

**Texas Prior Authorization Program
Clinical Edit Criteria**

Drug/Drug Class

Sitagliptin (Januvia)

Clinical Edit Information Included in this Document

Sitagliptin (Januvia) 25mg

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical edit
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical edit criteria rules
- **Logic diagram:** a visual depiction of the clinical edit criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes); provided when applicable
- **References:** clinical publications and sources relevant to this clinical edit

Sitagliptin (Januvia) 50mg

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Sitagliptin (Januvia) 100mg

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Note: Click the hyperlink to navigate directly to that section.

Revision Notes

- Removed steps 4 and 5 regarding moderate to severe renal failure for sitagliptin (Januvia) 25mg to reflect rules in system
- Changed step 3 to deny with a history of severe renal failure or ESRD for sitagliptin (Januvia) 50mg to reflect rules in system



**Sitagliptin (Januvia)
25mg**

Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
JANUVIA 25 MG TABLET	97398



Sitagliptin (Januvia)
25mg
Clinical Edit Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)

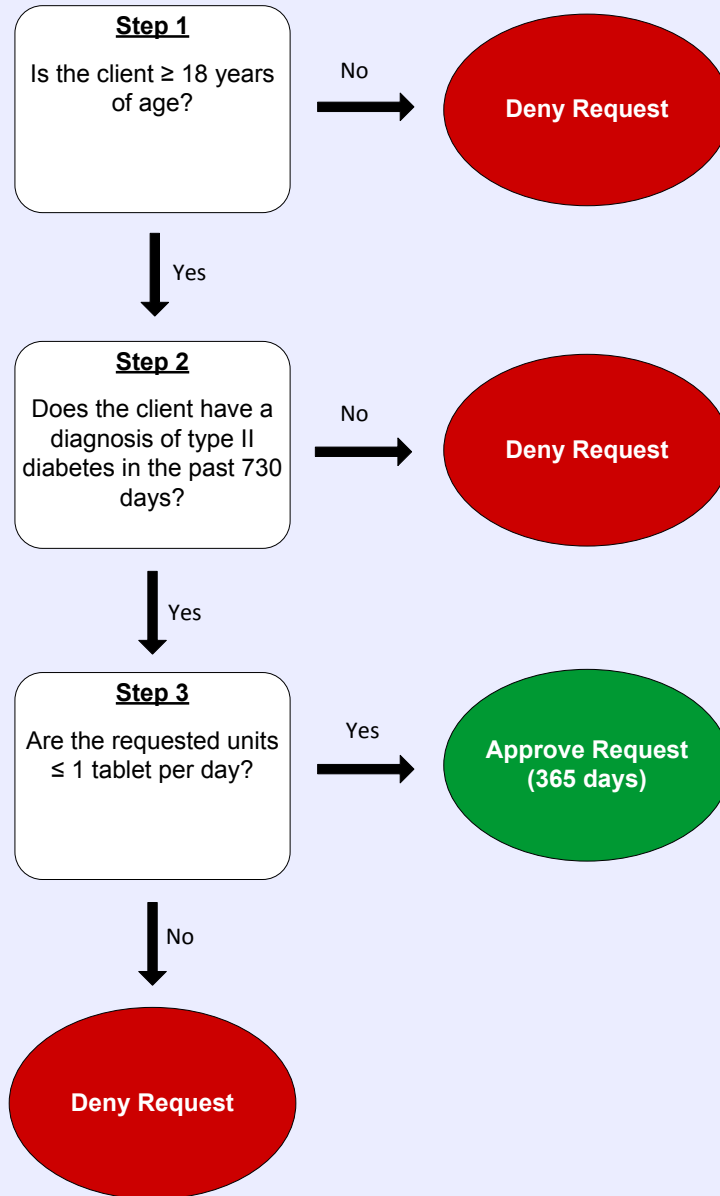
2. Does the client have a diagnosis of type II diabetes in the past 730 days?
 Yes (Go to #3)
 No (Deny)

