LOUISIANA BLUE

Insulins (Non-Long Acting Products)

Policy # 00395
Original Effective Date: 01/01/2014
Current Effective Date: 01/01/2027

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider non-long acting insulin products other than the Novolin, Kirsty™‡ (insulin aspart-xjhz), or Insulin Lispro [Authorized {branded} Generic] family of products (including, but not limited to Novolog®‡ products, Fiasp®‡, Humulin®, Humalog® products, Insulin Aspart [Authorized {branded} Generic], Apidra®, Afrezza®, Lyumjev™, Admelog® products, and Merilog™ [insulin-aspart-szjj])‡ to be **eligible for coverage**** when the below patient selection criteria are met:

Note that Novolog Mix 70/30 is not subject to this policy

Patient Selection Criterion

Coverage eligibility will be considered for non-long acting insulin products other than the Novolin, Kirsty (insulin aspart-xjhz), or Insulin Lispro (Authorized [branded] Generic) family of products when the following criteria are met:

- There is clinical evidence or patient history that suggests the use of the Novolin, Kirsty (insulin aspart-xjhz), or Insulin Lispro (Authorized [branded] Generic) family of products will be ineffective or cause an adverse reaction to the patient; **AND**
  (*Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.*)
- For Lyumjev Kwikpen U-200 and Humalog Kwikpen U-200 requests: Prescriber attests that the requested concentrated insulin will not be used in an external insulin pump when pump administration is not included in the FDA-approved labeling of the requested concentrated insulin product, or when use of concentrated insulin is not in accordance with the pump's FDA-cleared instructions for use; OR
- For Humulin R U-500 requests: Prescriber attests that the requested concentrated insulin will not be used in an external insulin pump when pump administration is not included in the FDA-approved labeling of the requested concentrated insulin product, or when use of concentrated insulin is not in accordance with the pump's FDA-cleared instructions for use.

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Note: External insulin pumps (including tubed and tubeless systems) are insulin delivery devices designed to provide continuous subcutaneous insulin infusion. Products may include, but are not limited to, Omnipod DASH®, Omnipod® 5, twiist™, Tandem t:slim X2™, Tandem Mobi™, Medtronic MiniMed™ 780G/770G/630G, and iLet® Bionic Pancreas.
Note: Concentrated insulins are formulated with a strength greater than 100 units per mL.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of non-long acting insulin products other than the Novolin, Kirsty (insulin aspart-xjhz), or Insulin Lispro (Authorized [branded] Generic) family of products when the patient selection criterion is not met or for usage not included in the above patient selection criterion to be **not medically necessary**.**

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of concentrated insulin in an external insulin pump when pump administration is not included in the FDA-approved labeling of the concentrated insulin product, or when use of the concentrated insulin is not in accordance with the pump's FDA-cleared instructions for use to be **investigational.***

Background/Overview

Insulin is indicated for patients with either Type 1 or Type 2 diabetes mellitus. There are various forms of insulin including regular, Neutral Protamine Hagedorn (NPH), rapid-acting, mixes, and long-acting insulin. Authorized generics and biosimilars of select products have also emerged in recent years. A biosimilar is a biological product approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as the reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. In February 2025, Merilog, a rapid-acting human insulin analog, received approval from the Food and Drug Administration (FDA) as the first biosimilar in the rapid-acting insulin category. Merilog's reference product is Novolog; however, Merilog is not interchangeable with Novolog. Kirsty, another rapid-acting human insulin analog and biosimilar to Novolog, received FDA approval as the second biosimilar in this category and has been designated as interchangeable with Novolog.

Insulin is available in different concentrations that affect dosing and delivery. U-100 insulin is the standard concentration used in most clinical settings and is compatible with the widest range of delivery devices, including syringes, pen devices, and external insulin pumps. Concentrated insulin products (e.g., U-200, U-300, and U-500 formulations) contain a higher number of units per milliliter and have specific administration requirements. Per the FDA-approved labeling for U-200, U-300, and U-500 formulations, concentrated insulin products must not be administered using an insulin pump. External insulin pumps are designed to provide continuous subcutaneous insulin infusion (CSII) and are generally categorized as traditional pumps and patch pumps. Traditional pumps consist of a durable, reusable device that delivers insulin via an external infusion set (tubing).

