



#### 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 6.25 mg, Brynovin 25 mg/mL, Januvia 25 mg, Nesina 6.25 mg, Saxagliptin 2.5 mg, Sitagliptin 25 mg, Tradjenta 5 mg, and Zituvio 25 mg

- <u>Drugs requiring prior authorization:</u> the list of drugs requiring prior authorization for this clinical criteria
- <u>Prior authorization criteria logic:</u> 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
- <u>Supporting tables:</u> 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 12.5 mg, Januvia 50 mg, Nesina 12.5 mg, Sitagliptan 50 mg, and Zituvio 50 mg

- <u>Drugs requiring prior authorization:</u> the list of drugs requiring prior authorization for this clinical criteria
- <u>Prior authorization criteria logic:</u> 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
- <u>Supporting tables:</u> 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 25 mg, Januvia 100 mg, Nesina 25 mg, Saxagliptan 5 mg, Sitagliptin 100 mg, and Zituvio 100 mg

- <u>Drugs requiring prior authorization:</u> the list of drugs requiring prior authorization for this clinical criteria
- <u>Prior authorization criteria logic:</u> 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
- <u>Supporting tables:</u> 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 Combination Agents**

- <u>Drugs requiring prior authorization:</u> the list of drugs requiring prior authorization for this clinical criteria
- <u>Prior authorization criteria logic:</u> 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
- <u>Supporting tables:</u> 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**

Added GCNs for Qtern (46474), sitagliptin-metformin ER (56041, 56043, 56042), Trijardy (47669, 47671, 47672, 47673), and Zituvimet (54977, 54976, 56041, 56043, 56042) to the Drugs Requiring PA Criteria Set D table



**Drugs Requiring Prior Authorization** 

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/searches/formulary-drug-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN 6.25 MG TABLET	34086
BRYNOVIN SOLUTION 25 MG/ML	56912
JANUVIA 25 MG TABLET	97398
NESINA 6.25 MG TABLET	34086
SAXAGLIPTIN HCL 2.5 MG TABLET	27393
SITAGLIPTIN 25 MG TABLET	54894
TRADJENTA 5 MG TABLET	29890
ZITUVIO 25 MG TABLET	54894

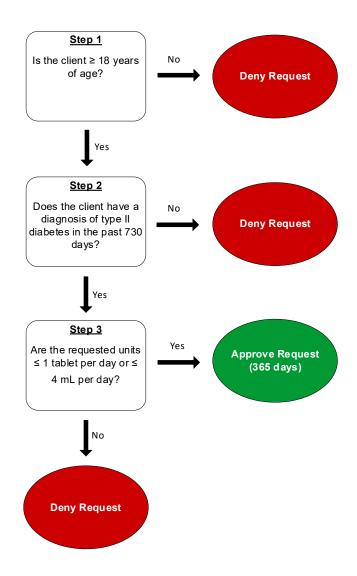


**Clinical Criteria Logic** 

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 $(\leq)$ 1 tablet per day or less than or equal to $(\leq)$ 4 mL per day?
	[] Yes – Approve (365 days)
	[] No – Deny



**Clinical Criteria Logic Diagram** 





**Clinical Criteria Supporting Tables** 

	Table 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	

#### Table 2 (diagnosis of type II diabetes) Required diagnosis: 1 Look back timeframe: 730 days **ICD-10 Code Description** TYPE 2 DIABETES MELLITUS WITH PROLIFERATIVE DIABETIC RETINOPATHY E11359 WITHOUT MACULAR EDEMA TYPE 2 DIABETES MELLITUS WITH DIABETIC CATARACT E1136 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 TYPE 2 DIABETES MELLITUS WITH DIABETIC AUTONOMIC E1143 (POLY)NEUROPATHY E1144 TYPE 2 DIABETES MELLITUS WITH DIABETIC AMYOTROPHY E1149 TYPE 2 DIABETES MELLITUS WITH OTHER DIABETIC NEUROLOGICAL **COMPLICATION** TYPE 2 DIABETES MELLITUS WITH DIABETIC PERIPHERAL ANGIOPATHY E1151 WITHOUT GANGRENE E1152 TYPE 2 DIABETES MELLITUS WITH DIABETIC PERIPHERAL ANGIOPATHY WITH GANGRENE TYPE 2 DIABETES MELLITUS WITH OTHER CIRCULATORY COMPLICATIONS E1159 E11610 TYPE 2 DIABETES MELLITUS WITH DIABETIC NEUROPATHIC ARTHROPATHY TYPE 2 DIABETES MELLITUS WITH OTHER DIABETIC ARTHROPATHY E11618 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

