BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 11/16/17**
SECTION: DRUGS	**LAST REVIEW DATE: 11/16/17**
	LAST CRITERIA REVISION DATE:
	ARCHIVE DATE:

APIDRA® (insulin glulisine) injection vial
APIDRA® SOLOSTAR® (insulin glulisine) subcutaneous solution pen-injector

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.

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.**

Apidra (insulin glulisine)

Medication class:
Antidiabetics – Insulin, Human Insulin

FDA-approved indication(s):
- Apidra is a rapid acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

Recommended Dose:
- The dosage of Apidra must be individualized.
- Subcutaneous injection: Administer within 15 minutes before a meal or within 20 minutes after starting a meal. Use in a regimen with an intermediate or long-acting insulin.
- Continuous subcutaneous infusion pump: Apidra must not be mixed or diluted when used in an external insulin infusion pump.
- Intravenous Infusion: Infuse intravenously (0.05 Units/mL to 1 Units/mL Apidra in 0.9% sodium chloride using polyvinyl chloride infusion bags) only under strict medical supervision with close monitoring of blood glucose and potassium.

Available Dosage Forms:
Apidra 100 units/mL (U-100) is available as:
- 10 mL vials
- 3 mL SoloStar prefilled pen

Warnings and Precautions:
- Never share an Apidra SoloStar pen between patients, even if the needle is changed
- Do not reuse or share needles or syringes between patients
- Dose adjustment and monitoring: Closely monitor blood glucose in all patients treated with insulin. Change insulin regimens cautiously and only under medical supervision.
- Hypoglycemia: Most common adverse reaction of insulin therapy and may be life-threatening
- Allergic reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with any insulin, including Apidra
- Hypokalemia: All insulins, including Apidra can cause hypokalemia, which if untreated, may result in respiratory paralysis, ventricular arrhythmia, and death
- Renal or hepatic impairment: Like all insulins, may require a reduction in the Apidra dose
- Mixing: Apidra for subcutaneous injection should not be mixed with insulins other than NPH insulin. Do not mix Apidra with any insulin for intravenous administration or for use in a continuous infusion pump
- Pump use: Change the Apidra in the pump reservoir every 48 hours
- Intravenous use: Frequently monitor for hypoglycemia and hypokalemia.
- Fluid retention and heart failure can occur with concomitant use of thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation of TZD if heart failure occurs

APIDRA® (insulin glulisine) injection vial
APIDRA® SOLOSTAR® (insulin glulisine) subcutaneous solution pen-injector (cont.)

Criteria:

- **Criteria for initial therapy:** Apidra is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual is 4 years of age or older
  2. A confirmed diagnosis of diabetes mellitus
  3. Individual has failure, contraindication or intolerance to Humalog

  Initial approval duration: 12 months

- **Criteria for continuation of coverage (renewal request):** Apidra 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:

Apidra. Package Insert. Revised by manufacturer 2/2015. 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.

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