3. Are the requested units less than or equal to (\leq) 1 tablet per day?
 Yes (Approve – 365 days)
 No (Deny)



Sitagliptin (Januvia) 25mg

Clinical Edit Criteria Logic Diagram





Sitagliptin (Januvia) 25mg

Clinical Edit Criteria Supporting Tables

Step 2 (diagnosis of type II diabetes)	
Required diagnosis: 1	
Look back timeframe: 730 days	
Type II Diabetes Diagnoses	
ICD-9 Code	Description
25000	DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25002	DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25010	DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25012	DIABETES WITH KETOACIDOSIS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25020	DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25022	DIABETES WITH HYPEROSMOLARITY, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25030	DIABETES WITH OTHER COMA, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25032	DIABETES WITH OTHER COMA, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25040	DIABETES WITH RENAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25042	DIABETES WITH RENAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25050	DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25052	DIABETES WITH OPHTHALMIC MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE UNCONTROLLED
25060	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25062	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25070	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25072	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
25080	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25082	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE UNCONTROLLED

Step 2 (diagnosis of type II diabetes)	
Required diagnosis: 1	
Look back timeframe: 730 days	
Type II Diabetes Diagnoses	
ICD-9 Code	Description
25090	DIABETES WITH UNSPECIFIED COMPLICATION, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
25092	DIABETES WITH UNSPECIFIED COMPLICATION, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED

Step 4 (diagnosis of moderate renal failure)	
Required diagnosis: 1	
Look back timeframe: 730 days	
Moderate Renal Failure Diagnoses	
ICD-9 Code	Description
5853	CHRONIC KIDNEY DISEASE, STAGE III (MODERATE)

Step 5 (diagnosis of severe renal failure or ESRD)	
Required diagnosis: 1	
Look back timeframe: 730 days	
Severe Renal Failure or ESRD Diagnoses	
ICD-9 Code	Description
5854	CHRONIC KIDNEY DISEASE, STAGE IV (SEVERE).
5855	CHRONIC KIDNEY DISEASE, STAGE V.
5856	END STAGE RENAL DISEASE.