Table 2 (diagnosis of type II diabetes) Required diagnosis: <i>1</i> Look back timeframe: <i>730</i> days		
ICD-10 Code Description		
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** 

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit txvendordrug.com/searches/formulary-drug-search.

Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN 12.5 MG TABLET	34085
JANUVIA 50 MG TABLET	97399
NESINA 12.5 MG TABLET	34085
SITAGLIPTIN 50 MG TABLET	54895
ZITUVIO 50 MG TABLET	54895

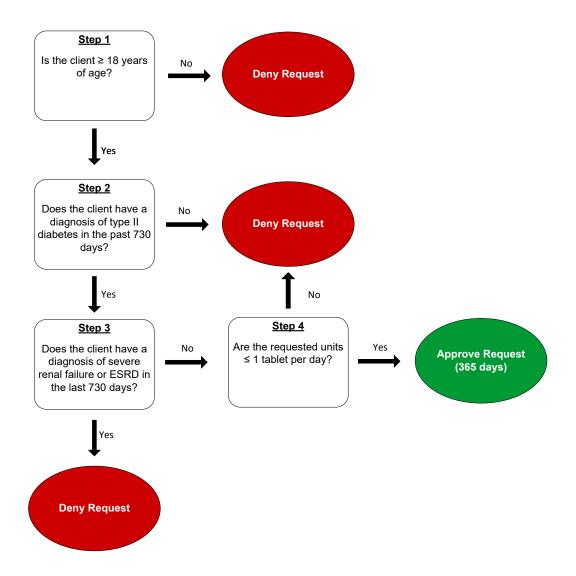


**Clinical Criteria Logic** 

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 Logic Diagram** 





**Clinical Criteria Supporting Tables** 

Table 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 <u>Type II Diabetes</u> <u>Diagnoses</u> table in the previous "Supporting Tables" section.

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

Table 3 (diagnosis of severe renal failure or ESRD)  Required diagnosis: <i>1</i> Look back timeframe: <i>730</i> 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** 

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Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN 25 MG TABLET	34076
JANUVIA 100 MG TABLET	97400
NESINA 25 MG TABLET	34076
SAXAGLIPTIN HCL 5 MG TABLET	27394
SITAGLIPTIN 100 MG TABLET	54893
ZITUVIO 100 MG TABLET	54893

#### PAYPRESS

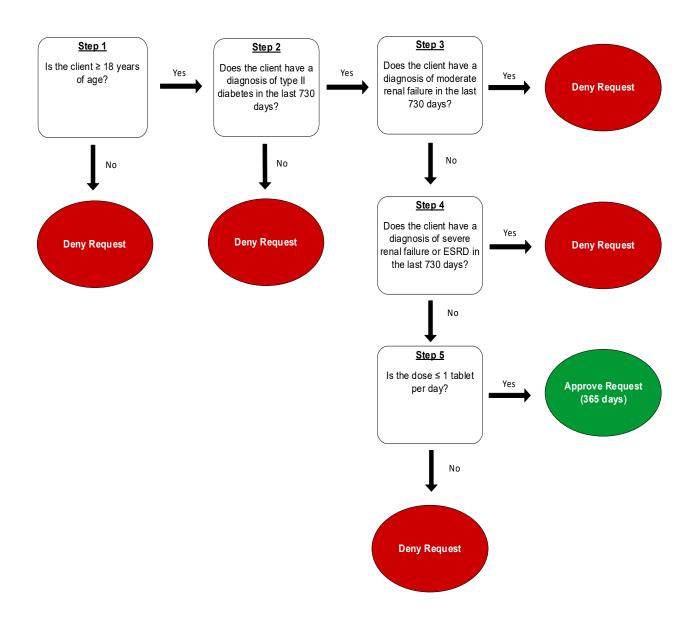
# Dipeptidyl Peptidase-4 (DPP-4) Inhibitors Criteria Set C

**Clinical Criteria Logic** 

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 Logic Diagram** 





**Clinical Criteria Supporting Tables** 

Table 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 <u>Type II Diabetes</u> <u>Diagnoses</u> table in a previous "Supporting Tables" section.

