



Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Clinical Criteria Information Included in this Document

DPP-4 Inhibitor Criteria A: Alogliptin 6.25mg, Januvia 25mg, Nesina 6.25mg, Onglyza 2.5mg and Tradjenta 5mg

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical 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 criteria

DPP-4 Inhibitor Criteria B: Alogliptin 12.5mg, Januvia 50mg and Nesina 12.5mg

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical 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 criteria

DPP-4 Inhibitor Criteria C: Alogliptin 25mg, Januvia 100mg, Nesina 25mg and Onglyza 5mg

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical 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 criteria

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

DPP-4 Inhibitor Combination Agents

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- Logic diagram: a visual depiction of the clinical 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 criteria

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

Revision Notes

Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table



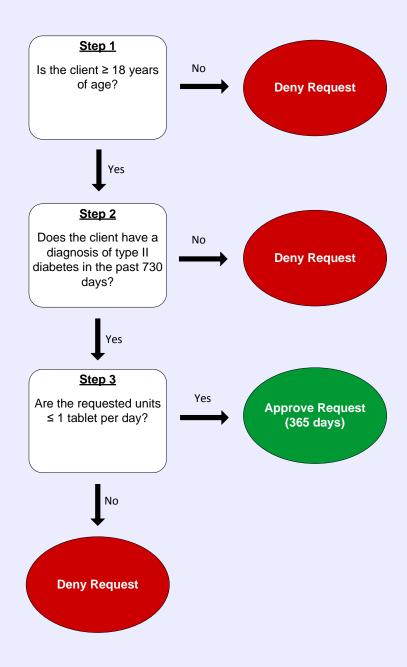
Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN 6.25 MG TABLET	34086
JANUVIA 25 MG TABLET	97398
NESINA 6.25 MG TABLET	34086
ONGLYZA 2.5 MG TABLET	27393
TRADJENTA 5 MG TABLET	29890



1.	Is the client greater than or equal to (≥) 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 (≤) 1 tablet per day? [] Yes (Approve – 365 days) [] No (Deny)







Clinical Criteria Supporting Tables

Step 2 (diagnosis of type II diabetes) Required diagnosis: 1			
	Look back timeframe: 730 days		
ICD-10 Code Description			
E1100	TYPE 2 DIABETES MELLITUS WITH HYPEROSMOLARITY WITHOUT NONKETOTIC HYPERGLYCEMIC-HYPEROSMOLAR COMA (NKHHC)		
E1101	TYPE 2 DIABETES MELLITUS WITH HYPEROSMOLARITY WITH COMA		
E1121	TYPE 2 DIABETES MELLITUS WITH DIABETIC NEPHROPATHY		
E1122	TYPE 2 DIABETES MELLITUS WITH DIABETIC CHRONIC KIDNEY DISEASE		
E1129	TYPE 2 DIABETES MELLITUS WITH OTHER DIABETIC KIDNEY COMPLICATION		
E11311	TYPE 2 DIABETES MELLITUS WITH UNSPECIFIED DIABETIC RETINOPATHY WITH MACULAR EDEMA		
E11319	TYPE 2 DIABETES MELLITUS WITH UNSPECIFIED DIABETIC RETINOPATHY WITHOUT MACULAR EDEMA		
E11321	TYPE 2 DIABETES MELLITUS WITH MILD NONPROLIFERATIVE DIABETIC RETINOPATHY WITH MACULAR EDEMA		
E11329	TYPE 2 DIABETES MELLITUS WITH MILD NONPROLIFERATIVE DIABETIC RETINOPATHY WITHOUT MACULAR EDEMA		
E11331	TYPE 2 DIABETES MELLITUS WITH MODERATE NONPROLIFERATIVE DIABETIC RETINOPATHY WITH MACULAR EDEMA		
E11339	TYPE 2 DIABETES MELLITUS WITH MODERATE NONPROLIFERATIVE DIABETIC RETINOPATHY WITHOUT MACULAR EDEMA		
E11341	TYPE 2 DIABETES MELLITUS WITH SEVERE NONPROLIFERATIVE DIABETIC RETINOPATHY WITH MACULAR EDEMA		
E11349	TYPE 2 DIABETES MELLITUS WITH SEVERE NONPROLIFERATIVE DIABETIC RETINOPATHY WITHOUT MACULAR EDEMA		
E11351	TYPE 2 DIABETES MELLITUS WITH PROLIFERATIVE DIABETIC RETINOPATHY WITH MACULAR EDEMA		
E11359	TYPE 2 DIABETES MELLITUS WITH PROLIFERATIVE DIABETIC RETINOPATHY WITHOUT MACULAR EDEMA		
E1136	TYPE 2 DIABETES MELLITUS WITH DIABETIC CATARACT		
E1139	TYPE 2 DIABETES MELLITUS WITH OTHER DIABETIC OPHTHALMIC COMPLICATION		
E1140	TYPE 2 DIABETES MELLITUS WITH DIABETIC NEUROPATHY, UNSPECIFIED		
E1141	TYPE 2 DIABETES MELLITUS WITH DIABETIC MONONEUROPATHY		
E1142	TYPE 2 DIABETES MELLITUS WITH DIABETIC POLYNEUROPATHY		
E1143	TYPE 2 DIABETES MELLITUS WITH DIABETIC AUTONOMIC (POLY)NEUROPATHY		

