UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Insulins

Program	Prior Authorization
Medication	Insulins
Markets in Scope	California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2009
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

FDA Approved Indications

Diabetes Mellitus

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

Preferred, Open Access Insulins	
Basaglar Kwikpen injection 100U/ML	PEN
Semglee injection 100U/ML	VIAL AND PEN
Humulin R injection 100U/ML	VIAL
Novolin R injection 100U/ML	VIAL
Novolin R Relion injection 100U/ML	VIAL
Humulin N injection 100U/ML	VIAL
Novolin N injection 100U/ML	VIAL
Novolin N Relion injection 100U/ML	VIAL
Insulin aspart protamine 70%/insulin aspart 30% (generic Novolog Mix injection 70/30 100U/ML)	VIAL
Humalog Mix injection 75/25 100U/ML	VIAL
Humalog Mix injection 50/50 100U/ML	VIAL
Humulin injection 70/30 100U/ML	VIAL
Novolin injection 70/30 100U/ML	VIAL
Novolin Relion injection 70/30 100U/ML	VIAL
Ademelog injection 100U/ML 100U/ML	VIAL

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2. Coverage Criteria:

Preferred with Step Therapy		**Clinical Criteria**
Admelog Solostar 100U/ML	Pen	**<u>One</u>** of the following: a. A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin; **OR** 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** c. History of failure to Admelog vial as demonstrated by poorly controlled diabetes based on hemoglobin A1c; **OR** 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 hemoglobin A1c

Non-Preferred, Rapid-Acting Insulin Vial Products: **Note: For Humalog or Novolog vials (BRAND NECESSARY) see next two sections**		**Clinical Criteria**
Apidra injection 100U/ML	Vial	History of failure, contraindication, or intolerance to Admelog vial
Insulin Aspart 100U/ML	Vial	
Fiasp injection 100U/ML	Vial	
Insulin Lispro injection 100U/ML	Vial	

Non-Preferred, Rapid-Acting Insulin Vial Products- HUMALOG VIAL (BRAND NECESSARY ONLY)		Clinical Criteria
Humalog injection 100U/ML	Vial	1. History of failure, contraindication, or intolerance to **both** of the following: a. Admelog vial b. Insulin Lispro vial (authorized generic for Humalog vial)

Non-Preferred, Rapid-Acting Insulin Vial Products- NOVOLOG VIAL (BRAND NECESSARY ONLY)		Clinical Criteria
Novolog injection 100U/ML	Vial	1. History of failure, contraindication, or intolerance to **both** of the following: a. Admelog vial b. Insulin Aspart vial (authorized generic of Novolog vial)

Non-Preferred, Insulin Mix Vial Products - NOVOLOG MIX VIAL (BRAND NECESSARY ONLY):		Clinical Criteria
Novolog Mix injection 70/30 100U/ML	Vial	1. History of failure, contraindication, or intolerance to the following: a. Insulin Aspart mix vial (authorized generic of Novolog Mix vial)

Non-Preferred, Short Acting Insulin Vial Products:		Clinical Criteria
Humulin R injection 500U/ML	Vial	Patient requires more than 200 units of insulin per day

Non-Preferred, Rapid-Acting Insulin Pen Products: Note: For Humalog or Novolog pens and cartridges (BRAND NECESSARY) see next two sections		Clinical Criteria
Apidra Solostar 100U/ML	Pen	1. **Both** of the following: a. **One** of the following:
Insulin Aspart injection penfill 100U/ML	Cartridge	

Insulin Aspart Flexpen 100U/ML	Pen	(1) History of failure, contraindication, or intolerance to Admelog vial **-OR-** (2) **<u>One</u>** of the following: • A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin • A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin • 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 hemoglobin A1c **-AND-** b. History of failure, contraindication, or intolerance to Admelog Solostar
Insulin Lispro Kwikpen 100U/ML	Pen	
Fiasp Flextouch 100U/ML	Pen	

