BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 1/18/18**
	LAST CRITERIA REVISION DATE: 1/18/18
	ARCHIVE DATE:

ADMELOG®, NOVOLIN®, RELION, NOVOLOG®, and FIASP®

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

ADMELOG®, NOVOLIN®, RELION, NOVOLOG®, and FIASP® (cont.)

Admelog (insulin lispro)

Medication class:
Antidiabetics - Insulin, Human Insulin

FDA-approved indication(s):
- Admelog is a rapid-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients 3 years and older with type 1 diabetes mellitus and adults with type 2 diabetes mellitus.

Available Dosage Forms:
- Admelog is supplied in 10 mL multiple-dose vials and 3 mL single patient use Solostar prefilled pens

Warnings and Precautions:
Admelog
- *Never share* an Admelog SoloStar disposable prefilled pen or syringe between patients, even if the needle is changed.
- *Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen:* Carry out under close medical supervision and increase frequency of blood glucose monitoring.
- *Hypoglycemia:* May be life-threatening. Monitor blood glucose and increase monitoring frequency with changes to insulin dosage, use of glucose lowering medications, meal pattern, physical activity; in patients with renal or hepatic impairment; and in patients with hypoglycemia unawareness.
- *Hypoglycemia Due to Medication Errors:* Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection.
- *Hypersensitivity Reactions:* Severe, life-threatening, generalized allergic, including anaphylaxis can occur. Discontinue Admelog, monitor and treat if indicated.
- *Hypokalemia:* May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated.
- *Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs):* Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.
- *Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction:* Monitor glucose and administer Admelog by subcutaneous injection if pump malfunction occurs.

Novolin N and Relion N (insulin NPH (human) (isophane))
Novolin R and Relion R (insulin regular (human))
Novolin 70/30 and Relion 70/30 (insulin NPH isophane & regular (human))

Medication class:
Antidiabetics - Insulin, Human Insulin

FDA-approved indication(s):
- Novolin N and Relion N is a man-made insulin (recombinant DNA origin) NPH, Human Insulin Isophane Suspension that is structurally identical to the insulin produced by the human pancreas that is used to control high blood sugar in patients with diabetes mellitus.
- Novolin R and Relion R is a short-acting recombinant human insulin indicated to improve glycemic control in adults and children with diabetes mellitus.
- Novolin 70/30 and Relion 70/30 is a man-made insulin (recombinant DNA origin) which is a mixture of 70% NPH, Human Insulin Isophane Suspension and 30% Regular, Human Insulin Injection that is structurally identical to the insulin produced by the human pancreas that is used to control high blood sugar in patients with diabetes mellitus.

Recommended Dose:
- See Full Prescribing Information for important administration and dosage instructions.

Available Dosage Forms:
- Novolin N and Relion N is supplied in 10 mL vials for use with syringe
- Relion N Innolet is supplied in 3 mL syringes
- Novolin R and Relion R, Regular, Human Insulin Injection (rDNA origin) USP, 100 units/mL (U-100), is supplied in 10 mL vials
- Novolin 70/30 and Relion 70/30 is supplied in 10 mL vials for use with syringe

Warnings and Precautions:

Novolin R and Relion R
- Hypoglycemia: Most common adverse reaction of insulin therapy and may be life-threatening. Closely monitor blood glucose. Changes in insulin or dosage should be made cautiously and only under medical supervision.
- Hypokalemia: Particularly when insulin is given intravenously or in settings of poor glycemic control. Use caution in patients predisposed to hypokalemia.
- Renal or hepatic impairment: As with other insulins, the dose requirements for Novolin R may be reduced.
- Allergic reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, may occur.
- Mixing: Do not mix Novolin R with any insulin for intravenous use. Do not mix with insulins other than NPH insulin for subcutaneous use.
- Fluid retention and heart failure can occur with concomitant use of thiazolidinediones (TZDs), which are PPAR-gamma agonists, and insulin, including Novolin R.

Fiasp (insulin aspart)
Novolog (insulin aspart)
Novolog Mix 70/30 (insulin aspart protamine and insulin aspart)

Medication class:
Antidiabetics - Insulin, Human Insulin

FDA-approved indication(s):
- Fiasp and Novolog are rapid acting human insulin analog **indicated to improve glycemic control in adults and children with diabetes mellitus.**
- Novolog Mix 70/30 is a mixture of insulin aspart protamine, an intermediate-acting human insulin analog, and insulin aspart, a rapid-acting human insulin analog, **indicated to improve glycemic control in patients with diabetes mellitus.**

Recommended Dose:
- See Full Prescribing Information for important administration and dosage instructions.

