

**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
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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 GCN for Kazano from 34807 to 34087



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set A

Drugs Requiring Prior Authorization

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.

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
SAXAGLIPTIN HCL 2.5 MG TABLET	27393
SITAGLIPTIN 25 MG TABLET	54894
TRADJENTA 5 MG TABLET	29890
ZITUVIO 25 MG TABLET	54894



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set A

Clinical Criteria Logic

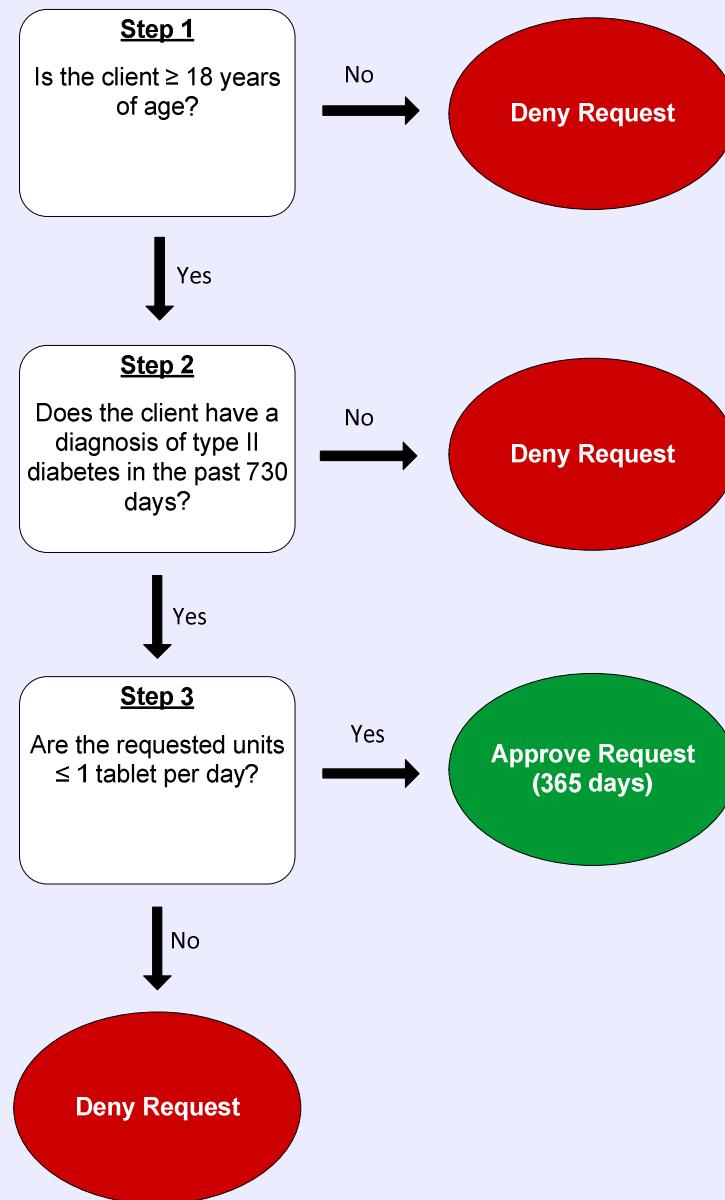
1. Is the client greater than or equal to (\geq) 18 years of age?
[] Yes (Go to #2)
[] No (Deny)
2. Does the client have a **diagnosis of type II diabetes** in the past 730 days?
[] Yes (Go to #3)
[] No (Deny)
3. Are the requested units less than or equal to (\leq) 1 tablet per day?
[] Yes (Approve –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



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set A

Clinical Criteria Logic Diagram





Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set A

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



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set B

Drugs Requiring Prior Authorization

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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



