MEDICAL MUTUAL®

Drug Policy

Policy:	**Insulin (other) Preferred Step Therapy**	**Annual Review Date:** **08/18/2022**
Impacted Drugs:	**Novolin N** **Novolin R** **Novolin 70/30**	**Last Revised Date:** **08/18/2022**

OVERVIEW

Insulin is an anabolic and anticatabolic hormone and plays a major role in protein, carbohydrate, and fat metabolism. Humulin and Novolin are lines of human insulin indicated for to improve glycemic control in adults and children with diabetes mellitus. These products substitute for inadequate endogenous insulin secretion and partially correct the disordered metabolism and inappropriate hyperglycemia of diabetes mellitus, which are caused by either a deficiency or reduction in the biologic effectiveness of insulin.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred product prior to the use of a non-preferred 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. Patients 18 years of age and older will be targeted in this preferred step therapy program. All approvals are provided for 1 year in duration.

Preferred Medications

- Humulin N vials and KwikPen (NPH, human insulin isophane suspension [rDNA origin] injection)
- Humulin R vials (regular insulin human injection, USP [rDNA origin] U-100 only)
- Humulin 70/30 vials and KwikPen (70% NPH, human insulin isophane suspension and 30% regular human insulin injection [rDNA origin])

Non-Preferred Medications

- Novolin N vials, FlexPen (NPH, human insulin isophane suspension [rDNA origin] injection)
- Novolin R vials for subcutaneous or intravenous use, FlexPen (regular human insulin injection [rDNA origin] solution)
- Novolin 70/30 vials and Flexpen (70% NPH, human insulin isophane suspension and 30% regular human insulin injection [rDNA origin])

Automation: Patients 18 years of age and older will be targeted in this preferred step therapy program. Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

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PREFERRED STEP THERAPY CRITERIA

1. If the patient has tried Humulin R, approval for Novolin R can be granted.
2. If the patient has tried Humulin N (vials or Kwikpen), approval for Novolin N can be granted.
3. If the patient has tried Humulin 70/30 (vials or Kwikpen), approval for Novolin 70/30 (vials and Flexpen) can be granted.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

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 [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **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 required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

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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

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