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**DEPARTMENT OF VETERANS AFFAIRS  
Veterans Health Administration  
Washington DC 20420**

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**UNDER SECRETARY FOR HEALTH'S INFORMATION LETTER**

**FORMULARY UTILIZATION OF INSULIN PENS**

**1. Background.** Over 40 percent of veterans with diabetes use insulin. While bedtime insulin, in combination with oral agents, is an effective regimen for many individuals with Type 2 diabetes, some individuals with Type 2 diabetes, and almost all persons with Type 1 diabetes are prescribed multidose regimens. Such regimens may include short- and long-acting insulin regimens, or fixed-dose mixed insulins. These insulin regimens can be delivered using multidose vial and syringe, or by smaller delivery devices referred to as "insulin pens." The purpose of this information letter is to review the literature comparing these two alternative delivery systems. The key considerations are:

a. What information is available regarding the safety, efficacy and cost-effectiveness of insulin pens versus vial and syringe administration? Are there long-term studies?

(1) The published literature indicates that insulin pens deliver accurate doses. Comparison studies of insulin pens versus vial and syringes in adults are limited. In one study, the efficacy and safety of pre-filled insulin pens in lowering A1c values compared to vial and syringe delivery was comparable using a cross-over study design. Short-term studies generally report a subject preference for the insulin pen over vials and syringes, although the possibility of significant selection biases is acknowledged. Long-term use of newer devices has not been evaluated. Although in an earlier study, injection force was a major factor in device discontinuation.

(2) In regards to safety, there is no evidence that hypoglycemia is significantly impacted by the use of one system over another. One study suggests that the risk of needle sticks during device disassembly may be six-fold higher with insulin pens. Cost-effectiveness has not been evaluated in a rigorous fashion, but pens are more expensive than syringes.

b. Are there subgroups for whom pens would be medically indicated? The Department of Veterans Affairs (VA) was unable to find medical evidence that assessed clinical benefit for the use of insulin pens as compared to the use of insulin syringes in subgroups of patients with disabilities (e.g., visually impaired, patients with tremors, or patients with mild cognitive impairment, etc.).

**2. Guidance.** In the absence of evidence of medical benefit, the formulary use of insulin pens for patients with diabetes should be considered on a case-by-case basis. The following factors need to be taken into consideration:

a. Inability to draw insulin from a multidose vial into a syringe (especially for extremely-low doses). Patient abilities must be evaluated by health care professionals knowledgeable in insulin administration, and the evaluation must be documented in the medical record.

b. Use of short-acting analogs in intensive multi-dose therapy for veterans based upon lifestyle.

**3. References**

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