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set B

Clinical Criteria Logic

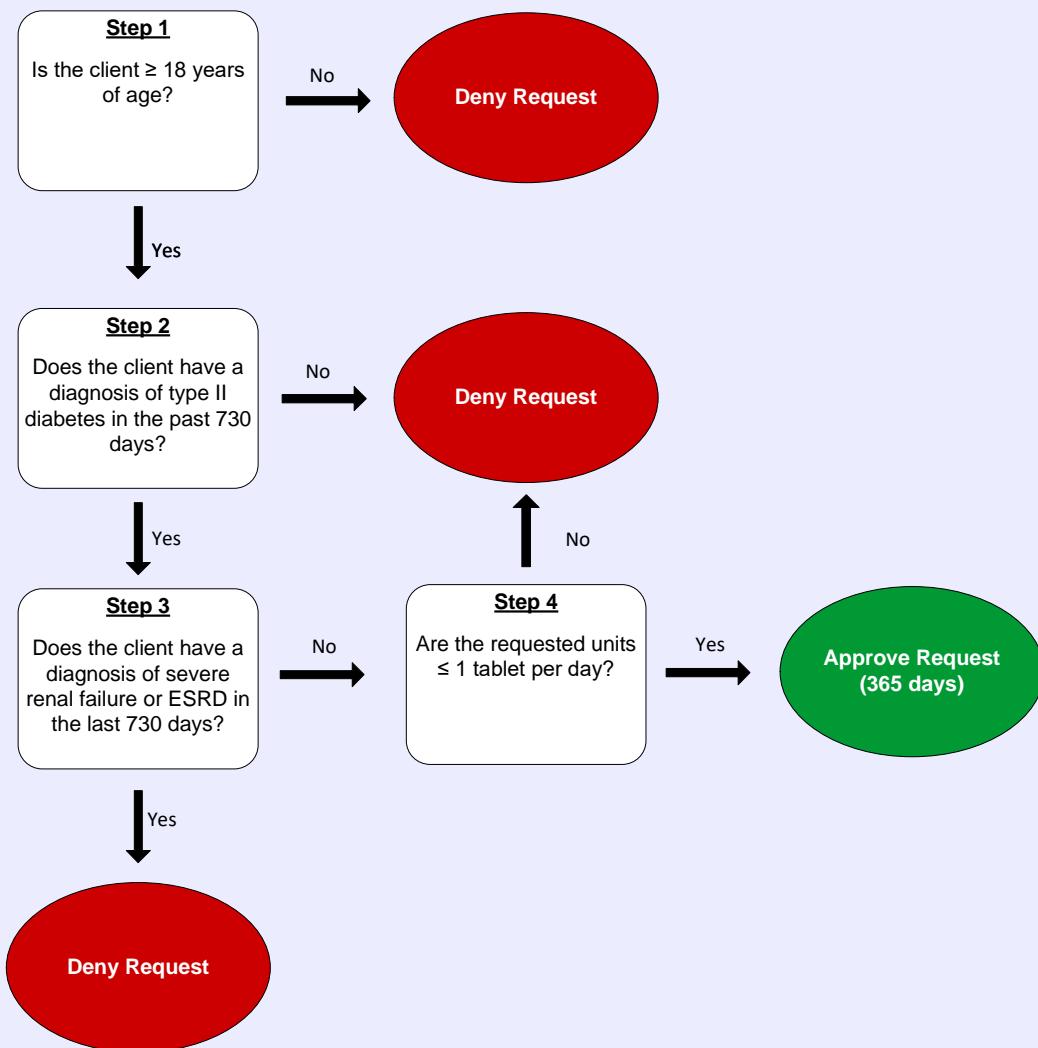
1. Is the client greater than or equal to (\geq) 18 years of age?
[] Yes (Go to #2)
[] No (Deny)
2. Does the client have a **diagnosis of type II diabetes** in the past 730 days?
[] Yes (Go to #3)
[] No (Deny)
3. Does this client have a **diagnosis of severe renal failure or ESRD** in the last 730 days?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



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set B

Clinical Criteria Logic Diagram





Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set B

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



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set C

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
ONGLYZA 5 MG TABLET	27394
SAXAGLIPTIN HCL 5 MG TABLET	27394
SITAGLIPTIN 100 MG TABLET	54893
ZITUVIO 100 MG TAB;ET	54893



