

Texas Prior Authorization Program Clinical Criteria

Drug/Drug Class

SGLT2 Inhibitor Agents

This criteria was recommended for review by an MCO to ensure appropriate and safe utilization

SGLT2 Inhibitors - Single Entity 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.

SGLT2 Inhibitors - 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

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Revision Notes

- Added criteria for SGLT2 Inhibitor Single Entity Agents. Approved by the DUR Board on April 26, 2019.



SGLT2 Inhibitors Single Entity Agents 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
FARXIGA 10 MG TABLET	34394
FARXIGA 5 MG TABLET	35698
INVOKANA 100 MG TABLET	34439
INVOKANA 300 MG TABLET	34441
JARDIANCE 10 MG TABLET	36716
JARDIANCE 25 MG TABLET	36723
STEGLATRO 15 MG TABLET	44259
STEGLATRO 5 MG TABLET	44248



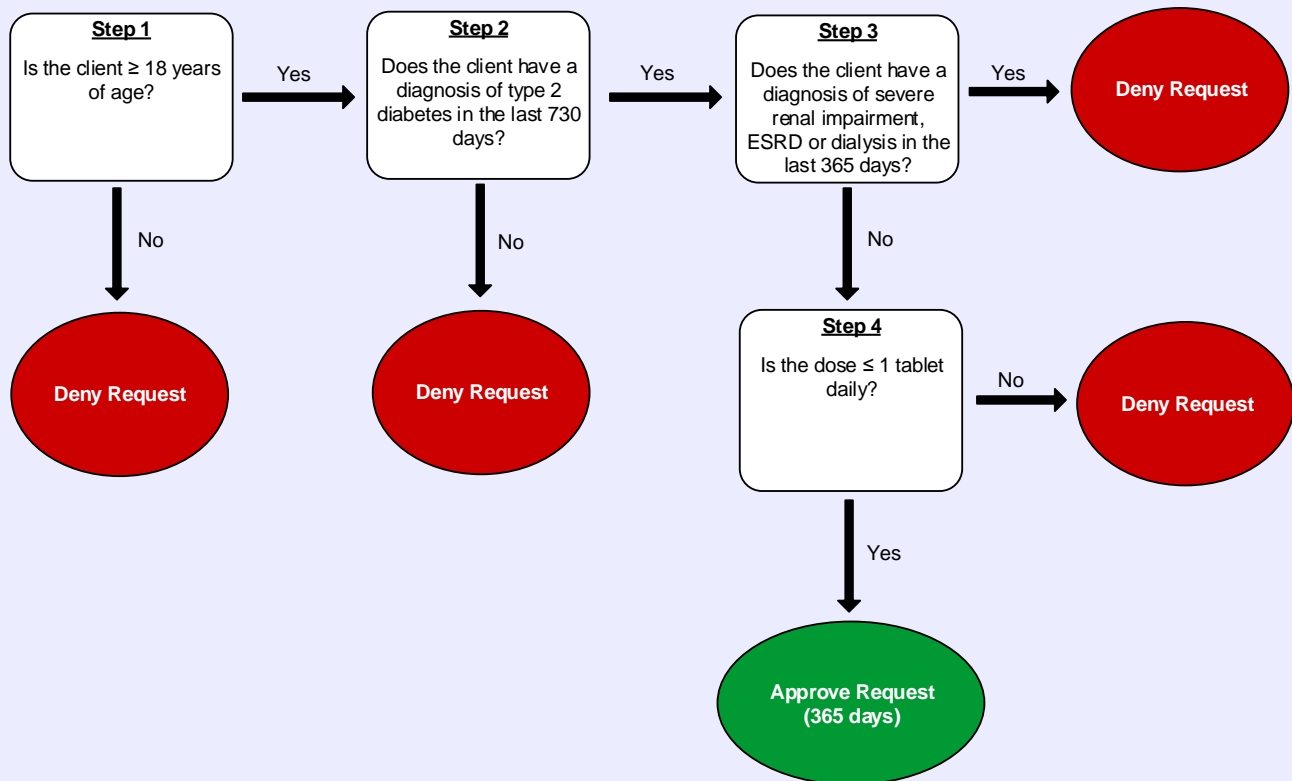
SGLT2 Inhibitors Single Entity Agents Clinical Criteria Logic

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 2 diabetes** in the last 730 days?
 Yes (Go to #3)
 No (Deny)
3. Does the client have a **diagnosis of severe renal impairment (eGFR less than 45 mL/minute/1.73m²), end stage renal disease (ESRD) or dialysis** in the last 365 days?
 Yes (Deny)
 No (Go to #4)
4. Is the daily dose less than or equal to (\leq) 1 tablet daily?
 Yes (Approve – 365 days)
 No (Deny)



