

## Texas Prior Authorization Program Clinical Criteria

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### 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

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

## Revision Notes

Annual review by staff

Added diagnosis of chronic kidney disease for Invokana and Jardiance

Updated references



**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](http://TxVendorDrug.com/formulary/formulary-search).*

<b>Drugs Requiring Prior Authorization</b>	
<b>Label Name</b>	<b>GCN</b>
FARXIGA 10 MG TABLET	34394
FARXIGA 5 MG TABLET	35698
INPEFA 200 MG TABLET	54239
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. Does the client have a history of **end stage renal disease (ESRD) or dialysis** in the last 365 days?  
 Yes (Go to #2)  
 No (Go to #3)
2. Does the client have a history of **kidney transplant** in the last 730 days?  
 Yes (Go to #3)  
 No (Deny)
3. Is the client greater than or equal to ( $\geq$ ) 18 years of age?  
 Yes (And the request is for Inpefa, go to #7)  
 Yes (And the request is for an agent other than Inpefa, go to #6)  
 No (And the request is for Jardiance, go to #4)  
 No (And the request is for an agent other than Jardiance, deny)
4. Is the client greater than or equal to ( $\geq$ ) 10 years of age?  
 Yes (Go to #5)  
 No (Deny)
5. Does the client have a **diagnosis of type 2 diabetes** in the last 730 days?  
 Yes (Go to #10)  
 No (Deny)
6. Does the client have a **diagnosis of type 2 diabetes** in the last 730 days?  
 Yes (Go to #10)  
 No (And the request is for Farxiga or Jardiance, go to #7)  
 No (And the request is for Invokana, go to #9)  
 No (And the request is for Steglatro, deny)
7. Does the client have a **diagnosis of heart failure** in the last 730 days?  
 Yes (Go to #10)  
 No (And the request is for Inpefa, go to #8)  
 No (And the request is for Farxiga or Jardiance, go to #9)
8. Does the client have a diagnosis of **type 2 diabetes, chronic kidney disease** and at least one **major cardiovascular risk factor** in the last 730 days?  
 Yes (Go to #10)  
 No (Deny)

9. Does the client have a diagnosis of **chronic kidney disease** in the last 730 days?

Yes (Go to #10)

No (Deny)

10. Is the daily dose less than or equal to ( $\leq$ ) 1 tablet daily?

Yes (Approve - 365 days)

No (Deny)





## SGLT2 Inhibitor Agents

### Clinical Criteria Supporting Tables

<b>Step 1 (ESRD or dialysis)</b> <b>Required diagnosis: 1</b> <b>Look back timeframe: 365 days</b>	
ICD-10 Code	Description
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
Z992	DEPENDENCE ON RENAL DIALYSIS

<b>Step 2 (history of kidney transplant)</b> <b>Required diagnosis: 1</b> <b>Look back timeframe: 730 days</b>	
ICD-10 Code	Description
Z940	KIDNEY TRANSPLANT STATUS

<b>Step 5/6/8 (diagnosis of type II diabetes)</b> <b>Required diagnosis: 1</b> <b>Look back timeframe: 730 days</b>	
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

<b>Step 5/6/8 (diagnosis of type II diabetes)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
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
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

<b>Step 5/6/8 (diagnosis of type II diabetes)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
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