**Sitagliptin (Januvia)
50mg**

Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
JANUVIA 50 MG TABLET	97399

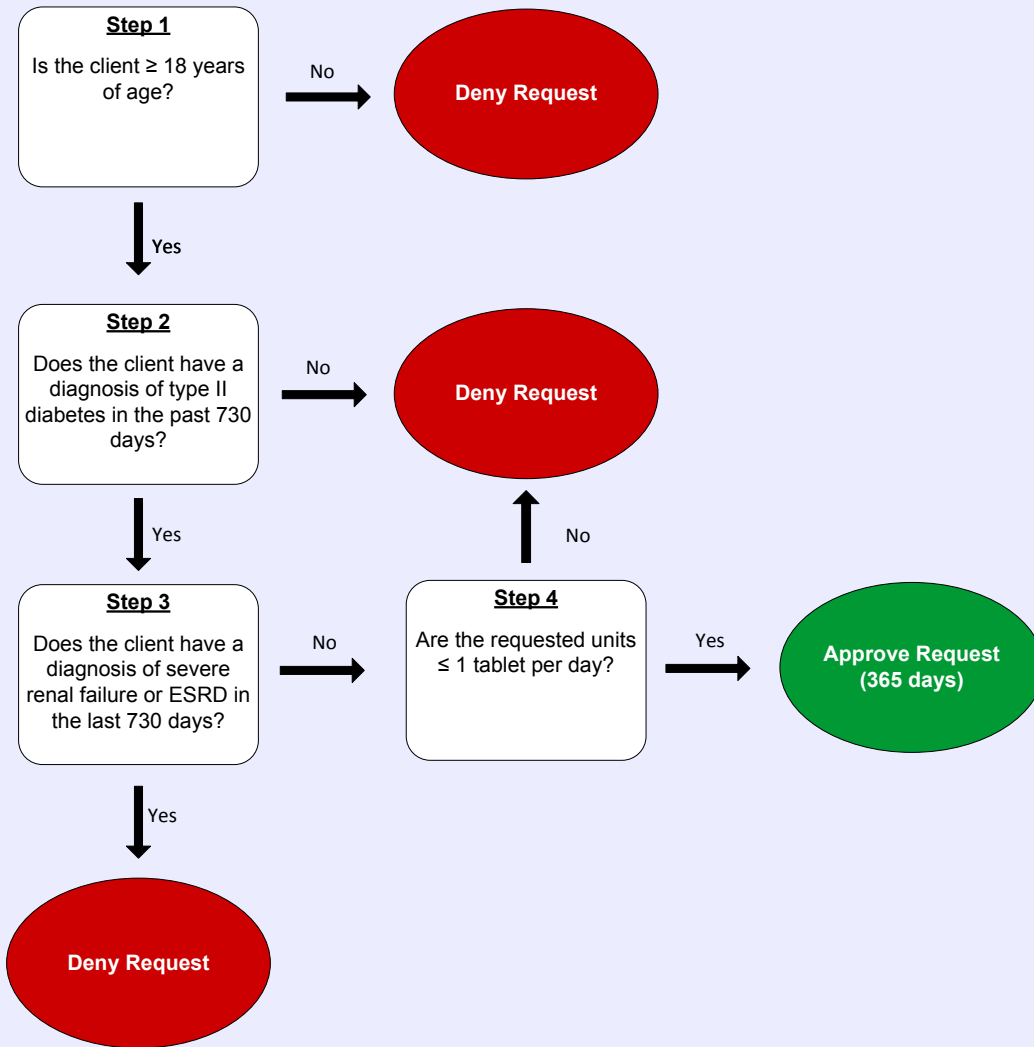


Sitagliptin (Januvia)
50mg
Clinical Edit Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of type II diabetes in the past 730 days?
 Yes (Go to #3)
 No (Deny)
3. Does this client have a diagnosis of severe renal failure or ESRD in the last 730 days?
 Yes (Deny)
 No (Go to #4)
4. Are the requested units less than or equal to (\leq) 1 tablet per day?
 Yes (Approve – 365 days)
 No (Deny)



Sitagliptin (Januvia) 50mg Clinical Edit Criteria Logic Diagram





Sitagliptin (Januvia) 50mg

Clinical Edit Criteria Supporting Tables

Step 2 (diagnosis of type II diabetes)

Required diagnosis: 1

Look back timeframe: 730 days

For the list of type II diabetes diagnosis codes that pertain to this step, see the **Type II Diabetes Diagnoses** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 3 (diagnosis of severe renal failure or ESRD)

Required diagnosis: 1

Look back timeframe: 730 days

For the list of severe renal failure or ESRD diagnosis codes that pertain to this step, see the **Severe Renal Failure or ESRD Diagnoses** table in the previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.



**Sitagliptin (Januvia)
100mg**

Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
JANUVIA 100 MG TABLET	97400



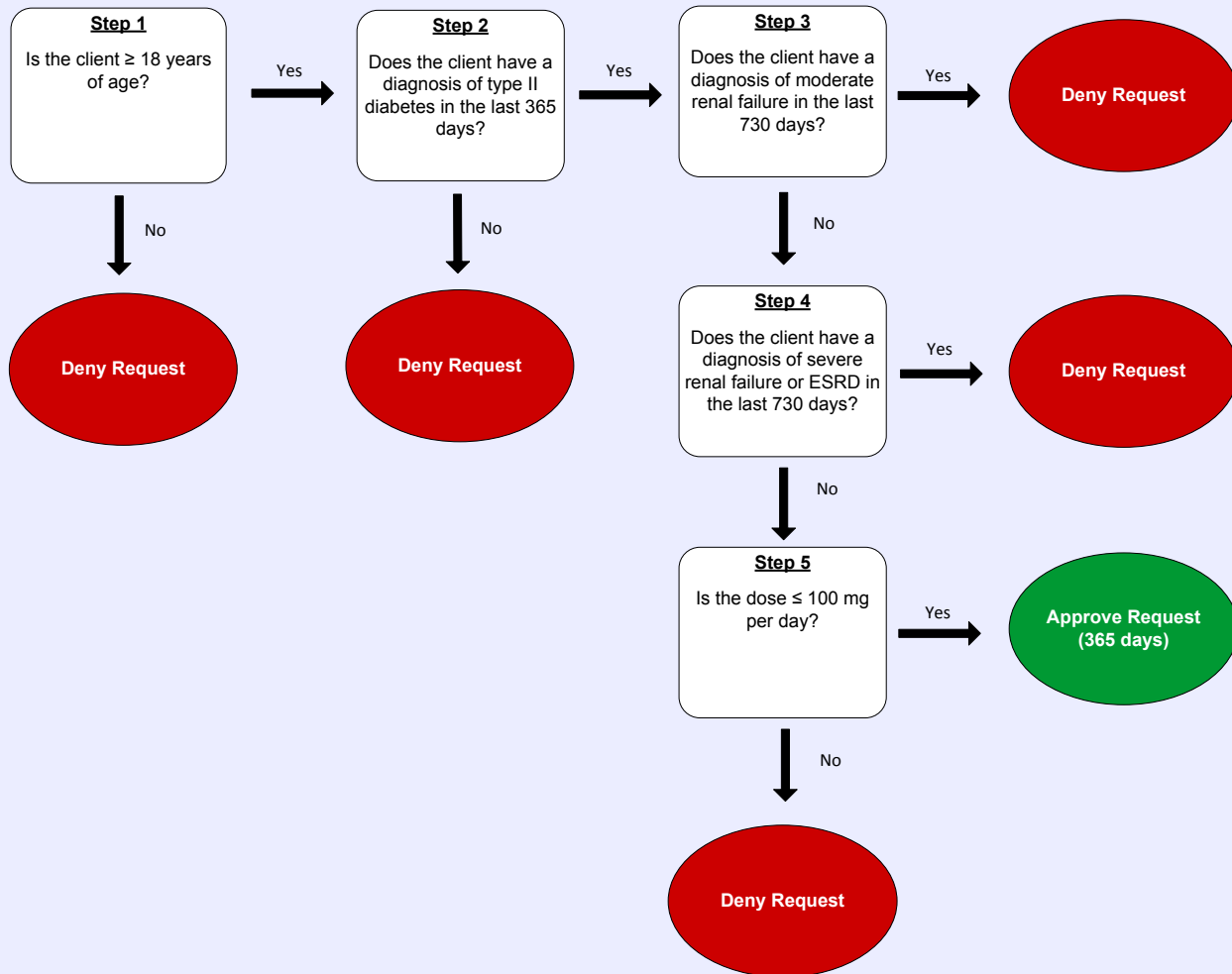
Sitagliptin (Januvia)
100mg
Clinical Edit Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes (Go to #2)
 No (Deny)
2. Does the client have a diagnosis of type II diabetes in the past 730 days?
 Yes (Go to #3)
 No (Deny)
3. Does the client have a diagnosis of moderate renal failure in the last 730 days?
 Yes (Deny)
 No (Go to #4)
4. Does the client have a diagnosis of severe renal failure or ESRD in the last 730 days?
 Yes (Deny)
 No (Go to #5)
5. Is the dose less than or equal to (\leq) 100 mg per day?
 Yes (Approve – 365 days)
 No (Deny)