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set C

Clinical Criteria Logic

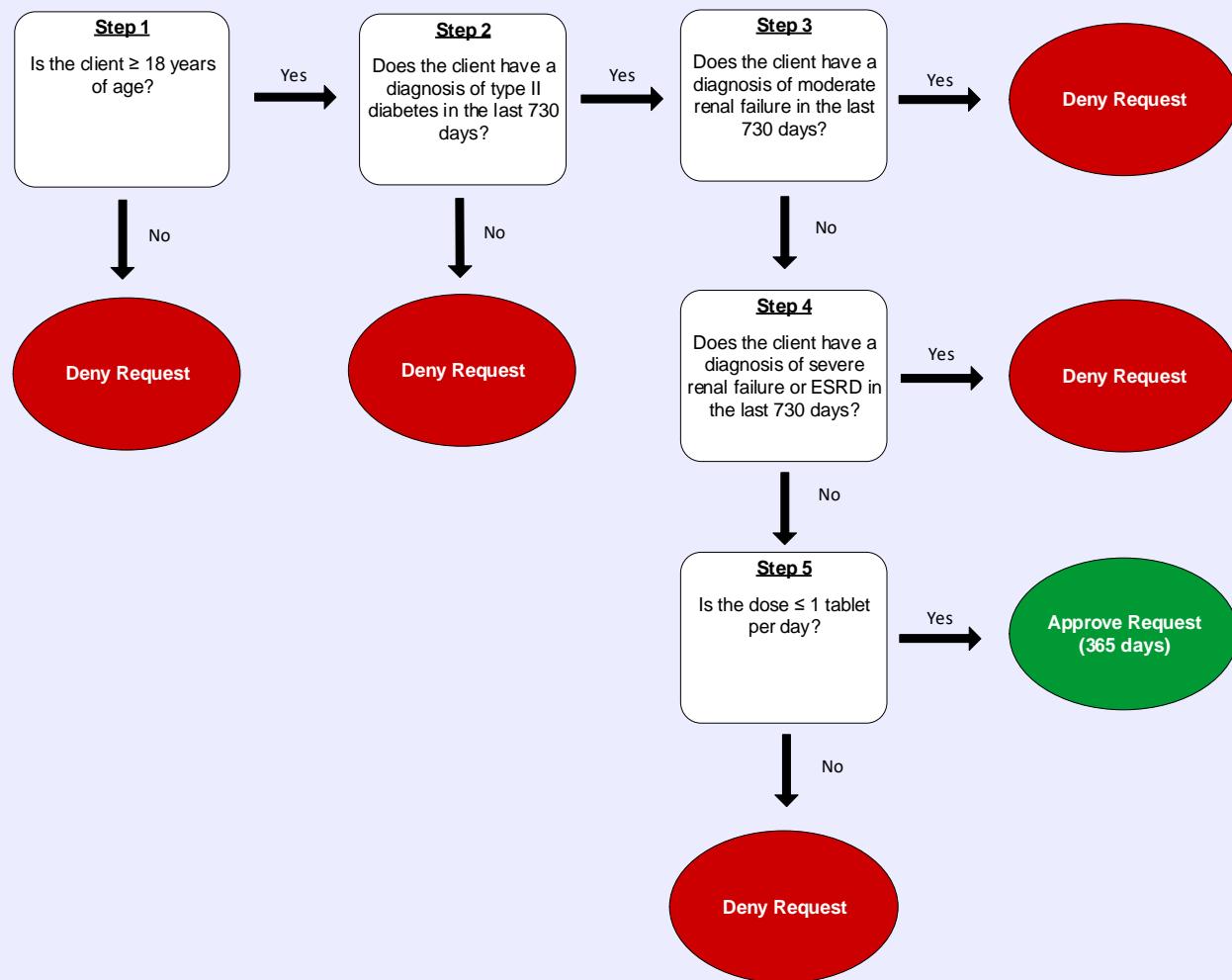
1. Is the client greater than or equal to (\geq) 18 years of age?
[] Yes (Go to #2)
[] No (Deny)
2. Does the client have a **diagnosis of type II diabetes** in the past 730 days?
[] Yes (Go to #3)
[] No (Deny)
3. Does the client have a **diagnosis of moderate renal failure** in the last 730 days?
[] 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) 1 tablet per day?
[] Yes (Approve – 365 days)
[] No (Deny)



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set C

Clinical Criteria Logic Diagram





Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set C

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
N18.3	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.



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set D

Drugs Requiring Prior Authorization

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.

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
KAZANO 12.5-500 MG TABLET	34087
KOMBIGLYZE XR 2.5-1000 MG TAB	29225
KOMBIGLYZE XR 5-1000 MG TAB	29224
KOMBIGLYZE XR 5-500 MG TABLET	29118
OSENI 12.5-30 MG TABLET	34083
OSENI 25-15 MG TABLET	34077
OSENI 25-30 MG TABLET	34078
OSENI 25-45 MG TABLET	34079
QTERN 10-5 MG TABLET	43126
SAXAGLIPTIN-METFORMIN ER 5-500	29118
SAXAGLIPTIN-METFORM ER 2.5-1000	29225
SAXAGLIPTIN-METFORMN ER 5-1000	29224

Drugs Requiring Prior Authorization	
Label Name	GCN
SITAGLIPTIN-METFORMIN 50-500	54977
SITIGLIPTIN-METFORMIN 50-100	54976
STEGLUJAN 15-100 MG TABLET	44238
STEGLUJAN 5-100 MG TABLET	44237
TRIJARDY XR 10/5/1000 MG TABLET	47672
TRIJARDY XR 12.5/2.5/1000 MG TABLET	47671
TRIJARDY XR 25-5-1000 MG TABLET	47673
TRIJARDY XR 5-2.5-1000 MG TABLET	47669
ZITUVIMET XR 100-1,000 MG TAB	56042
ZITUVIMET XR 50-1,000 MG TABLET	56043
ZITUVIMET XR 50-500 MG TABLET	56041



