



PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 11/16/17  
LAST REVIEW DATE: 11/16/17  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

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**LEVEMIR® (insulin detemir) subcutaneous solution**  
**LEVEMIR® FLEXTOUCH® (insulin detemir) subcutaneous solution pen-injector**

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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](http://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](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**



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## Levemir (insulin detemir)

**Medication class:**

Antidiabetics – Insulin, Human Insulin

**FDA-approved indication(s):**

- To improve glycemic control in adults and children with diabetes mellitus.

**Recommended Dose:**

- The starting dose should be individualized based on the type of diabetes and whether the patient is insulin-naïve.
- Administer subcutaneously once daily or in divided doses twice daily. Once daily administration should be given with the evening meal or at bedtime.
- Rotate injection sites within an injection area (abdomen, thigh, or deltoid) to reduce the risk of lipodystrophy.
- Converting from other insulin therapies may require adjustment of timing and dose of Levemir. Closely monitor glucoses especially upon converting to Levemir and during the initial weeks thereafter

**Available Dosage Forms:**

Solution for injection 100 Units/mL (U-100) is available in:

- 3 mL Levemir FlexTouch
- 10 mL vial

**Limitations of use:**

- Not recommended for treating diabetic ketoacidosis. Use intravenous, rapid-acting or short-acting insulin instead.

**Warnings and Precautions:**

- Never Share a Levemir FlexTouch between patients, even if the needle is changed.
  - Dose adjustment and monitoring: Monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision.
  - Administration: Do not dilute or mix with any other insulin or solution. Do not administer subcutaneously via an insulin pump, intramuscularly, or intravenously because severe hypoglycemia can occur.
  - Hypoglycemia is the most common adverse reaction of insulin therapy and may be life-threatening.
  - Allergic reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur.
  - Renal or hepatic impairment: May require adjustment of the Levemir dose.
  - Fluid retention and heart failure can occur with concomitant use of thiazolidinediones (TZDs), which are PPAR-gamma agonists, and insulin, including Levemir
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**Criteria:**

- **Criteria for initial therapy:** Levemir 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 is **EITHER** of the following:
  - 2 years of age or older with type 1 diabetes
  - 18 years of age or older with type 2 diabetes
3. Individual has failure, contraindication, or intolerance to Lantus
4. There are **NO** contraindications.
  - Contraindications include:
    - Hypersensitivity to Levemir or any of its excipients

**Initial approval duration:** 12 months

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

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**Resources:**

Levemir. 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](mailto: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](http://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	
<input type="checkbox"/> Standard <input type="checkbox"/> Urgent. Sign here: _____	<input type="checkbox"/> Exigent (requires prescriber to include a written statement)

Clinical Information	
1. What is the diagnosis? Please specify below.	
ICD-10 Code: _____	Diagnosis Description: _____
2. <input type="checkbox"/> Yes <input type="checkbox"/> No    Was this medication started on a recent hospital discharge or emergency room visit?	
3. <input type="checkbox"/> Yes <input type="checkbox"/> 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

# 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.