

Clinical Policy: Diabetes – Insulin

Reference Number: OH.PHAR.PPA.49

Effective Date: 01.20

Last Review Date: 11.21

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

ENDOCRINE AGENTS: DIABETES - INSULINS - Rapid and Short Acting

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
APIDRA® vial and pen (insulin glulisine) HUMULIN R 500-U® vial and pen (insulin regular human) HUMALOG® vial and pen (insulin lispro) INSULIN ASPART vial and pen (authorized generic of Novolog®) INSULIN LISPRO vial and pen (authorized generic of Humalog®) NOVOLOG® vial and pen (insulin aspart)	ADMELOG® (insulin lispro)† AFREZZA® inhalation powder (insulin human) FIASP® (insulin aspart) HUMALOG U-200® pen (insulin lispro) HUMULIN R® (insulin regular human) LYUMJEV® (insulin lispro-aabc, recombinant) NOVOLIN R® (insulin regular human)

†Due to the nature of the drug, allergy or therapeutic failure to Humalog is insufficient to justify use

ENDOCRINE AGENTS: DIABETES - INSULINS - Intermediate Acting

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
HUMALOG MIX 50/50, 75/25® vial and pen (insulin lispro protamine/insulin lispro) HUMULIN 70/30® vial and pen (insulin NPH/regular) INSULIN ASPART PROTAMINE/INSULIN ASPART vial and pen (authorized generic of Novolog Mix 70/30®) NOVOLOG MIX 70/30® vial and pen	HUMULIN N® vial and pen (insulin NPH)* NOVOLIN N® (insulin NPH)* NOVOLIN 70/30® (insulin NPH/regular)

*Medications are approved in pregnant members. Pharmacy is able to use override to bypass PA if member is pregnant.

ENDOCRINE AGENTS: DIABETES - INSULINS - Long Acting

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
LANTUS® vial and pen (insulin glargine) LEVEMIR® vial and pen (insulin detemir) TOUJEO® (insulin glargine)	TRESIBA (insulin degludec)	BASAGLAR® (insulin glargine)† SEMGLEE® (insulin glargine-yfgn)

†Due to the nature of the drug, allergy or therapeutic failure to Lantus is insufficient to justify use

FDA approved indication(s)

All Insulin products are indicated for type 1 diabetes mellitus or for type 2 diabetes mellitus inadequately managed by diet, exercise, and oral hypoglycemics.

Humulin R and Novolin R are also indicated for:

- Treatment of gestational diabetes or for the treatment of patients with pre-existing diabetes mellitus (Type 1 or type 2) who are now pregnant

- Treatment of diabetic ketoacidosis (DKA)
- Treatment of hyperosmolar hyperglycemic state (HHS) in patients with type 2 diabetes mellitus

Humulin N and Novolin N are also indicated for:

- Treatment of gestational diabetes or for the treatment of patients with pre-existing diabetes mellitus (Type 1 or type 2) who are now pregnant

Insulin aspart, insulin detemir, insulin glargine, and insulin lispro are also indicated for:

- Treatment of gestational diabetes or for the treatment of patients with pre-existing diabetes mellitus (Type 1 or type 2) who are now pregnant

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan, an affiliate of Centene Corporation® that Insulin products are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

1. Prescribed indication is FDA-approved or supported by standard pharmacopeias;
2. Member must meet labeled age requirements for the medication;
3. If request is for a step therapy medication, failure of at least one preferred medication within the same class, unless member meets one of the following (a, b, c, or d):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
 - d. condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia);
4. If request is for a non-preferred medication, failure of at least two preferred medications within the same class, unless member meets one of the following (a, b, c, or d):
 - a. allergy to medications not requiring prior approval;
 - b. contraindication to or drug interaction with medications not requiring prior approval;
 - c. history of unacceptable/toxic side effects to medications not requiring prior approval;
 - d. condition is difficult to control (i.e. prone to ketoacidosis, hypoglycemia);
5. Failure to reach HbA1c goal with documented adherence and appropriate dose escalation of current regimen;
6. If request is for inhaled insulin (Afrezza), the following must be met (a, b, c, and d):
 - a. Member has type 2 diabetes or a claim for a long-acting insulin in the previous 120 days;
 - b. Member has not been diagnosed with asthma or COPD;
 - c. Spirometry shows FEV1 \geq 70% predicted;
 - d. Member has not smoked for at least 180 days.

Approval Duration: 12 months

II. Continued Therapy

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose.

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation Key

COPD: chronic obstructive pulmonary disease

DKA: diabetic ketoacidosis

FDA: Food and Drug Administration

FEV1: forced expiratory volume-one second

HHS: hyperosmolar hyperglycemic state

Appendix B: Therapeutic Alternatives

- Dosing varies by drug product. See FDA approved dosing and administration.

Appendix C: Contraindications/Boxed Warnings

- Refer to Clinical Pharmacology or other appropriate clinical resource.

V. Dosage and Administration

- A. Varies by drug product. See FDA approved dosing and administration.

VI. Product Availability

- A. Varies by drug product. Please refer to Clinical Pharmacology or other appropriate clinical resource for product availability.

VII. References

Refer to package inserts.

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created	10.19	
Annual review: added Lyumjev as a non-preferred rapid/short-acting insulin	10.20	

Reviews, Revisions, and Approvals	Date	Approval Date
Annual review: Added Semglee as a non-preferred long-acting insulin; updated FDA approved indications to include gestational diabetes for insulin aspart, insulin detemir, insulin glargine, and insulin lispro. Added notation that Humulin N and Novolin N are approved for pregnant members and the pharmacy can use override to bypass PA requirements.	10.21	
Added the following to non-preferred: Humulin R, Novolin R, Novolin 70-30, Humalog U-200. Added the following to preferred: Apidra, Novolog 70/30, and Toujeo.	11.21	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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