<b>Step 7 (diagnosis of heart failure)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
I501	LEFT VENTRICULAR FAILURE
I5020	UNSPECIFIED SYSTOLIC (CONGESTIVE) HEART FAILURE
I5021	ACUTE SYSTOLIC (CONGESTIVE) HEART FAILURE
I5022	CHRONIC SYSTOLIC (CONGESTIVE) HEART FAILURE
I5023	ACUTE ON CHRONIC SYSTOLIC (CONGESTIVE) HEART FAILURE
I5030	UNSPECIFIED DIASTOLIC (CONGESTIVE) HEART FAILURE
I5031	ACUTE DIASTOLIC (CONGESTIVE) HEART FAILURE
I5032	CHRONIC DIASTOLIC (CONGESTIVE) HEART FAILURE
I5033	ACUTE ON CHRONIC DIASTOLIC (CONGESTIVE) HEART FAILURE
I5040	UNSPECIFIED COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I5041	ACUTE COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I5042	CHRONIC COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I5043	ACUTE ON CHRONIC COMBINED SYSTOLIC (CONGESTIVE) AND DIASTOLIC (CONGESTIVE) HEART FAILURE
I50810	RIGHT HEART FAILURE UNSPECIFIED
I50811	ACUTE RIGHT HEART FAILURE
I50812	CHRONIC RIGHT HEART FAILURE
I50813	ACUTE ON CHRONIC RIGHT HEART FAILURE
I50814	RIGHT HEART FAILURE DUE TO LEFT HEART FAILURE
I5082	BIVENTRICULAR HEART FAILURE
I5083	HIGH OUTPUT HEART FAILURE
I5084	END STAGE HEART FAILURE
I5089	OTHER HEART FAILURE
I509	HEART FAILURE, UNSPECIFIED

<b>Step 8 (diagnosis of chronic kidney disease)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
N181	CHRONIC KIDNEY DISEASE, STAGE 1
N182	CHRONIC KIDNEY DISEASE, STAGE 2 (MILD)
N1830	CHRONIC KIDNEY DISEASE, STAGE 3 (MODERATE) UNSPECIFIED
N1831	CHRONIC KIDNEY DISEASE, STAGE 3A (MODERATE)
N1832	CHRONIC KIDNEY DISEASE, STAGE 3B (MODERATE)
N184	CHRONIC KIDNEY DISEASE, STAGE 4 (SEVERE)
N185	CHRONIC KIDNEY DISEASE, STAGE 5
N186	END STAGE RENAL DISEASE
N189	CHRONIC KIDNEY DISEASE, UNSPECIFIED

<b>Step 8 (diagnosis major cardiovascular risk factor)</b>	
<b>Required quantity: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
E7801	FAMILIAL HYPERCHOLESTEROLEMIA
E782	MIXED HYPERLIPIDEMIA
E785	HYPERLIPIDEMIA, UNSPECIFIED
I10	ESSENTIAL (PRIMARY) HYPERTENSION
I2101	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT MAIN CORONARY ARTERY
I2102	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT ANTERIOR DESCENDING CORONARY ARTERY
I2109	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF ANTERIOR WALL
I2111	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING RIGHT CORONARY ARTERY
I2119	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER CORONARY ARTERY OF INFERIOR WALL
I2121	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING LEFT CIRCUMFLEX CORONARY ARTERY
I2129	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION INVOLVING OTHER SITES
I213	ST ELEVATION (STEMI) MYOCARDIAL INFARCTION OF UNSPECIFIED SITE
I214	NON-ST ELEVATION (NSTEMI) MYOCARDIAL INFARCTION

<b>Step 8 (diagnosis major cardiovascular risk factor)</b>	
<b>Required quantity: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
I240	ACUTE CORONARY THROMBOSIS NOT RESULTING IN MYOCARDIAL INFARCTION
I248	OTHER FORMS OF ACUTE ISCHEMIC HEART DISEASE
I70201	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70202	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70203	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70208	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70209	UNSPECIFIED ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY
I70211	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, RIGHT LEG
I70212	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, LEFT LEG
I70213	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, BILATERAL LEGS
I70218	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, OTHER EXTREMITY
I70219	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH INTERMITTENT CLAUDICATION, UNSPECIFIED EXTREMITY
I70221	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, RIGHT LEG
I70222	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, LEFT LEG
I70223	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, BILATERAL LEGS
I70228	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, OTHER EXTREMITY
I70229	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH REST PAIN, UNSPECIFIED EXTREMITY
I70231	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF THIGH
I70232	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF CALF
I70233	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF ANKLE
I70234	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70235	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF FOOT

