BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

NON-PREFERRED INSULIN THERAPY

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for Non-Preferred Insulin Therapy

Criteria for Initial Therapy:

Indication
- Diabetes mellitus

Age Requirement
- Age must be appropriate for the requested insulin product

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, intolerance, or not a candidate for a preferred insulin product

ORIGINAL EFFECTIVE DATE: 02/20/2025 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/19/2026

PHARMACY COVERAGE GUIDELINE

NON-PREFERRED INSULIN THERAPY

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

Safety
- No significant interacting drugs

Additional Requirements
- Requested dosage and duration must align with FDA approved labeling

Documentation Requirements
- Completed request form must be submitted including:
  - Chart notes
  - Lab results (including A1C values if applicable).
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 12 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Clinical Response
- **ALL** of the following:
  - No evidence of disease progression
  - Documented evidence of efficacy, disease stability, and/or improvement
  - No unacceptable adverse drug reactions

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the United States Food and Drug Administration (FDA) (see Definitions section)

Safety
- **NONE** of the following:
  - Significant drug to drug interactions
  - Contraindications or other significant adverse drug effects

Documentation Requirements
- Chart notes

- Supporting clinical documentation with evidence of improvement in diabetes mellitus
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Prescription Drug Benefit plans apply various management strategies that put limitations on certain medications. These limitations may include, but are not limited to, prior authorization (or prior authorization), quantity limits and step therapy.

BCBSAZ determines which medications are subject to limitations based upon medication product labeling, nationally recognized compendia, or guidelines, and established clinical trials that have been published in peer reviewed professional medical journals. Medication limitations are subject to change at any time without prior notice.

Step Therapy is the practice of beginning a drug for a medical condition with a preferred drug before progressing to another therapy. It requires trying a Step Therapy Drug A before getting Step Therapy Drug B. Step therapy guidelines are developed and reviewed by a panel of practicing physicians and pharmacists.

Prior authorization allows providers to submit medical record documentation of failure, intolerance, or contraindications that may exist for Drug “A” which would suggest approval to bypass use of the preferred product. BCBSAZ will review the information presented and if approved, an authorization for Drug “B” can be entered into the member’s pharmacy record.

BCBSAZ maintains a list of medications that require step therapy and is available on www.azblue.com/pharmacy by selecting the appropriate plan option, or click here.

There is no evidence that any injectable insulin is safer or more effective than another for reducing A1C or the risk of long-term complications from diabetes mellitus. Treatment guidelines do not recommend one brand of injectable insulin over another within each formulation.

PHARMACY COVERAGE GUIDELINE

NON-PREFERRED INSULIN THERAPY

Non-preferred injectable insulins may be considered medically necessary in patients with type 1 or type 2 diabetes mellitus when treatment with a preferred injectable insulin is contraindicated, not tolerated, or ineffective in reducing A1C to goal of 7% or less after 90 days of therapy.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Examples of Preferred and Non-Preferred Insulins: (Note: Not a complete listing)