SGLT2 Inhibitor Agents

Clinical Criteria Logic Diagram





SGLT2 Inhibitor Agents

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

Step 2 (diagnosis of type II diabetes)	
Required diagnosis: 1	
Look back timeframe: 730 days	
E1143	TYPE 2 DIABETES MELLITUS WITH DIABETIC AUTONOMIC (POLY)NEUROPATHY
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

Step 3 (diagnosis of severe renal impairment, ESRD or dialysis)	
Required diagnosis: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
V56	ENCOUNTER FOR DIALYSIS AND DIALYSIS CATHETER CARE
V560	RENAL DIALYSIS ENCOUNTER
V561	FT/ADJ XTRCORP DIAL CATH
V562	FIT/ADJ PERIT DIAL CATH
V563	ENCOUNTER FOR ADEQUACY TESTING FOR DIALYSIS
V5631	HEMODIALYSIS TESTING
V5632	PERITONEAL DIALYSIS TEST

Step 3 (diagnosis of severe renal impairment, ESRD or dialysis)	
Required diagnosis: 1	
Look back timeframe: 730 days	
V568	DIALYSIS ENCOUNTER, NEC
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE)
N185	CHRONIC KIDNEY DISEASE, STAGE 5
N186	END STAGE RENAL DISEASE
Z4901	ENCOUNTER FOR FITTING AND ADJUSTMENT OF EXTRACORPOREAL DIALYSIS CATHETER
Z4902	ENCOUNTER FOR FITTING AND ADJUSTMENT OF PERITONEAL DIALYSIS CATHETER
Z4931	ENCOUNTER FOR ADEQUACY TESTING FOR HEMODIALYSIS
Z4932	ENCOUNTER FOR ADEQUACY TESTING FOR PERITONEAL DIALYSIS



SGLT2 Inhibitors Combination Agents

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
INVOKAMET 150-1000 MG TABLET	36859
INVOKAMET 150-500 MG TABLET	36953
INVOKAMET 50-1000 MG TABLET	36857
INVOKAMET 50-500 MG TABLET	36954
INVOKAMET XR 150-1000 MG TABLET	42315
INVOKAMET XR 150-500 MG TABLET	42314
INVOKAMET XR 50-1000 MG TABLET	42313
INVOKAMET XR 50-500 MG TABLET	42312
SEGLUROMET 2.5-1000 MG TABLET	44285
SEGLUROMET 2.5-500 MG TABLET	44284
SEGLUROMET 7.5-1000 MG TABLET	44287
SEGLUROMET 7.5-500 MG TABLET	44286
SYNJARDY 12.5-1000 MG TAB	38932
SYNJARDY 12.5-500 MG TAB	39378
SYNJARDY 5-1000 MG TAB	38929
SYNJARDY XR 10-1000 MG TAB	42788
SYNJARDY XR 12.5-1000 MG TAB	42787
SYNJARDY XR 25-1000 MG TAB	42789
SYNJARDY XR 5-1000 MG TAB	42786
XIGDUO XR 10-1000 MG TAB	37344
XIGDUO XR 10-500 MG TAB	37342
XIGDUO XR 5-100 0MG TAB	37343
XIGDUO XR 5-500 MG TAB	37339

