

**Criteria for Non-Formulary Use of
Long-acting Insulin Analogs (Insulin Glargine and Insulin Detemir)
VHA Pharmacy Benefits Management Strategic Healthcare Group and Medical Advisory Panel**

The following recommendations are based on current medical evidence and expert opinion from clinicians. The content of the document is dynamic and will be revised as new clinical data becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician should utilize this guidance and interpret it in the clinical context of the individual patient situation.

Indications (must select at least one of the following)
<input type="checkbox"/> Type 1 diabetes <input type="checkbox"/> Candidates for insulin pump therapy (offer trial before going to insulin pump) <input type="checkbox"/> Unable to achieve glycemic target because of documented episodes of symptomatic hypoglycemia, especially nocturnal hypoglycemia, with NPH despite several attempts at adjusting the regimen (including but not limited to dietary counseling, adjusting NPH dose, and when appropriate adding or adjusting bolus meal insulin)* <input type="checkbox"/> Type 2 diabetics with special circumstances where the risk of severe hypoglycemia and/or its potential consequences are significant and/or catastrophic (e.g. frail elderly, liver failure, severe renal failure, workers with frequent rotating shifts and occupations such as truck or bus drivers or heavy machinery operators).
Issues for consideration
<ul style="list-style-type: none"> Patients are accustomed to the concept that longer-acting agents such as NPH are cloudy and short-acting agents are clear. Patients must be taught that glargine and detemir are long-acting insulins that are clear in color and that they should not be mistaken for short-acting agents Insulin glargine or detemir must not be mixed in the same syringe with any other insulin
Criteria for continuation
Improvement in glucose control or hypoglycemia during the first 6 months of treatment. If no improvement is noted referral to an endocrinologist or diabetes specialist is recommended or switch to formulary insulin

* Horvath K, et al. Long-acting insulin analogs versus NPH insulin for type 2 diabetes mellitus. Cochrane Database Syst Rev. 2007 Apr 18; (2):CD005613.

DOSING

- Each milliliter contains 100 units of insulin glargine or insulin detemir.
- Close glucose monitoring is recommended during the transition from NPH and in the initial weeks thereafter. Dose and timing of concurrent short-acting insulin or other concomitant antidiabetic treatment may need to be adjusted.
- Dosing requirements may need to be adjusted in patients with renal or hepatic impairment.
- The dosage of insulin glargine and insulin detemir may not be equivalent. One randomized controlled trial in type 2 diabetes showed that the mean dose required to achieve a similar A1c was higher with detemir than glargine and that approximately half the patients receiving detemir required twice daily dosing. However, a large observational study (includes patients switched from NPH or glargine, and new starts for insulin) showed approximately 13% of patients required twice daily dosing.

Insulin glargine	Insulin detemir
Insulin glargine may be administered at any time during the day. It should be administered once a day at the same time each day. (Some patients may require twice daily dosing) <u>Switching from NPH to insulin glargine</u> <ul style="list-style-type: none"> Patients on NPH once daily - may be switched unit-for-unit to insulin glargine once daily at bedtime Patients on NPH twice daily – total glargine dose should be approximately 80% of the previous NPH dose and should be given once daily. 	Insulin detemir can be administered once- or twice-daily. If given once daily, the dose should be administered with the evening meal or at bedtime. If given twice-daily, the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose. <u>Switching from NPH to insulin detemir</u> Changing the basal insulin to detemir can be done on a unit-to-unit basis. Some patients with type 2 diabetes may require higher doses of detemir than NPH.