Step 2 (diagnosis of type II diabetes)			
	Required diagnosis: 1 Look back timeframe: 730 days		
ICD-10 Code	Description		
E1144	TYPE 2 DIABETES MELLITUS WITH DIABETIC AMYOTROPHY		
E1149	TYPE 2 DIABETES MELLITUS WITH OTHER DIABETIC NEUROLOGICAL COMPLICATION		
E1151	TYPE 2 DIABETES MELLITUS WITH DIABETIC PERIPHERAL ANGIOPATHY WITHOUT GANGRENE		
E1152	TYPE 2 DIABETES MELLITUS WITH DIABETIC PERIPHERAL ANGIOPATHY WITH GANGRENE		
E1159	TYPE 2 DIABETES MELLITUS WITH OTHER CIRCULATORY COMPLICATIONS		
E11610	TYPE 2 DIABETES MELLITUS WITH DIABETIC NEUROPATHIC ARTHROPATHY		
E11618	TYPE 2 DIABETES MELLITUS WITH OTHER DIABETIC ARTHROPATHY		
E11620	TYPE 2 DIABETES MELLITUS WITH DIABETIC DERMATITIS		
E11621	TYPE 2 DIABETES MELLITUS WITH FOOT ULCER		
E11622	TYPE 2 DIABETES MELLITUS WITH OTHER SKIN ULCER		
E11628	TYPE 2 DIABETES MELLITUS WITH OTHER SKIN COMPLICATIONS		
E11630	TYPE 2 DIABETES MELLITUS WITH PERIODONTAL DISEASE		
E11638	TYPE 2 DIABETES MELLITUS WITH OTHER ORAL COMPLICATIONS		
E11641	TYPE 2 DIABETES MELLITUS WITH HYPOGLYCEMIA WITH COMA		
E11649	TYPE 2 DIABETES MELLITUS WITH HYPOGLYCEMIA WITHOUT COMA		
E1165	TYPE 2 DIABETES MELLITUS WITH HYPERGLYCEMIA		
E1169	TYPE 2 DIABETES MELLITUS WITH OTHER SPECIFIED COMPLICATION		
E118	TYPE 2 DIABETES MELLITUS WITH UNSPECIFIED COMPLICATIONS		
E119	TYPE 2 DIABETES MELLITUS WITHOUT COMPLICATIONS		