Non-Preferred, Rapid-Acting Insulin Vial Products- HUMALOG PEN AND CARTRDIGE (BRAND NECESSARY ONLY)		**Clinical Criteria**
Humalog injection 100U/ML	Cartridge	1. History of failure, contraindication, or intolerance to **<u>both</u>** of the following: • Admelog Solostar • Insulin Lispro Kwikpen (authorized generic for Humalog Kwikpen)
Humalog Kwikpen 100U/ML	Pen	
Humalog Kwikpen 200U/ML	Pen	

Non-Preferred, Rapid-Acting Insulin Vial Products- NOVOLOG PENFILL	**Clinical Criteria**

AND FLEXPEN (BRAND NECESSARY ONLY)		
Novolog injection penfill 100U/ML	Cartridge	1. History of failure, contraindication, or intolerance to **both** of the following: • Admelog Solostar • Insulin Aspart pen or cartridge (authorized generic of Novolog Flexpen)
Novolog Flexpen 100U/ML	Pen	

Non-Preferred, Short Acting Insulin Pen Products:		Clinical Criteria
Humulin R Kwikpen 500U/ML	Pen	a. **One** of the following: (1) **Both** of the following: • Patient requires more than 200 units of insulin per day • History of failure, contraindication, or intolerance to Humulin R U-500 vial **-OR-** (2) **Both** of the following: (a) **One** of the following: • A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin • A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin • 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 hemoglobin A1c **-AND-**

		(b) Patient requires more than 200 units of insulin per day

Non-Preferred, Intermediate-Acting Insulin Pen Products:		**Clinical Criteria**
Humulin N Kwikpen 100U/ML	Pen	a. **<u>One</u>** of the following: (1) History of failure, contraindication, or intolerance to **<u>one</u>** of the following: • Humulin N U-100 vial • Novolin N U-100 vial **-OR-** (2) **<u>One</u>** of the following: • A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin • A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin • 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 hemoglobin A1c

Non-Preferred, Insulin Mix Pen Products: **Note: For Novolog Mix pen (BRAND NECESSARY) see next section**		**Clinical Criteria**
Humalog Mix Kwikpen 75/25 100U/ML	Pen	One of the following: (1) History of failure, contraindication, or intolerance to the corresponding preferred insulin mix vial
Humalog Mix Kwikpen 50/50 100U/ML	Pen	
Insulin Aspart Flexpen 70/30 100U/ML	Pen	

Humulin Kwikpen 70/30 100U/ML	Pen	**-OR-** (2) **One** of the following: • A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin • A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin • 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 hemoglobin A1c
Novolin Flexpen 70/30 100U/ML	Pen	

Non-Preferred, Insulin Mix Pen Products:- NOVOLOG MIX FLEXPEN (BRAND NECESSARY ONLY)		**Clinical Criteria**
Novolog Mix Flexpen 70/30 100U/ML	Pen	One of the following: (1) History of failure, contraindication, or intolerance to the corresponding preferred insulin mix vial **-OR-** (2) **Both** of the following: a. **One** of the following: • A visual impairment that prevents the patient from using a vial and syringe to accurately draw up the dose of insulin • A physical disability or handicap that prevents the patient from using a vial and syringe to draw up the dose and administer the insulin

		• 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 hemoglobin A1c **-AND-** b. History of failure, contraindication, or intolerance to Insulin Aspart Flexpen 70/30 100U/ML (Authorized generic of Novolog Mix Flexpen)

Non-Preferred, Insulin Glargine Pen Products:		**Clinical Criteria**
Lantus Solostar 100U/ML	Pen	One of the following: (1) History of failure, intolerance, or contraindication to **both** Basaglar KwikPen and Semglee (pens or vials) **-OR-** (2) **Both** of the following: a. The request is for Toujeo Solostar 300 iu/ml b. The provider has given clinical justification why the patient needs a concentrated formulation
Toujeo Solostar 300 IU/ML	Pen	

Non-Preferred, Long Acting Insulin Pen Products:		**Clinical Criteria**
Levemir Flextouch 100U/ML	Pen	One of the following: (1) History of failure, intolerance, or contraindication to Basaglar KwikPen or Semglee (pens or vials)
Tresiba Flextouch 100U/ML	Pen	
Tresiba Flextouch 200U/ML	Pen	