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

Table 3 (diagnosis of moderate renal failure)  Required diagnosis: 1			
	Look back timeframe: 730 days		
ICD-10 Code	ICD-10 Code Description		
N183	CHRONIC KIDNEY DISEASE, STAGE 3 (MODERATE)		

# Table 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 <u>Severe Renal</u> 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** 

The listed GCNs may not be an indication of Texas Medicaid Formulary coverage. To learn the current formulary coverage, visit <a href="txvendordrug.com/searches/formulary-drug-search">txvendordrug.com/searches/formulary-drug-search</a>.

Drugs Requiring Prior Authorization	
Label Name	GCN
ALOGLIPTIN-METFORMIN 12.5-1000	34088
ALOGLIPTIN-METFORMIN 12.5-500	34087
ALOGLIPTIN-PIOGLIT 12.5-30 MG	34083
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

Drugs Requiring Prior Authorization		
Label Name	GCN	
KAZANO 12.5-500 MG TABLET	34087	
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	
QTERN 5 MG-5 MG TABLET	46474	
QTERN 10-5 MG TABLET	43126	
SAXAGLIPTIN-METFORMIN ER 5-500	29118	
SAXAGLIPTN-METFORM ER 2.5-1000	29225	
SAXAGLIPTIN-METFORMN ER 5-1000	29224	
SITAGLIPTIN-METFORMIN 50-500	54977	
SITIGLIPTIN-METFORMIN 50-100	54976	
SITAGLIPTIN-METFORM ER 50-500	56041	
SITAGLIPTIN-METFOR ER 50-1,000	56043	
SITAGLIPTIN-METFO ER 100-1,000	56042	
STEGLUJAN 15-100 MG TABLET	44238	
STEGLUJAN 5-100 MG TABLET	44237	
TRIJARDY XR 5-2.5-1,000 MG TAB	47669	
TRIJARDY XR 12.5-2.5-1,000 MG	47671	
TRIJARDY XR 10-5-1,000 MG TAB	47672	
TRIJARDY XR 25-5-1,000 MG TAB	47673	
ZITUVIMET 50-500 MG TABLET	54977	

Drugs Requiring Prior Authorization		
Label Name	GCN	
ZITUVIMET 50-1,000 MG TABLET	54976	
ZITUVIMET XR 50-500 MG TABLET	56041	
ZITUVIMET XR 50-1000 MG TABLET	56043	
ZITUVIMET XR 100-1,000 MG TAB	56042	

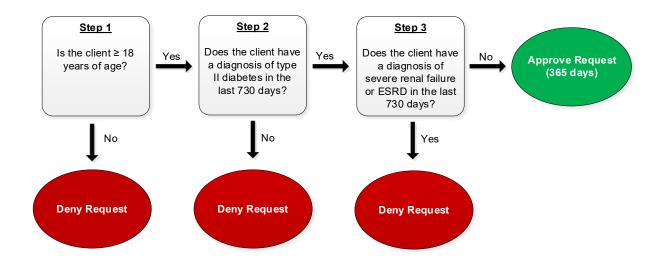


**Clinical Criteria Logic** 

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 <u>diagnosis of severe renal failure or ESRD</u> in the last 730 days?	
	[] Yes – Deny	
	[] No – Approve (365 days)	



**Clinical Criteria Logic Diagram** 





**Clinical Criteria Supporting Tables** 

Table 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 <u>Type II Diabetes</u> Diagnoses table in a previous "Supporting Tables" section.