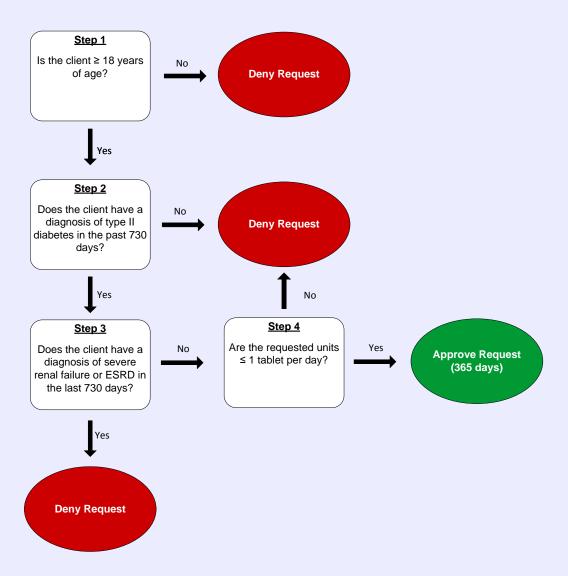
Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN 12.5 MG TABLET	34085
JANUVIA 50 MG TABLET	97399
NESINA 12.5 MG TABLET	34085



1.	Is the client greater than or equal to (≥) 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 (≤) 1 tablet per day? [] Yes (Approve – 365 days) [] No (Deny)







Clinical 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	
ICD-10 Code Description		
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE)	
N185	CHRONIC KIDNEY DISEASE, STAGE 5	
N186	END STAGE RENAL DISEASE	



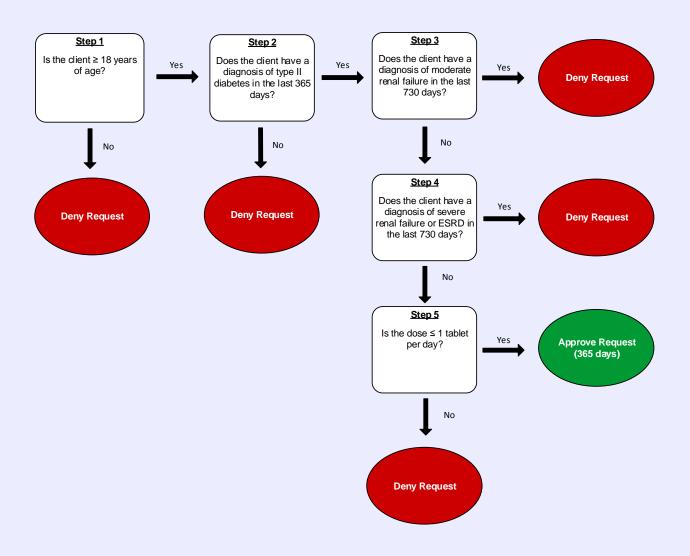
Drugs Requiring Prior Authorization

Drugs Requiring Prior Authorization		
Label Name	GCN	
ALOGLIPTIN 25 MG TABLET	34076	
JANUVIA 100 MG TABLET	97400	
NESINA 25 MG TABLET	34076	
ONGLYZA 5 MG TABLET	27394	



1.	Is the client greater than or equal to (≥) 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 (≤) 1 tablet per day? [] Yes (Approve – 365 days) [] No (Deny)







Clinical 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		
ICD-10 Code Description		
N183	CHRONIC KIDNEY DISEASE, STAGE 3 (MODERATE)	

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.



