Criteria for Non formulary Use of
Exenatide (Byetta™)

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.

Inclusion criteria

The following 3 criteria must be met:

- The provider specializes in diabetes management
- Patient has type 2 diabetes
- Patient has not achieved desired HbA1c using combinations of ≥ 2 oral hypoglycemic agents at maximally tolerated doses (this excludes those patients with significant contraindications to SU, metformin, or TZDs that would preclude using at least 2 agents in combination)

And at least 1 of the following:

- Documented true insulin allergy
- Documented history of frequent or severe nocturnal hypoglycemia with insulin despite multiple attempts with various dosing regimens (including the use of insulin analogs)
- Patient has a job that does not allow the use of insulin to treat diabetes (must be confirmed with patients place of employment)*

*Congress has passed a new law which will allow the use of insulin for interstate commercial drivers who have diabetes, provided that stable control has been demonstrated. http://www.diabetes.org/advocacy-and-legalresources/discrimination/CDLFAQ.jsp

Exclusion criteria

- Type 1 diabetes
- Patient requires insulin therapy
- Patient has end-stage renal disease or CrCl < 30ml/min
- Patient has severe gastrointestinal disease, including gastroparesis

Dosing

- Exenatide is administered with a sulfonylurea, metformin, or the combination. When exenatide is added to sulfonylurea therapy, a reduction in the dose of sulfonylurea may be considered to reduce the risk of hypoglycemia. Patients using metformin may continue to use their current dose.
- Initial dose of exenatide is 5 mcg per dose administered twice daily at any time within the 60-minute period before the morning and evening meals. Exenatide should not be administered after a meal. If a dose is missed, the treatment regimen should be resumed with the next scheduled dose.
- If the patient tolerated the initial dose and a dosage increase is indicated, exenatide can be increased to 10 mcg twice daily after 1 month of therapy.
- Exenatide is injected subcutaneously in the thigh, abdomen, or upper arm.

Cautions regarding concomitant medications
• Exenatide has not been studied in combination with insulin, meglitinides (e.g. repaglinide, nateglinide), alpha-glucosidase inhibitors (e.g. acarbose, miglitol), or thiazolidinediones (e.g. rosiglitazone, pioglitazone); concurrent use should be avoided • Exenatide should be used with caution in patients taking oral medications that require rapid gastric absorption • Oral medications that are dependent on threshold concentrations for efficacy should be taken at least 1 hour before exenatide administration (e.g. antibiotics, oral contraceptives) • Drugs that are administered with food should be taken with a meal or snack when exenatide is not administered

Follow-up
• After initial prescription, patient must be reevaluated at least within 1-2 months by the prescribing clinician (initial prescription should only be written for up to 2 months including refills). • Discontinue if there is a < 10% decrease in HbA1c (after 3-6 months of therapy). However, exenatide may be continued if patient has reached glycemic target regardless of the magnitude of drop in HbA1c

The drug monograph for exenatide can be found at www.pbm.va.gov