

Pharmacy Policy Bulletin

Title: Insulin Policy
Policy #: Rx.01.270

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for **Humulin®**, **Humalog® (insulin lispro)**, **Humalog TMPO®**, **Apidra®**, **Admelog®**, **Lyumjev®**, **Lyumjev TMPO®**, **Fiasp®**, **Novolog Relion** or **Novolin Relion**, **Insulin aspart**, **Basaglar®**, **Basaglar TMPO®**, **Levemir®**, **Tresiba® (insulin degludec)**, **Insulin glargine**, **Semglee® (insulin glargine-YFGN)** as provided under the member's prescription drug benefit.

Description:

Type 1 diabetes mellitus (T1DM) is characterized by absolute insulin deficiency due to autoimmune β cell destruction. Insulin is the mainstay of therapy for T1DM. Childhood type 1 diabetes mellitus can present with chronic polydipsia, polyuria, weight loss with hyperglycemia and ketonemia or ketonuria, diabetic ketoacidosis or asymptomatic incidental discovery.

Type 2 diabetes mellitus (T2DM) is characterized by insulin resistance and usually relative (rather than absolute) insulin deficiency. Patients with T2DM may have insulin levels that appear normal or elevated. However, the higher blood glucose levels in these patients would be expected to result in even higher insulin values with normally functioning beta cells. Hence, insulin secretion is defective and insufficient to compensate for insulin resistance. Adults with type 2 diabetes are at risk for obesity, hypertension, dyslipidemia, fatty liver disease, sleep apnea, as well as periodontal disease.

Insulin and its analogs lower blood glucose levels by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis and enhances protein synthesis. Insulin, secreted by the beta cells of the pancreas, is the principal hormone required for proper glucose use in normal metabolic processes.

Policy:

Humulin®, Humalog® (insulin lispro), Humalog TMPO®, Apidra®, Admelog®, Lyumjev®, Lyumjev TMPO®, Fiasp®, Novolog Relion or Novolin Relion is approved when ALL of the following are met:

1. Diagnosis of diabetes mellitus; and
2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
 - a. Novolin®; or
 - b. Novolog®

Authorization duration: 2 years

Insulin aspart is approved when ALL of the following are met:

1. Diagnosis of diabetes mellitus; and
2. Paid claims or submission of medical records (e.g., chart notes) confirming trial of brand Novolin or brand Novolog for at least 6 months within the previous 365 days

Authorization duration: 2 years

Basaglar®, Basaglar TMPO®, Levemir®, Tresiba®, Insulin Degludec, Insulin glargine-YFGN/Semglee® or insulin Glargine is approved when ALL of the following are met:

1. Diagnosis of diabetes mellitus; and
2. Paid claims or submission of medical records (e.g., chart notes) confirming an inadequate response or inability to tolerate ONE of the following:
 - a. Lantus®; or
 - b. Toujeo®

Authorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

N/A

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

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Admelog® [package insert]. Bridgewater, NJ 08807. Sanofi-Aventis U.S. LLC. December 2017. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209196s000lbl.pdf. Accessed April 20, 2023.

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Fiasp® [package insert]. Denmark, Bagsvaerd 2880. Novo Nordisk A/S. September 2017. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208751s000lbl.pdf. Accessed April 20, 2023.

Humalog®/Humalog TMPO® [package insert]. Indianapolis, IN 46285. Lilly USA LLC. November 2019. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/020563s115lbl.pdf . Accessed April 20, 2023.

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Levemir® [package insert]. Denmark, Bagsvaerd 2880. Novo Nordisk A/S. 2019. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021536s054lbl.pdf . Accessed April 20, 2023.

Lyumjev®/Lyumjev TMPO® [package insert]. Indianapolis, IN 46285, USA. Eli Lilly and Company. October 2022. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761109s000lbl.pdf . Accessed April 20, 2023.

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Novolog® [package insert].Denmark, Bagsvaerd 2880. Novo Nordisk A/S. 2015. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/020986s082lbl.pdf . Accessed April 20, 2023.

Semglee® [package insert]. Morgantown, WV 26505 U.S.A. Mylan Pharmaceutical Inc. July 2021. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761201Orig1s000lbl.pdf . Accessed April 20, 2023.

Tresiba® [package insert]. Denmark, Bagsvaerd 2880. Novo Nordisk A/S. September 2015. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/203314lbl.pdf . Accessed April 20, 2023.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Admelog®	Insulin Lispro
Apidra®	Insulin Glulisine
Basaglar®/Basaglar TMPO®	Insulin Glargine
Fiasp®	Insulin Aspart
Humalog®/Humalog TMPO®	Insulin Lispro
Humulin®	Insulin Regular
Insulin aspart	
Insulin glargine	
Levemir®	Insulin Detemir
Lyumjev®/Lyumjev TMPO®	Insulin Lispro-aabc
Novolin® Relion	Insulin Regular
Novolog® Relion	Insulin aspart
Semglee®	Insulin Glargine-yfqn
Tresiba®	Insulin Degludec
Insulin Degludec	

Cross References:

Off-Label Use Policy Rx.01.33

Quantity level limits for pharmaceuticals covered under the prescription drug benefit Rx.01.76

Policy Version Number:	3.00
P&T Approval Date:	March 16, 2023
Policy Effective Date:	July 01, 2023
Next Required Review Date:	September 15, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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