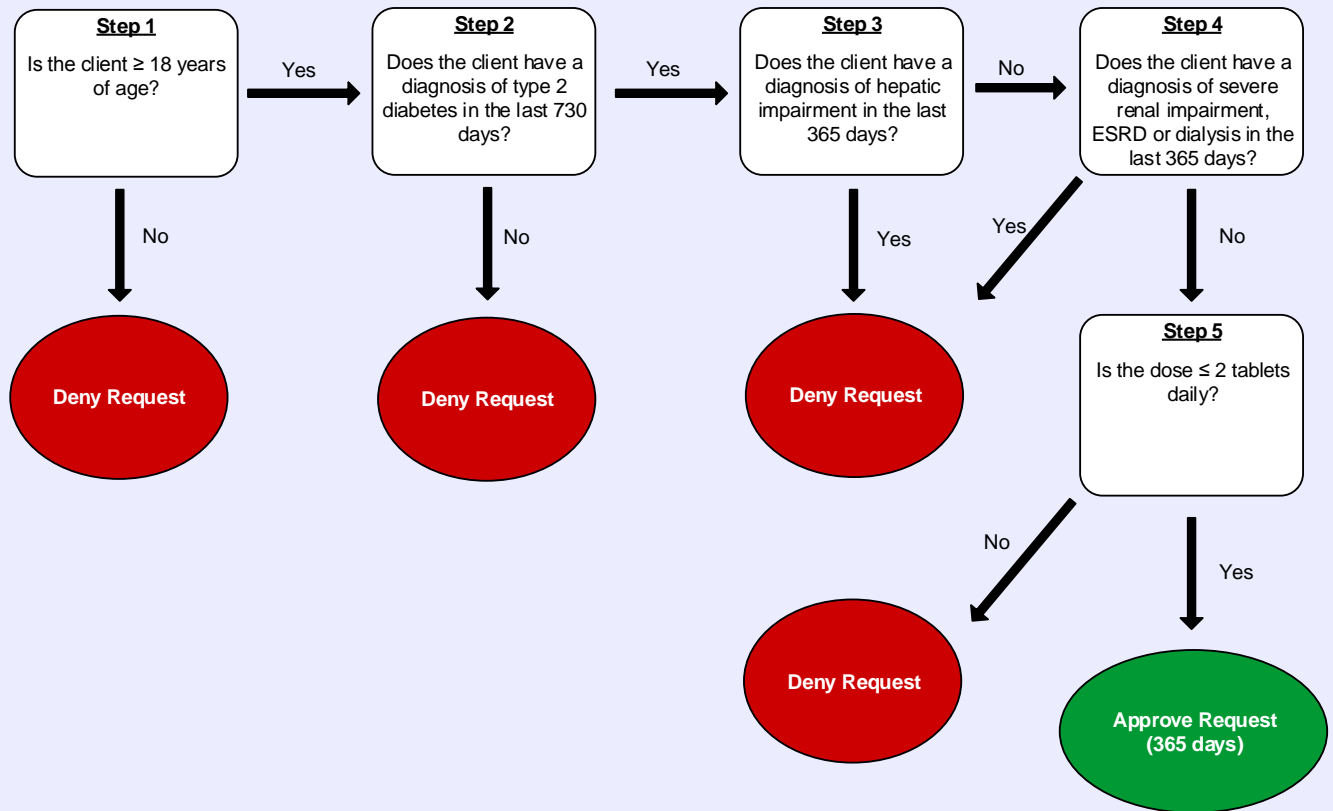


SGLT2 Inhibitors Combination Agents Clinical Criteria Logic

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 2 diabetes** in the last 730 days?
 Yes (Go to #3)
 No (Deny)
3. Does the client have a **diagnosis of hepatic impairment** in the last 365 days?
 Yes (Deny)
 No (Go to #4)
4. Does the client have a **diagnosis of severe renal impairment (eGFR less than 30 mL/minute/1.73m²), end stage renal disease (ESRD) or dialysis** in the last 365 days?
 Yes (Deny)
 No (Go to #5)
5. Is the daily dose less than or equal to (\leq) 2 tablets daily?
 Yes (Approve – 365 days)
 No (Deny)



SGLT2 Inhibitors Combination Agents Clinical Criteria Logic Diagram





SGLT2 Inhibitor Combination Agents

Clinical Criteria Supporting Tables

Step 2 (diagnosis of type 2 diabetes)

Required quantity: 1

Look back timeframe: 730 days

For the list of type 2 diabetes diagnosis codes that pertain to this step, see the **Type 2 Diabetes Diagnoses** table in the previous "Supporting Tables" section.

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

Step 3 (diagnosis of hepatic impairment)

Required diagnosis: 1

Look back timeframe: 365 days

ICD-10 Code	Description
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA

Step 3 (diagnosis of hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS

Step 3 (diagnosis of hepatic impairment)	
Required diagnosis: 1	
Look back timeframe: 365 days	
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE

Step 4 (diagnosis of severe renal impairment, ESRD or dialysis)

Required diagnosis: 1

Look back timeframe: 730 days

For the list of severe renal impairment, ESRD or dialysis diagnosis codes that pertain to this step, see the [SRI/ESRD/Dialysis Diagnoses](#) table in the previous "Supporting Tables" section.

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



SGLT2 Inhibitor Agents

Clinical Criteria References

1. 2019 ICD-10-CM Diagnosis Codes. 2019. Available at www.icd10data.com. Accessed on April 26, 2019.
2. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2019. Available at www.clinicalpharmacology.com. Accessed on April 26, 2019.
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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
07/27/2018	<ul style="list-style-type: none">Initial publication and presentation of the SGLT2i combination agents to the DUR Board
03/29/2019	<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
04/26/2019	<ul style="list-style-type: none">Initial presentation of the SGLT2i single entity agents to the DUR Board
05/01/2019	<ul style="list-style-type: none">Addition of single entity agents to the criteria as approved by the DUR Board on April 26, 2019