<b>Step 8 (diagnosis major cardiovascular risk factor)</b>	
<b>Required quantity: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
I70238	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF OTHER PART OF LOWER RIGHT LEG
I70239	ATHEROSCLEROSIS OF NATIVE ARTERIES OF RIGHT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I70241	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF THIGH
I70242	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF CALF
I70243	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF ANKLE
I70244	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF HEEL AND MIDFOOT
I70245	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF FOOT
I70248	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF OTHER PART OF LOWER LEFT LEG
I70249	ATHEROSCLEROSIS OF NATIVE ARTERIES OF LEFT LEG WITH ULCERATION, OF UNSPECIFIED SITE
I7025	ATHEROSCLEROSIS OF NATIVE ARTERIES OF OTHER EXTREMITIES WITH ULCERATION
I70261	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, RIGHT LEG
I70262	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, LEFT LEG
I70263	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, BILATERAL LEGS
I70268	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, OTHER EXTREMITY
I70269	ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES WITH GANGRENE, UNSPECIFIED EXTREMITY
I70291	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, RIGHT LEG
I70292	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, LEFT LEG
I70293	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, BILATERAL LEGS
I70298	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, OTHER EXTREMITY
I70299	OTHER ATHEROSCLEROSIS OF NATIVE ARTERIES OF EXTREMITIES, UNSPECIFIED EXTREMITY