Sitagliptin (Januvia) 100mg

Clinical Edit Criteria Logic Diagram



**Sitagliptin (Januvia)****100mg****Clinical Edit Criteria Supporting Tables****Step 2 (diagnosis of type II diabetes)****Required diagnosis: 1****Look back timeframe: 730 days**

For the list of type II diabetes diagnosis codes that pertain to this step, see the **Type II Diabetes Diagnoses** table in a previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 3 (diagnosis of moderate renal failure)**Required diagnosis: 1****Look back timeframe: 730 days**

For the list of type II diabetes diagnosis codes that pertain to this step, see the **Moderate Renal Failure Diagnoses** table in a previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.

Step 4 (diagnosis of severe renal failure or ESRD)**Required diagnosis: 1****Look back timeframe: 730 days**

For the list of type II diabetes diagnosis codes that pertain to this step, see the **Severe Renal Failure or ESRD Diagnoses** table in a previous "Supporting Tables" section.

Note: Click the hyperlink to navigate directly to the table.



Sitagliptin (Januvia)

Clinical Edit Criteria References

1. Clinical pharmacology: sitagliptin monograph. Available at: <http://www.clinicalpharmacology.com>. Accessed on December 8, 2006.
2. MICROMEDEX Health Services. DRUGDEX evaluations: sitagliptin drug evaluation. Available at <http://www.micromedex.com>. Accessed on December 8, 2006.
3. Januvia® (sitagliptin) [prescribing information]. Whitehouse Station, NJ: Merck & Company, Inc. 2006.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/31/2011	Initial publication and posting to website
05/11/2012	<ul style="list-style-type: none"> • Separated sitagliptin (Januvia) into three sections: one for 25mg, one for 50mg, and one for 100mg • Added a new section to specify the drugs requiring prior authorization for each strength of sitagliptin (Januvia) • In each "Clinical Edit Supporting Tables" section, revised tables to specify the diagnosis codes pertinent to steps 2, 4, and 5 of the logic diagrams
07/18/2012	<ul style="list-style-type: none"> • Removed steps 4 and 5 regarding moderate to severe renal failure for sitagliptin (Januvia) 25mg to reflect rules in system • Changed step 3 to deny with a history of severe renal failure or ESRD for sitagliptin (Januvia) 50mg to reflect rules in system