Examples include Tandem Diabetes Care systems (e.g., t:slim X2 insulin pump, Tandem Mobi insulin pump) and Medtronic MiniMed systems. Patch-based, tubeless insulin delivery devices are worn directly on the body and are disposable. Examples include Omnipod systems (e.g., Omnipod 5, Omnipod DASH), as well as disposable mechanical patch pumps such as CeQur Simplicity™ and V-Go®. According to FDA-cleared manufacturer instructions for use, currently available external insulin delivery devices are compatible only with rapid-acting U-100 insulin formulations. Because these systems are calibrated for rapid-acting U-100 insulin, use of concentrated formulations may result in dosing errors or unpredictable insulin delivery. Manufacturer labeling does provide dosing safeguards or algorithm validation for non-U-100 insulin within product labeling. Therefore, use of concentrated insulin in an external insulin delivery device is considered off-label.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The patient selection criteria presented in this policy take into consideration clinical evidence or patient history that suggests the use of the Novolin, Kirsty (insulin aspart-xjhz), or Insulin Lispro (Authorized [branded] Generic) family of products will be ineffective or cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using a non-long acting insulin product other than the Novolin, Kirsty (insulin aspart-xjhz), or Insulin Lispro (Authorized [branded] Generic) family of products (such as Novolog, Fiasp, Humalog, Humulin, Insulin Aspart [Authorized {branded} Generic], Apidra, Afrezza, Lyumjev, Admelog,or Merilog) over the Novolin, Kirsty (insulin aspart-xjhz), or Insulin Lispro (Authorized [branded] Generic) family of products. This policy does not pertain to the long acting insulin products such as Lantus®‡, Toujeo®‡, or Tresiba®‡. Kirsty has demonstrated biosimilarity to Novolog for the condition(s) of use described in the package insert, including indication(s), dosing regimen(s), strength(s), dosage form(s), and route(s) of administration. Based on review of available data, there is no advantage of using the reference product, Novolog, over Kirsty. Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using branded Humalog products over the lower cost Insulin Lispro products.

The patient selection criteria also take into consideration the FDA-approved labeling for concentrated insulin products and the FDA-cleared instructions for use of external insulin pump devices, which do not include administration of concentrated insulin via an external insulin pump.

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10/10/2013	Medical Policy Committee review
10/16/2013	Medical Policy Implementation Committee approval. New policy.
10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. Added Afrezza to the insulin policy.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/04/2018	Medical Policy Committee review
01/17/2018	Medical Policy Implementation Committee approval. Added Fiasp to the first-line products.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Added Admelog to the policy.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Added the Insulin Lispro branded generic to the policy.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/01/2020	Medical Policy Committee review
10/07/2020	Medical Policy Implementation Committee approval. Discussion involving preferred insulin products and Authorized Generic placement. Final decision dependent on P&T.
12/03/2020	Medical Policy Committee review
12/09/2020	Medical Policy Implementation Committee approval. Authorized Generics decision finalized by P&T. Added the Authorized Generic, Insulin Aspart, and a new product, Lyumjev, to the list of non-preferred products.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review

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08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/06/2025	Medical Policy Committee review
11/12/2025	Medical Policy Implementation Committee approval. Added new product, Merilog to the policy as a non-preferred product.
02/05/2026	Medical Policy Committee review
02/11/2026	Medical Policy Implementation Committee approval. Updated background section and references.
05/07/2026	Medical Policy Committee review
05/13/2026	Medical Policy Implementation Committee approval. Added new criterion requiring that concentrated insulin products will not be used in an external insulin pump.
07/21/2026	Pre Pharmacy and Therapeutics Committee review
07/22/2026	Pharmacy and Therapeutics Committee approval. Effective 08/01/2026, added new product Kirsty to policy as a non-preferred product. Effective 01/01/2027, preferred insulin products updated to Kirsty and Insulin Lispro products. Novolog and Fiasp products were moved to non-preferred. Added new criterion requiring that Humulin R U-500 will not be used in an external insulin pump.

Next Scheduled Review Date: 07/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan.