

Policy # 00395

Original Effective Date: 01/01/2014 Current Effective Date: 09/09/2024

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.

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 Novolog^{®‡}, Novolin^{®‡}, or Fiasp^{®‡} family of products (including, but not limited to Humulin[®], Humalog[®], Insulin Lispro [Authorized {branded} Generic], Insulin Aspart [Authorized {branded} Generic], Apidra[®], Afrezza[®], Lyumjev[™], and Admelog[®] products)[‡] to be **eligible for coverage**** when the below patient selection criterion is met:

Patient Selection Criterion

Coverage eligibility will be considered for non-long acting insulin products other than the Novolog, Novolin, or Fiasp family of products when the following criterion is met:

• There is clinical evidence or patient history that suggests the use of the Novolin, Novolog, or Fiasp family of products will be ineffective or cause an adverse reaction to the patient.

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, Novolog, or Fiasp 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**.**

©2024 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

^{**}Note that Humulin U-500 is not subject to this policy**



Policy # 00395

Original Effective Date: 01/01/2014 Current Effective Date: 09/09/2024

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.

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 federal regulations, other plan medical policies, and accredited national guidelines.

References

- 1. Dipiro JT, Talbert RL, Yee GC, et al. Pharmacotherapy: A Pathophysiologic Approach, 8th edition. New York: McGraw-Hill, 2011
- 2. Eli Lilly Products webpage.
- 3. NovoNordisk Products webpage.
- 4. Afrezza product webpage.
- 5. Admelog products webpage.

Policy History

Original Effecti	ve Date: 01/01/2014
Current Effectiv	re Date: 09/09/2024
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

01/01/2014

©2024 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00395 Original Effective Date: 01/01/2014 Current Effective Date: 09/09/2024

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
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

©2024 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00395

Original Effective Date: 01/01/2014 Current Effective Date: 09/09/2024

08/01/2024 Medical Policy Committee review

08/14/2024 Medical Policy Implementation Committee approval. Coverage eligibility

unchanged.

Next Scheduled Review Date: 08/2025

**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.

©2024 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.



Policy # 00395

Original Effective Date: 01/01/2014 Current Effective Date: 09/09/2024

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.

©2024 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.