INSULIN TYPES	PREFERRED	NON-PREFERRED
Rapid-acting	HUMALOG INJ 100/ML (100 UNIT/ML) HUMALOG INJ 100/ML (CARTRIDGE 100 UNIT/ML) HUMALOG JR INJ 100/ML (PEN-INJECTOR 100 UNIT/ML (0.5 UNIT DIAL)) HUMALOG KWIK INJ 100/ML (PEN-INJECTOR 100 UNIT/ML (1 UNIT DIAL)) HUMALOG TMPO INJ 100/ML (PEN-INJ W/TRANSMITTER PORT 100 UNIT/ML) INSULIN ASPA INJ 100/ML (SOLN 100 UNIT/ML) INSULIN ASPA INJ FLEXPEN (PEN-INJECTOR 100 UNIT/ML) INSULIN ASPA INJ PENFILL (CARTRIDGE 100 UNIT/ML) INSULIN LISP INJ 100/ML (PEN-INJECTOR 100 UNIT/ML (1 UNIT DIAL)) INSULIN LISP INJ 100/ML (100 UNIT/ML) INSULIN LISP INJ JUNIOR (PEN-INJECTOR 100 UNIT/ML (0.5 UNIT DIAL) KIRSTY (PEN-INJECTOR 100UNIT/ML) KIRSTY (100 UNIT/ML) MERILOG (PEN-INJECTOR 100 UNIT/ML) MERILOG (100 UNIT/ML) NOVOLOG INJ 100/ML (100 UNIT/ML) NOVOLOG INJ FLEX REL (PEN-INJECTOR 100 UNIT/ML) NOVOLOG INJ FLEXPEN PEN-INJECTOR 100 UNIT/ML) NOVOLOG INJ PENFILL (CARTRIDGE 100 UNIT/ML) NOVOLOG INJ RELION (100 UNIT/ML)	ADMELOG INJ 100U/ML (100 UNIT/ML) ADMELOG SOLO INJ 100U/ML (PEN-INJECTOR 100 UNIT/ML (1 UNIT DIAL)) APIDRA INJ SOLOSTAR (PEN-INJECTOR 100 UNIT/ML) APIDRA INJ U-100 (100 UNIT/ML) FIASP FLEX INJ TOUCH (WITH NIACINAMIDE) PEN-INJ 100 UNIT/ML) FIASP INJ 100/ML (WITH NIACINAMIDE) 100 UNIT/ML) FIASP PENFIL INJ U-100 (WITH NIACINAMIDE) CARTRIDGE 100 UNIT/ML) FIASP PMPCRT INJ U-100 (WITH NIACINAMIDE) CARTRIDGE 100 UNIT/ML) HUMALOG KWIK INJ 200/ML (PEN-INJECTOR 200 UNIT/ML) LYUMJEV INJ 100UT/ML (LISPRO-AABC 100 UNIT/ML) LYUMJEV KWPN INJ 100UT/ML (LISPRO-AABC PEN-INJ 100 UNIT/ML (1 UNIT DIAL)) LYUMJEV KWPN INJ 200UT/ML (LISPRO-AABC PEN-INJECTOR 200 UNIT/ML) LYUMJEV TMPO INJ 100UT/ML (LISPRO-AABC PEN-INJ W/TRANSMIT PORT 100 UNIT/ML)
Short-acting	HUMULIN R INJ U-100 (100 UNIT/ML) NOVOLIN R INJ 100 UNIT (100 UNIT/ML) NOVOLIN R INJ 100 UNIT (PEN-INJECTOR 100 UNIT/ML) NOVOLIN R INJ RELION (100 UNIT/ML)	HUMULIN R INJ U-500 (500 UNIT/ML) HUMULIN R INJ U-500 (PEN-INJECTOR 500 UNIT/ML)
Intermediate-acting	HUMULIN N INJ U-100 (NPH (ISOPHANE) 100 UNIT/ML) HUMULIN N INJ U-100KWP (NPH (ISOPHANE) PEN-INJECTOR 100 UNIT/ML) NOVOLIN N INJ 100 UNIT (NPH (ISOPHANE) PEN-INJECTOR 100 UNIT/ML) NOVOLIN N INJ RELION (NPH (ISOPHANE) INJ 100 UNIT/ML) NOVOLIN N INJ U-100 (NPH (ISOPHANE) INJ 100 UNIT/ML)	