		-OR- (2) **Both** of the following: a. The request is for Tresiba Flextouch 200 iu/ml b. The provider has given clinical justification why the patient needs a concentrated formulation

Non-Preferred, Insulin Glargine Vial Products:		**Clinical Criteria**
Lantus injection 100U/ML	Vial	History of failure, intolerance, or contraindication to **both** Basaglar KwikPen and Semglee (pens or vials)

Non-Preferred, Long Acting Insulin Vial Products:		**Clinical Criteria**
Levemir injection 100U/ML	Vial	History of failure, intolerance, or contraindication to Basaglar KwikPen or Semglee (pens or vials)
Tresiba injection 100U/ML	Vial	

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

Quantity Limits
Quantity requests exceeding the limited amount will be approved based on physician confirmation that the patient requires a greater quantity due to poorly controlled diabetes based on blood glucose and/or hemoglobin A1c. **Authorization will be issued for 12 months**

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. REFERENCES

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3. Novolin 70/30 [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
4. Novolin N [package 2019]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
5. Novolin R [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
6. Novolog [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
7. Novolog Mix 70/30 [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
8. Toujeo [package insert]. Bridgewater, NJ: Sanofi-Aventis; December 2019.
9. Basaglar [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
10. Admelog [package insert]. Bridgewater, NJ: Sanofi-Aventis; November 2019.
11. Fiasp [package insert]. Plainsboro, NJ: Novo Nordisk; December 2019.
12. Humulin R [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
13. Humulin N [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
14. Humulin 70/30 [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
15. Humalog Mix 75/25 [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
16. Humalog Mix 50/50 [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
17. Humalog [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
18. Tresiba [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
19. Apidra [package insert]. Bridgewater, NJ: Sanofi-Aventis; November 2019.
20. Humulin R U-500 [package insert]. Indianapolis, IN: Eli Lilly; November 2019.
21. Insulin Lispro [package insert]. Indianapolis, IN: Eli Lilly; February 2020.
22. Insulin Aspart [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
23. Insulin Aspart Protamine and Insulin Aspart [package insert]. Plainsboro, NJ: Novo-Nordisk Inc.; November 2019.
24. Semglee [package insert]. Morgantown, WV: Mylan Specialty L.P.; June 2020.

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	Changed name of policy to “Insulins” because the criteria now has a step therapy for Lantus Vials. Replaced existing formulary grid with an updated grid to specifically show the PDL status of each insulin and by type of device. 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 Added new Lantus Step Therapy criteria Updated reference with Toujeo
4/2016	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. Reformatted the policy so that each type of insulin product is in its own section. Updated policy template.
9/2016	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
11/2016	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.
6/2017	Updated references and policy template
4/2018	Added Admelog vial/Solostar and Fiasp products to the policy. Moved open access insulin table to background. Updated preferred products. Added review criteria for Admelog Solostar. Revised criteria for short-acting pen products. Updated references.
9/2018	Added Novolog Penfill to the policy.

10/2018	Updated policy to reflect Toujeo will be non-preferred on 1/1/19. Moved Humulin N and Insulin Pen Mixes into their own section of the policy. Added Novolin Relion products to the policy. Separated rapid, short and intermediate acting products into their own categories.
1/2019	Updated Humulin R U-500 vial and pen criteria to remove the step through Humulin R U-100 or Novolin-R U 100 vial.
6/2019	Added Tresiba vials to the policy. Updated references.
9/2019	Added Insulin Lispro authorized brand alternative to the policy.
4/2020	Updated criteria to reflect that the brand formulations of Novolog and Novolog mix products require a step through the authorized generic. Updated references.
7/2020	Updated criteria to clarify that step through the authorized generic formulations applies to brand necessary requests.
12/2020	Added Semglee to the policy as a preferred medication. Updated trial and failure language for non-preferred long acting insulins. Updated references.