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set D

Clinical Criteria Logic

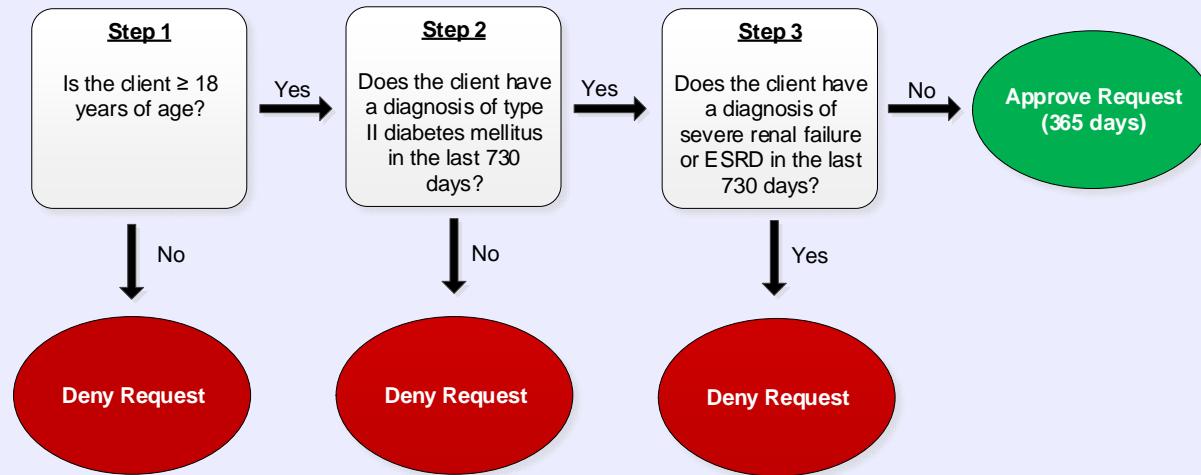
1. Is the client greater than or equal to (\geq) 18 years of age?
[] Yes (Go to #2)
[] No (Deny)
2. Does the client have a **diagnosis of type II diabetes** in the last 730 days?
[] Yes (Go to #3)
[] No (Deny)
3. Does the client have a **diagnosis of severe renal failure or ESRD** in the last 730 days?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



Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set D

Clinical Criteria Logic Diagram





Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Criteria Set D

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. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at www.clinicalpharmacology.com. Accessed on July 31, 2024.
3. Micromedex [online database]. Available at www.micromedexsolutions.com. Accessed on July 31, 2024.
4. American Diabetes Association. Standards of Medical Care in Diabetes-2021. Diabetes Care. January 2021;44(suppl 1):S1-S232.
5. Garber AJ, Handelsman Y, Grunberger G, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2020 Executive Summary. Endocr Pract. 2020 Jan;26(1):107-139.
6. Januvia Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. July 2023.
7. Nesina Prescribing Information. Deerfield, IL. Takeda Pharmaceuticals. March 2022.
8. Kazano Prescribing Information. Deerfield, IL. Takeda Pharmaceuticals. July 2023.
9. Oseni Prescribing Information. Deerfield, IL. Takeda Pharmaceuticals. June 2024.
10. Tadjentra Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
11. Onglyza Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. June 2021.
12. Jentadueto Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
13. Jentadueto XR Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. June 2023.
14. Kombiglyze XR Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. October 2019.

- 15.Janumet Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. July 2022.
- 16.Janumet XR Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. July 2022.
- 17.Glyxambi Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. October 2023.
- 18.Qtern Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. June 2024.
- 19.Steglujan Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. June 2024.
- 20.Trijardy XR Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. October 2023.
- 21.American Diabetes Association. Standards of Care in Diabetes-2023. Diabetes Care 2023;46(S1).
- 22.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.

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
04/03/2015	<ul style="list-style-type: none"> Updated to include ICD-10s
04/03/2018	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Added GCNs for Trijardy XR to drug table Updated references
04/30/2021	<ul style="list-style-type: none"> Annual review by staff Updated references
04/25/2023	<ul style="list-style-type: none"> Removed GCNs for alogliptin/pioglitazone and Oseni (34080 and 34084) – products have been discontinued Updated references
12/08/2023	<ul style="list-style-type: none"> Annual review by staff Added GCN for saxagliptin (27393, 27394), saxagliptin-metformin (29118, 29225, 29224) to Drugs Requiring PA table Updated references
06/24/2024	<ul style="list-style-type: none"> Added GCNs for sitagliptin-metformin (54977, 54976) to Drugs Requiring PA for the DPP-4 combination agents

Publication Date	Notes
06/30/2024	<ul style="list-style-type: none">Added GCNs for sitagliptin (54894, 54895, 54893) to Drugs Requiring PA
07/31/2024	<ul style="list-style-type: none">Annual review by staffAdded GCNs for Zituvio (54894, 54895, 54893)Updated references
10/15/2024	<ul style="list-style-type: none">Added GCNs for Zituvimet XR (56041, 56043, 56042) to Drugs Requiring PA
11/04/2024	<ul style="list-style-type: none">Updated GCN for Kazano from 34807 to 34087