Non-Formulary Criteria for Use of Sitagliptin (Januvia™)

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.

Because sitagliptin modestly reduces HbA1c, has no long-term safety and outcomes data, and is significantly more costly compared to the formulary agents, it should be made available based on the following recommendations.

Sitagliptin as monotherapy (Must meet both criteria)

- ☐ Patient is a candidate for oral therapy and is intolerant of or has contraindications to **all** of the following: metformin, sulfonylureas, and thiazolidinediones (TZDs)[1]

AND

- ☐ Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data [2]

Sitagliptin as part of a 2-drug regimen (Must meet both criteria)

- ☐ Patient has inadequate glycemic control with metformin monotherapy and requires the addition of a second agent **AND** has contraindications to or is unable to tolerate both sulfonylureas and TZDs[1]

OR

Patient has inadequate glycemic control with TZD monotherapy and requires the addition of a second agent **AND** has contraindications to or is unable to tolerate both sulfonylureas and metformin[1]

AND

- ☐ Target value for HbA1c based on VA/DoD Guidelines http://www.oqp.med.va.gov/cpg/DM_base.htm is likely to be attainable based on clinical trial data [3,4]

NOTE: Addition of nighttime insulin remains as an alternative to using sitagliptin; however, it should be the preferred strategy when baseline HbA1c is > 1.5% above target value

Dosage

Sitagliptin is administered as 100mg once daily and may be taken with or without food.

Dosage adjustment is recommended for patients with moderate-severe renal insufficiency and endstage renal disease (ESRD).

- 50mg once daily for patients with moderate renal impairment (CrCl ≥ 30 to <50mL/min or SCr >1.7- ≤ 3.0mg/dl for males >1.5- ≤ 2.5mg/dl females)
- 25mg once daily for patients with severe renal impairment (CrCl < 30mL/min or SCr > 3.0mg/dl for males or > 2.5mg/dl for females) and for ESRD requiring dialysis. Sitagliptin may be administered without regard to time of dialysis.

Discontinuation criteria

If HbA1c goals are not met after 3-6 months of sitagliptin therapy, sitagliptin should be discontinued and insulin initiated (no safety and efficacy data for combined use with insulin at this time).

[1] Intolerance to other oral agents includes but is not limited to the following: Sulfonylureas (clinically significant hypoglycemia); metformin (persistent severe GI effects); TZDs (clinically significant edema, new onset or worsening heart failure)

[2] In clinical trials, the average absolute decrease in HbA1c (placebo-subtracted) with sitagliptin monotherapy was 0.44-0.57% for baseline HbA1c <8.0%; 0.6-0.8% for baseline HbA1c 8-8.9%; 1.2-1.5% for baseline HbA1c > 9%

[3] In clinical trials, the average absolute decrease in HbA1c when combining sitagliptin with metformin was 0.53% for baseline HbA1c < 8.0%; 0.82-1.13% for baseline HbA1c 8-8.9%; 0.91-1.68% for HbA1c > 9%

[4] In clinical trials, the average absolute decrease in HbA1c when combining sitagliptin with a TZD was 0.73% for baseline HbA1c < 8.5% and 1.17% for HbA1c ≥ 8.5%

- Combination of sitagliptin with sulfonylureas or insulin is not recommended until data on its safety and efficacy are available.
- There are limited safety and efficacy data with sitagliptin as part of a 3-drug oral therapy regimen. Sitagliptin is not recommended for use as part of a 3-drug oral regimen.

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Updated versions may be found at www.pbm.va.gov or http://vaww.pbm.va.gov