Long acting	INSULIN GLARGINE-YFGN INJ 100U/ML (GLARGINE-YFGN PEN INJECTOR 100 UNIT/ML) by *CIVICA* GLARGIN YFGN INJ 100U/ML (GLARGINE-YFGN PEN-INJECTOR 100 UNIT/ML) GLARGIN YFGN SOL 100U/ML (GLARGIN YFGN 100 UNIT/ML) INS DEGL FLX INJ 100UNIT (DEGLUDEC PEN-INJECTOR 100 UNIT/ML) INS DEGL FLX INJ 200UNIT (DEGLUDEC PEN-INJECTOR 200 UNIT/ML) INSULIN DEGL INJ 100UNIT (DEGLUDEC 100 UNIT/ML) LANTUS INJ 100/ML (GLARGINE 100 UNIT/ML) LANTUS SOLOS INJ 100/ML (GLARGINE PEN-INJECTOR 100 UNIT/ML) LEVEMIR INJ (DETEMIR 100 UNIT/ML) LEVEMIR INJ FLEXPEN (DEGLUDEC PEN-INJECTOR 100 UNIT/ML) REZVOGLAR KWIKPEN (INSULIN GLARGINE-AGLR SOLN PEN-INJECTOR 100 UNIT/ML)	BASAGLAR INJ 100UNIT (GLARGINE PEN-INJECTOR 100 UNIT/ML) BASAGLAR INJ TEMPO PN (PEN-INJ WITH TRANSMITTER PORT 100 UNIT/ML) INSULIN GLAR INJ 100/ML (PEN-INJECTOR 100 UNIT/ML) INSULIN GLAR INJ 300/ML (PEN-INJECTOR 300 UNIT/ML (1 UNIT DIAL)) INSULIN GLAR INJ 300/ML (PEN-INJECTOR 300 UNIT/ML (2 UNIT DIAL)) INSULIN GLAR 100/ML (100 UNIT/ML) SEMGLEE INJ 100U/ML (GLARGINE-YFGN INJ 100 UNIT/ML) SEMGLEE INJ 100U/ML (GLARGINE-YFGN PEN-INJECTOR 100 UNIT/ML) SOLIQUA INJ 100/33 (GLARGINE-LIXISENATIDE PEN-INJ 100-33 UNIT-MCG/ML) TOUJEO MAX INJ 300/ML (PEN-INJECTOR 300 UNIT/ML (2 UNIT DIAL) TOUJEO SOLO INJ 300/ML (PEN-INJECTOR 300 UNIT/ML (1 UNIT DIAL) TRESIBA FLEX INJ 100UNIT (DEGLUDEC PEN-INJECTOR 100 UNIT/ML) TRESIBA FLEX INJ 200UNIT (DEGLUDEC PEN-INJECTOR 200 UNIT/ML) TRESIBA INJ 100UNIT (DEGLUDEC INJ 100 UNIT/ML) XULTOPHY INJ 100/3.6 (DEGLUDEC-LIRAGLUTIDE PEN-INJ 100-3.6 UNIT-MG/ML)
Mixtures	HUMALOG MIX INJ 50/50 (100 UNIT/ML (50-50)) HUMALOG MIX INJ 50/50KWP (PEN-INJ 100 UNIT/ML (50-50)) HUMALOG MIX INJ 75/25KWP (PEN-INJ 100 UNIT/ML (75-25)) HUMALOG MIX SUS 75/25 (100 UNIT/ML (75-25)) HUMULIN INJ 70/30 (NPH & REGULAR INJ 100 UNIT/ML (70-30)) HUMULIN INJ 70/30KWP (NPH & REGULAR PEN-INJ 100 UNIT/ML (70-30)) INS ASP PROT INJ FLEXPEN (PEN-INJ 100 UNIT/ML (70-30)) INSULIN ASPA INJ 70/30 (100 UNIT/ML (70-30)) INSULIN LISP INJ PROTAMIN (PEN-INJ 100 UNIT/ML (75-25)) NOVOLIN 70/30 INJ RELION (NPH & REGULAR 100 UNIT/ML (70-30))	

ORIGINAL EFFECTIVE DATE: 02/20/2025 | ARCHIVE DATE: | LAST REVIEW DATE: 02/19/2026 | LAST CRITERIA REVISION DATE: 02/19/2026

	NOVOLIN INJ 70/30 (NPH & REGULAR 100 UNIT/ML (70-30)) NOVOLIN INJ 70/30 FP (NPH & REGULAR PEN-INJ 100 UNIT/ML (70-30)) NOVOLOG MIX INJ 70/30 (100 UNIT/ML (70-30)) NOVOLOG MIX INJ FLEX REL (PEN-INJ 100 UNIT/ML (70-30)) NOVOLOG MIX INJ FLEXPEN (PEN-INJ 100 UNIT/ML (70-30)) NOVOLOG RELI INJ 70/30 (100 UNIT/ML (70-30))	