Drugs Requiring Prior Authorization

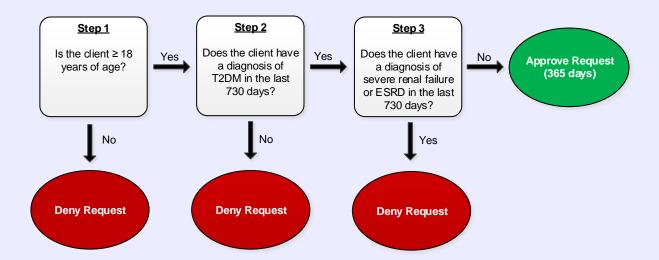
Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN-METFORMIN 12.5-1000	34088
ALOGLIPTIN-METFORMIN 12.5-500	34087
ALOGLIPTIN-PIOGLIT 12.5-15 MG	34080
ALOGLIPTIN-PIOGLIT 12.5-30 MG	34083
ALOGLIPTIN-PIOGLIT 12.5-45 MG	34084
ALOGLIPTIN-PIOGLIT 25-15 MG	34077
ALOGLIPTIN-PIOGLIT 25-30 MG	34078
ALOGLIPTIN-PIOGLIT 25-45 MG	34079
GLYXAMBI 10-5 MG TABLET	37832
GLYXAMBI 25-5 MG TABLET	37833
JANUMET 50-1000 MG TABLET	98307
JANUMET 50-500 MG TABLET	98306
JANUMET XR 100-1000 MG TABLET	31348
JANUMET XR 50-1000 MG TABLET	31340
JANUMET XR 50-500 MG TABLET	31339
JENTADUETO 2.5-1000 MG TAB	31317
JENTADUETO 2.5-500 MG TAB	31315
JENTADUETO 2.5-850 MG TAB	31316
JENTADUETO XR 2.5-1000 MG TAB	41637
JENTADUETO XR 5-1000 MG TAB	41639
KAZANO 12.5-1000 MG TABLET	34088
KAZANO 12.5-500 MG TABLET	34807
KOMBIGLYZE XR 2.5-1000 MG TAB	29225
KOMBIGLYZE XR 5-1000 MG TAB	29224
KOMBIGLYZE XR 5-500 MG TABLET	29118
OSENI 12.5-15 MG TABLET	34080
OSENI 12.5-30 MG TABLET	34083
OSENI 12.5-45 MG TABLET	34084
OSENI 25-15 MG TABLET	34077
OSENI 25-30 MG TABLET	34078
OSENI 25-45 MG TABLET	34079

Drugs Requiring Prior Authorization		
Label Name	GCN	
QTERN 10-5 MG TABLET	43126	
STEGLUJAN 15-100 MG TABLET	44238	
STEGLUJAN 5-100 MG TABLET	44237	



1.	Is the client greater than or equal to (≥) 18 years of age? [] Yes (Go to #2) [] No (Deny)
2.	Does the client have a diagnosis of type II diabetes in the last 730 days? [] Yes (Go to #3) [] No (Deny)
3.	Does the client have a diagnosis of severe renal failure or ESRD in the last 730 days? [] Yes (Deny) [] No (Approve – 365 days)







Clinical 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 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.



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Clinical Criteria References

- 1. 2015 ICD-10-CM Diagnosis Codes. 2015. Available at **www.icd10data.com**. Accessed on April 3, 2015.
- 2. American Medical Association data files. 2015 ICD-10-CM Diagnosis Codes. Available at **www.commerce.ama-assn.org**.
- Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2018. Available at www.clinicalpharmacology.com. Accessed on April 3, 2018.
- 4. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on April 3, 2018.
- 5. American Diabetes Association. Standards of Medical Care in Diabetes-2017. Diabetes Care. January 2017;40(1):S1-S135.
- 6. Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm 2017 Executive Summary. Endocr Pract. 2017 Feb;23(2):207-38.
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- 9. Kazano Prescribing Information. Deerfield, IL. Takeda Pharmaceuticals. February 2017.
- 10.Oseni Prescribing Information. Deerfield, IL. Takeda Pharmaceuticals. December 2017.
- 11.Tradjenta Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. August 2017.
- 12.Onglyza Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. February 2017.
- 13.Jentadueto Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. August 2017.
- 14.Jentadueto XR Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. August 2017.

- 15. Kombiglyze XR Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. February 2017.
- 16. Janumet Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. February 2018.
- 17. Janumet XR Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. February 2018.
- 18.Glyxambi Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. December 2017.
- 19.Qtern Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. February 2017.
- 20. Steglujan Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. February 2018.

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	 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	 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
04/03/2015	Updated to include ICD-10s
04/03/2018	 Annual review by staff Removed ICD-9 codes Added GCNs for alogliptin, Nesina, Tradjenta, Onglyza and the DPP-4 inhibitor combination products Added logic and logic diagram for combination products
03/27/2019	Updated to include formulary statement (The listed GCNS may not be an indication of TX Medicaid Formulary coverage. To learn the current formulary coverage, visit TxVendorDrug.com/formulary/formulary-search.) on each 'Drug Requiring PA' table