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

Table 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 <u>Severe Renal Failure or ESRD Diagnoses</u> 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. 2025 ICD-10-CM Diagnosis Codes. 2025. Available at <a href="https://www.icd10data.com">www.icd10data.com</a>. Accessed on March 15, 2025.
- 2. Micromedex [online database]. Available at <a href="https://www.micromedexsolutions.com">www.micromedexsolutions.com</a>. Accessed on March 15, 2025.
- 3. Januvia Prescribing Information. Rahway, NJ: Merck Sharp & Dohme LLC; July 2023.
- 4. Nesina Prescribing Information. Cambridge, MA: Takeda Pharmaceuticals America Inc; February 2025.
- 5. Kazano Prescribing Information. Cambridge, MA: Takeda Pharmaceuticals America Inc; February 2025.
- 6. Oseni Prescribing Information. Cambridge, MA. Takeda Pharmaceuticals America, Inc. February 2025.
- 7. Tradjenta Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
- 8. Jentadueto Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
- 9. Jentadueto XR Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
- 10. Janumet Prescribing Information. Rahway, NJ. Merck Sharp & Dohme LLC. July 2022.
- 11. Janumet XR Prescribing Information. Rahway, NJ. Merck Sharp & Dohme LLC. July 2022.
- 12. Glyxambi Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. October 2023.
- 13. Qtern Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. November 2024.
- 14. Steglujan Prescribing Information. Rahway, NJ. Merck Sharp & Dohme LLC. December 2024.
- 15. Trijardy XR Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. October 2023.
- 16. Brynovin Prescribing Information. Woburn, MA. Azurity Pharmaceuticals, Inc. January 2025.

- 17. American Diabetes Association. Standards of Care in Diabetes 2025. Diabetes Care 2025; 48(S1).
- 18. Samson SL, Vellanki P, Blonde L, et al. American Association of Clinical Endocrinology Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm 2023 Update. Endocr Pr 2023;29(5):305-340.



#### **Dipeptidyl Peptidase-4 (DPP-4) Inhibitors**

**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 <u>Revision Notes</u> on the first page of this document.

Publication Date	Notes
01/31/2011	Initial publication and posting to website
05/11/2012	<ul> <li>Separated sitagliptin (Januvia) into three sections: one for 25mg, one for 50mg, and one for 100mg</li> </ul>
	Added a new section to specify the drugs requiring prior authorization for each strength of sitagliptin (Januvia)
	<ul> <li>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</li> </ul>
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
	<ul> <li>Added GCNs for alogliptin, Nesina, Tradjenta, Onglyza and the DPP-4 inhibitor combination products</li> </ul>
	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
06/01/2020	Added GCNs for Trijardy XR to drug table
	Updated references
04/30/2021	Annual review by staff
	Updated references
04/25/2023	Removed GCNs for alogliptin/pioglitazone and Oseni (34080 and 34084) – products have been discontinued

Publication Date	Notes
	Updated references
12/08/2023	<ul> <li>Annual review by staff</li> <li>Added GCN for saxagliptin (27393, 27394), saxagliptin-metformin (29118, 29225, 29224) to Drugs Requiring PA table</li> <li>Updated references</li> </ul>
06/24/2024	Added GCNs for sitagliptin-metformin (54977, 54976) to Drugs Requiring PA for the DPP-4 combination agents
06/30/2024	Added GCNs for sitagliptin (54894, 54895, 54893) to Drugs Requiring PA
07/31/2024	<ul> <li>Annual review by staff</li> <li>Added GCNs for Zituvio (54894, 54895, 54893)</li> <li>Updated references</li> </ul>
10/15/2024	Added GCNs for Zituvimet XR (56041, 56043, 56042) to Drugs Requiring PA
11/04/2024	Updated GCN for Kazano from 34807 to 34087
4/30/2025	<ul> <li>Annual review by staff</li> <li>Added GCN for Brynovin (56912) to Criteria Set A</li> <li>Updated the check for maximum dose in Criteria Set A</li> <li>Updated GCNs for Oseni (34080, 34804)</li> <li>Removed GCNs for Onglyza (27393, 27394) and Kombiglyze (29225, 29224, 29118) – products discontinued</li> <li>Updated references</li> </ul>
09/16/2025	<ul> <li>Added GCNs for Qtern (46474), sitagliptin-metformin ER (56041, 56043, 56042), Trijardy (47669, 47671, 47672, 47673), and Zituvimet (54977, 54976, 56041, 56043, 56042) to the Drugs Requiring PA Criteria Set D table</li> </ul>