration of factors such as comorbid conditions, duration of diabetes, history of hypoglycemia, hypoglycemia unawareness, patient education, motivation, adherence, age, limited life expectancy, and use of other medications [7].

Appendix 1: Injectable Insulin Products

Preferred Insulin Products (Eli Lilly)	Non-Preferred Insulin Products
Rapid Acting	
insulin lispro (Humalog®)	insulin aspart (Novolog®) insulin aspart (Fiasp®) insulin glulisine (Apidra®)
Short Acting	
insulin regular (Humulin® R)	insulin regular (Novolin R®)
Intermediate Acting	
insulin isophane (Humulin N)	insulin isophane (Novolin N)
Pre-mixed	
insulin lispro protamine/insulin lispro (Humalog Mix 50/50, Humalog Mix 75/25)	insulin aspart protamine/insulin aspart (Novolog Mix 70/30)
insulin isophane/insulin regular (Humulin Mix 70/30)	insulin isophane/insulin regular (Novolin Mix 70/30)

Appendix 2: Pharmacokinetic properties of Injectable Insulin Products [2,8,9]

Insulin	Brand	Onset	Peak	Duration of Action
Rapid-Acting insulin				
Lispro	Humalog®	5-15 mins	30-120 mins	< 5 hours
Aspart	Novolog®	5-15 mins	30-120 mins	< 5 hours
Glulisine	Apidra®	5-15 mins	60 minutes	< 4 to 12 hours
Short-Acting insulin				
Regular	Humulin® R	30-60 mins	2-3 hours	5 – 8 hours
	Novolin® R			
Intermediate –Acting insulin				
NPH	Humulin N	1 – 4 hours	4-10 hours	10-18 hours
	Novolin N			
Long-Acting insulin				
Glargine	Lantus	1 hour	No significant peak	10.8 – 24 hours
Detemir	Levemir	1-2 hours	No significant peak	7.6 – 24 hours
Premixed insulin				
NPH/regular	Humulin 70/30	30-60 mins	Dual	10-16 hours
	Novolin 70/30			
Lispro protamine /lispro	Humalog Mix 75/25	5-15 mins	Dual	10-16 hours
Aspart protamine /aspart	Novolog Mix 70/30	5-15 mins	Dual	10-16 hours

Codes	Number	Description
N/A		

Cross References
Afrezza, inhaled insulin, dru371

References

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8. Lantus® [package insert]. Bridgewater, NJ: sanofi-aventis U.S. LLC.; October 2013. Bridgewater, NJ: sanofi-aventis U.S. LLC.; July 2015
9. Levemir® [package insert]. Plainsboro, NJ: Novo Nordisk Inc; February 2015

Revision History

Revision Date	Revision Summary
10/12/2017	Added Fiasp to policy.
07/14/2017	No criteria changes with this annual update
05/13/2016	No changes to coverage criteria with this annual update