MEDICAL MUTUAL®

Drug Policy

Policy:	Insulin (Rapid-Acting) Preferred Step Therapy Policy	Annual Review Date: 11/21/2024
Impacted Drugs:	• Lyumjev Tempo®	Last Revised Date: 11/21/2024

OVERVIEW

The rapid-acting insulin analogs are indicated for the **management of hyperglycemia** in adults and pediatric patients with diabetes mellitus.[1-9]

POLICY STATEMENT

A step therapy program has been developed to encourage the use of a Humalog product prior to the use of an Apidra, Admelog, Fiasp, Novolog product. If the preferred step therapy rule is not met for a non-preferred agent at the point of service, coverage will be determined by the preferred step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Preferred Medications

- Humalog® (insulin lispro injection – Lilly [U-100 and U-200], authorized generic for U-100)
- Humalog® 50/50 mix (50% insulin lispro protamine suspension/50% insulin lispro injection – Lilly)
- Humalog® Mix 75/25 (75% insulin lispro protamine suspension/25% insulin lispro injection – Lilly, authorized generic)
- Humalog Tempo Pen (insulin lispro injection – Lilly)
- Lyumjev™ (vials and KwikPen) (insulin lispro-aabc injection – Eli Lilly)

Non-Preferred Medications

- Lyumjev Tempo Pen

PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried a preferred medication, then authorization for a non-preferred medication may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 2 years
B) *Extended Approval:* 2 years

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Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics*; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent*; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as *. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Admelog® injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; December 2020.
2. Apidra® injection [prescribing information]. Bridgewater, NJ: sanofi-aventis; December 2020.
3. Fiasp® injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; June 2023.
4. Humalog® injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.
5. Humalog® Mix 50/50 injection [prescribing information]. Indianapolis, IN: Lilly; July 2023.
6. Humalog® Mix 75/25 injection [prescribing information]. Indianapolis, IN: Lilly; July 2023. Available at: https://uspl.lilly.com/humalog7525/humalog7525.html#pi. Accessed on September 14, 2023.
7. Lyumjev™ injection [prescribing information]. Indianapolis, IN: Lilly; October 2022.
8. NovoLog® injection [prescribing information]. Princeton, NJ: Novo Nordisk; February 2023.
9. NovoLog® Mix 70/30 injection [prescribing information]. Princeton, NJ: Novo Nordisk; February 2023.