UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3050-14
Program	Step Therapy – Insulin
Medication	Apidra® (insulin glulisine)*, Apidra SoloStar® (insulin glulisine)*, Fiasp® (insulin aspart)*, Novolin® N (NPH, human insulin isophane)*, Novolin R (regular, human insulin)*, Novolin 70/30 (70% NPH, human insulin isophane and 30% regular, human insulin)*, Novolog® (insulin aspart)*, Novolog Mix 70/30 (70% insulin aspart protamine and 30% insulin aspart)*
P&T Approval Date	12/2014, 10/2015, 10/2016, 10/2017, 5/2018, 10/2018, 6/2019, 6/2020, 2/2021, 2/2022, 2/2023, 11/2023
Effective Date	2/1/2024

1. Background:

The American Diabetes Association recommends insulin therapy for Type II diabetes when the appropriate step wise non-insulin approach has failed to lower HbA1c. In Type I diabetes insulin monotherapy is the appropriate treatment. The ADA does not differentiate between brands of insulin but does make recommendations for the initiation of basal insulins or intermediate to short acting insulins.

2. Coverage Criteria[a,b]:

A. **Novolin 70/30*** will be approved based on the following criteria:

1. History of failure after at least a three month trial[c], contraindication, or intolerance (list reason for therapeutic failure, contraindication, or intolerance) to Humulin 70/30

B. **Apidra*, Apidra Solostar*, or Novolog*** pens and vials will be approved based on the following criteria:

1. History of failure after at least a three month trial[c], contraindication, or intolerance (list reason for therapeutic failure, contraindication, or intolerance) to Humalog* or Insulin Lispro (unbranded Humalog)

C. **Fiasp*** pens and vials will be approved based on the following criteria:

1. History of failure after at least a three month trial[c], contraindication, or intolerance (list reason for therapeutic failure, contraindication, or intolerance) to **BOTH** of the following:

(1) Humalog* or Insulin Lispro (unbranded Humalog)
(2) Lyumjev

D. **Novolin N*** will be approved based on the following criteria:

1. History of failure after at least a three month trial[c], contraindication, or intolerance (list reason for therapeutic failure, contraindication, or intolerance) to Humulin N

E. **Novolin R*** will be approved based on the following criteria:

1. History of failure after at least a three month trial[c], contraindication, or intolerance (list reason for therapeutic failure, contraindication, or intolerance) to Humulin R

F. **Novolog Mix 70/30*** pens and vials will be approved based on the following criteria:

1. History of failure after at least a three month trial[c], contraindication, or intolerance (list reason for therapeutic failure, contraindication, or intolerance) to Humalog 75/25

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

[b] In Florida, Maine, and Tennessee only, diabetes medications may be approved based on both of the following: 1) Provider attests use of this product is medically necessary; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

[c] For Connecticut business, only a 60-day trial will be required. For Kentucky and Mississippi business, only a 30-day trial will be required.

* Apidra, Apidra SoloStar, Fiasp, Humalog vials (Humalog cartridge, Jr Pen and KwikPen not included), Novolin N, Novolin R, Novolin 70/30, Novolog, and Novolog Mix 70/30 are typically excluded from coverage.

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:

1. Novolog [package insert]. Plainsboro, NJ: Novo Nordisk Inc. February 2023.
2. Novolin 70/30 [package insert]. Plainsboro, NJ: Novo Nordisk Inc. November 2022.
3. Apidra [package insert]. Bridgewater, NJ: Sanofi Aventis. November 2022.
4. American Diabetes Association. Standard of Medical Care in Diabetes- 2022. *Diabetes Care* 2022;45 (Supplement 1)

5. Novolin N [package insert]. Plainsboro, NJ: Novo Nordisk Inc. November 2022.
6. Novolin R [package insert]. Plainsboro, NJ: Novo Nordisk Inc. November 2022.
7. Fiasp [package insert]. Plainsboro, NJ: Novo Nordisk Inc. June 2023.
8. Novolog Mix [package insert]. Plainsboro, New Jersey: Novo Nordisk Inc.; February 2023.

Program	Step Therapy- Insulin
Change Control	
12/2014	New program
10/2015	Added authorization period. Separated out Novolog Mix 70/30 criteria. Added Maryland Continuation of Care
7/2016	Added Indiana and West Virginia coverage information.
10/2016	Removed Humulin from step one agents for Novolin 70/30. Administrative changes.
2/2017	Administrative change. Oxford effective date updated.
10/2017	Added Fiasp to criteria. State mandate reference language updated. References updated.
5/2018	Added statement that Fiasp is typically excluded from coverage.
10/2018	Retire program for 1/1/2019.
6/2019	Program re-implemented. Updated to note all targeted products are typically excluded from coverage. Updated references.
6/2020	Annual Review. Updated references.
2/2021	Updated criteria for Fiasp to require a trial of both Humalog and Lyumjev for patients 18 years old and older.
8/2021	Administrative change to add Oxford effective date.
2/2022	Annual review. Updated references. Added Florida, Maine, and Tennessee mandate language. Updated state mandate language for CT and KY.
2/2023	Updated criteria for Fiasp to require trial of Humalog and Lyumjev for all ages. Updated state mandate language for Mississippi. Updated references.
11/2023	Updated trial and failure of Humalog to include Insulin Lispro (unbranded Humalog). Updated references.