Available Dosage Forms:
Fiasp 100 units of insulin aspart per mL available in:
- 10 mL vial multiple-dose vial
- 3 mL single-patient use Fiasp FlexTouch pen

Novolog 100 units of insulin aspart per mL available in:
- 10 mL vial
- 3 mL PenFill cartridges
- 3 mL FlexPen
- 3 mL FlexTouch

Novolog Mix 70/30 100 units per mL, 70% insulin aspart protamine and 30% insulin aspart, available in:
- 10 mL vial
- 3 mL Novolog Mix 70/30 FlexPen

Limitations of use:
Novolog Mix 70/30
- Not recommended for the treatment of diabetic ketoacidosis.
- The proportions of rapid-acting and long-acting insulins are fixed and do not allow for basal versus prandial dose adjustments.

Warnings and Precautions:
Fiasp
- *Never share* a FIASP FlexTouch pen between patients, even if the needle is changed.
- *Hyper- or hypoglycemia with changes in insulin regimen*: Carry out under close medical supervision and increase frequency of blood glucose monitoring.
- *Hypoglycemia:* May be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, coadministered glucose lowering medications, meal pattern, physical activity; and in patients with renal impairment or hepatic impairment or hypoglycemia unawareness.

ADMELOG®, NOVOLIN®, RELION, NOVOLOG®, and FIASP® (cont.)

- *Hypoglycemia due to medication errors*: Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection.
- *Hypokalemia*: May be life-threatening. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.
- *Hypersensitivity reactions:* Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue FIASP, monitor and treat if indicated.
- *Fluid retention and heart failure with concomitant use of thiazolidinediones (TZDs):* Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.

Novolog

- *Never share* a Novolog FlexPen or a Novolog Flex Touch, PenFill cartridge or PenFill cartridge device between patients, even if the needle is changed.
- *Hyper- or hypoglycemia with changes in insulin regimen:* Carry out under close medical supervision and increase frequency of blood glucose monitoring.
- *Hypoglycemia:* May be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity; and in patients with renal or hepatic impairments and hypoglycemia unawareness.
- *Medication Errors:* Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection.
- *Hypersensitivity reactions:* Severe, life-threatening, generalized allergy, including anaphylaxis, may occur. Discontinue Novolog, treat, and monitor, if indicated.
- *Hypokalemia:* May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated.
- *Fluidretention and heart failure with concomitant use of thiazolidinediones (TZDs):* Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs.
- *Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction:* Monitor glucose and administer Novolog by subcutaneous injection if pump malfunction occurs.

Novolog Mix 70/30

- Inject Novolog Mix 70/30 subcutaneously in the abdominal region, buttocks, thigh, or upper arm.
- Administer the dose within 15 minutes before meal initiation. For patients with type 2 diabetes, the dose may also be given after meal initiation.
- Rotate injection sites within the same region from one injection to the next.
- Inspect visually before use. Appearance should be uniformly white and cloudy. Do not use it if it looks clear or if it contains solid particles.
- Novolog Mix 70/30 must be resuspended immediately before use. Resuspension is easier when the insulin has reached room temperature.
- Do not administer intravenously or use in insulin infusion pumps.
- Novolog Mix 70/30 is typically dosed twice-daily (with each dose intended to cover 2 meals or a meal and a snack).
- Individualize dosage based on metabolic needs, blood glucose monitoring results, glycemic control goal.
- Dosage adjustments may be needed with changes in physical activity, changes in meal patterns (i.e., macronutrient content or timing of food intake), changes in renal or hepatic function or during acute illness.
- Dosage adjustment may be needed when switching from another insulin to Novolog Mix 70/30.

ADMELOG®, NOVOLIN®, RELION, NOVOLOG®, and FIASP® (cont.)

Criteria:

- **Criteria for initial therapy:** Admelog, Novolin, Relion, Novolog or Fiasp is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. A confirmed diagnosis of diabetes mellitus

  2. Individual has failure, contraindication, or intolerance to the following:
     - Humalog for Novolog or Fiasp or Admelog
     - Humalog 75/25 for Novolog 70/30
     - Humulin N for Novolin N or Relion N
     - Humulin R for Novolin R or Relion R
     - Humulin 70/30 for Novolin 70/30 or Relion 70/30

  3. There are **NO** contraindications.
     - Contraindications include:
       - Use during episodes of hypoglycemia
       - Patients with hypersensitivity to product or one of its excipients

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Admelog, Novolin, Relion, Novolog or Fiasp is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual has been compliant with the insulin

  Renewal duration: 12 months

Resources:

Admelog. Package Insert. Revised by manufacturer 12/2017. Accessed 1/3/18.

Fiasp. Package Insert. Revised by manufacturer 10/2017. Accessed 10/27/17.

Novolin N. Package Insert. Revised by manufacturer 1/2016. Accessed 10/18/17.

Novolin R. Package Insert. Revised by manufacturer 1/2016. Accessed 10/18/17.

Novolin 70/30. Package Insert. Revised by manufacturer 1/2016. Accessed 10/18/17.

Novolog. Package Insert. Revised by manufacturer 3/2017. Accessed 10/18/17.

Novolog Mix 70/30. Package Insert. Revised by manufacturer 5/2017. Accessed 10/18/17.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.