

Clinical Pharmacy Program Guidelines for Insulins

Program	Prior Authorization
Medication	Insulins
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	6/2017
Effective Date	8/2017

1. Background:

FDA Approved Indications

1. Diabetes Mellitus

Insulin is indicated for the treatment of diabetes mellitus for the control of hyperglycemia.

2. Coverage Criteria:

Preferred, Open Access Insulins:		Clinical Criteria
TOUJEO SOLO INJ 300IU/ML	PEN	Open Access, no clinical criteria
BASAGLAR KWIKPEN INJ 100U/ML	PEN	
HUMULIN R INJ U-100	VIAL	
NOVOLIN R INJ U-100	VIAL	
HUMULIN N INJ U-100	VIAL	
NOVOLIN N INJ U-100	VIAL	
NOVOLOG INJ 100/ML	VIAL	
HUMALOG INJ 100/ML	VIAL	
NOVOLOG MIX INJ 70/30	VIAL	
HUMALOG MIX SUS 75/25	VIAL	
HUMALOG MIX INJ 50/50	VIAL	
HUMULIN INJ 70/30	VIAL	
NOVOLIN INJ 70/30	VIAL	

Non-Preferred, Short and Intermediate Insulin Vial Products:		Clinical Criteria
APIDRA INJ U-100	VIAL	History of failure, intolerance, or contraindication to a majority (not more than 3) of the preferred
HUMULIN R INJ U-500	VIAL	

		alternatives
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Non-Preferred, Short and Intermediate Insulin Pen Products:		Clinical Criteria
APIDRA INJ SOLOSTAR	PEN	<p><u>One</u> of the following:</p> <p>a. A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin; OR</p> <p>b. A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin; OR</p> <p>c. History of failure, intolerance, or contraindication to a majority (not more than 3) of the preferred alternatives; OR</p> <p>d. The patient is unable to use the vial dosage form of the drug due to documented poor compliance with vials and syringes resulting in poorly controlled diabetes based on A1C</p>
HUMALOG INJ 100/ML	CARTRIDGE	
NOVOLOG INJ FLEXPEN	PEN	
HUMALOG KWIK INJ 100/ML	PEN	
HUMALOG KWIK INJ 200/ML	PEN	
HUMULIN N INJ U-100KWP	PEN	
NOVOLOG MIX INJ FLEXPEN	PEN	
HUMALOG MIX INJ 75/25KWP	PEN	
HUMALOG MIX INJ 50/50KWP	PEN	
HUMULIN INJ 70/30KWP	PEN	
HUMULIN R U-500 KWIKPEN	PEN	

Non-Preferred, Long Acting Insulin Pen Products:		Clinical Criteria
LANTUS INJ SOLOSTAR	PEN	History of failure, intolerance, or contraindication to Toujeo Solostar or Basaglar KwikPen
LEVEMIR INJ FLEXTUOC	PEN	
TRESIBA FLEX INJ 100UNIT	PEN	
TRESIBA FLEX INJ 200UNIT	PEN	

Non-Preferred, Long Acting Insulin Vial Products:		Clinical Criteria
LEVEMIR INJ	VIAL	History of failure, intolerance, or contraindication to Toujeo Solostar or Basaglar KwikPen
LANTUS INJ 100-U/ML	VIAL	

If the above criteria are met, authorization of therapy will be issued for 12 months

3. REFERENCES

1. Lantus™ Prescribing Information. Sanofi-Aventis, August 2015.
2. Levemir™ Prescribing Information. Novo-Nordisk Inc., February 2015.
3. Novolin 70/30™ Prescribing Information. Novo-Nordisk Inc., January 2016.
4. Novolin N™ Prescribing Information. Novo-Nordisk Inc., February 2015.
5. Novolin R™ Prescribing Information. Novo-Nordisk Inc., January 2016.
6. Novolog™ Prescribing Information. Novo-Nordisk Inc., March 2017.
7. Novolog Mix 70/30™ Prescribing Information. Novo-Nordisk Inc., May 2017.
8. Toujeo Prescribing Information. Sanofi-Aventis, September 2015.
9. Basaglar Prescribing Information. Lilly, July 2016.

Program	Prior Authorization- Insulins
Change Control	
Date	Change
9/2009	Criteria taken from previously approved AmeriChoice policy. Policy reformatted.
6/2010	Added pediatric criteria under B.1 and B.2
3/2011	Annual Review
3/2012	Annual Review
3/2013	Annual Review
12/2015	<p>Changed name of policy to “Insulins” because the criteria now has a step therapy for Lantus Vials.</p> <p>Replaced existing formulary grid with an updated grid to specifically show the PDL status of each insulin and by type of device.</p> <p>Criteria sections A and B: Changed “formulary” to “Non-Preferred” as this section of the criteria is intended to review non-preferred pens or prefilled cartridges</p> <p>Added new Lantus Step Therapy criteria</p> <p>Updated reference with Toujeo</p>

4/2016	<p>Updated the step therapy requirements for non-preferred pre-filled insulin syringe, pen, or cartridge. Also added non-preferred insulin vials criteria for adults and pediatric patients.</p> <p>Reformatted the policy so that each type of insulin product is in its own section.</p> <p>Updated policy template.</p>
9/2016	<p>Updated clinical criteria for Non-Preferred, Long Acting Insulin Pen Products to include a trial/failure of Toujeo Solostar and one of the following: visual impairment, physical disability, or poor compliance</p>
11/2016	<p>Added Basaglar as open access. Moved Lantus vial to Non-Preferred, Long Acting Insulin Vial Products Section. Updated Non-Preferred, Long Acting Insulin Vial and Pen Products to include history of failure, intolerance, or contraindication to Toujeo Solostar or Basaglar KwikPen. Removed visual impairment, physical disability, or unable to use a vial from Non-Preferred, Long Acting Insulin Pen Products. Added Humulin R U-500 KwikPen to policy.</p>
6/2017	<p>Updated references and policy template</p>