## 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](http://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

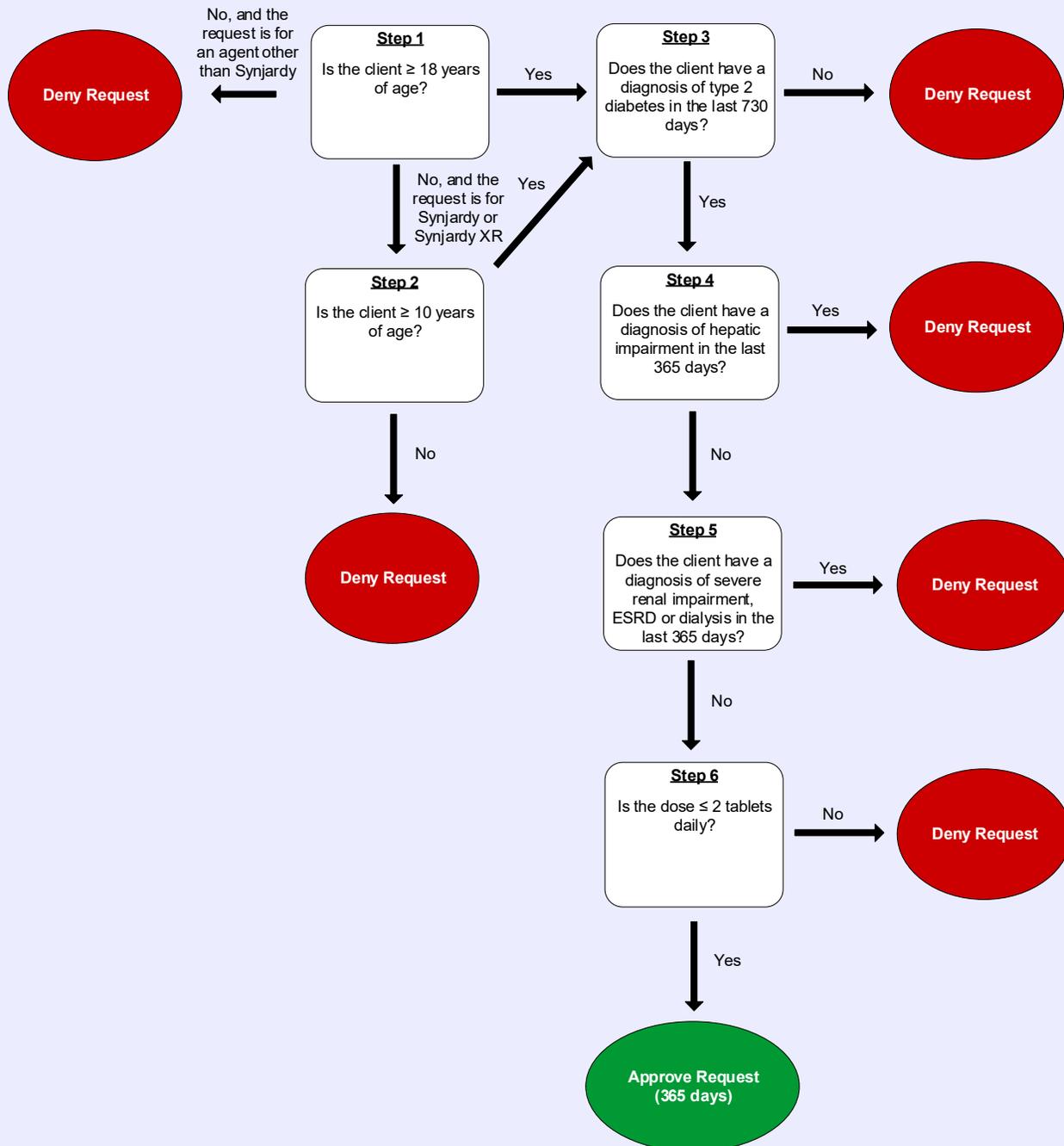


## SGLT2 Inhibitors Combination Agents Clinical Criteria Logic

1. Is the client greater than or equal to ( $\geq$ ) 18 years of age?
  - Yes (Go to #3)
  - No (And the request is for Synjardy or Synjardy XR, go to #2)
  - No (And the request is for an agent other than Synjardy, deny)
  
2. Is the client greater than or equal to ( $\geq$ ) 10 years of age?
  - Yes (Go to #3)
  - No (Deny)
  
3. Does the client have a **diagnosis of type 2 diabetes** in the last 730 days?
  - Yes (Go to #4)
  - No (Deny)
  
4. Does the client have a **diagnosis of hepatic impairment** in the last 365 days?
  - Yes (Deny)
  - No (Go to #5)
  
5. Does the client have a **diagnosis of severe renal impairment (eGFR less than 30 mL/minute/1.73m<sup>2</sup>), end stage renal disease (ESRD) or dialysis** in the last 365 days?
  - Yes (Deny)
  - No (Go to #6)
  
6. 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 3 (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 4 (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

<b>Step 4 (diagnosis of hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
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

<b>Step 4 (diagnosis of hepatic impairment)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 365 days</b>	
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

<b>Step 5 (diagnosis of chronic kidney disease, end stage renal disease or dialysis)</b>	
<b>Required diagnosis: 1</b>	
<b>Look back timeframe: 730 days</b>	
<b>ICD-10 Code</b>	<b>Description</b>
N185	CHRONIC KIDNEY DISEASE, STAGE 5 (eGFR 15-29)
N186	END STAGE RENAL DISEASE (eGFR < 15)
N189	CHRONIC KIDNEY DISEASE, UNSPECIFIED
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
Z992	DEPENDENCE ON RENAL DIALYSIS



## SGLT2 Inhibitor Agents

### Clinical Criteria References

1. 2022 ICD-10-CM Diagnosis Codes. 2022. Available at [www.icd10data.com](http://www.icd10data.com). Accessed on July 22, 2022.
2. Inpefa Prescribing Information. The Woodlands, TX. Lexicon Pharmaceuticals, Inc. January 2024.
3. Clinical Pharmacology [online database]. Tampa, FL: Elsevier/Gold Standard, Inc.; 2024. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed on January 30, 2024.
4. Drug Facts and Comparisons. eFacts [online]. 2024. Available from Wolters Kluwer Health, Inc. Accessed on January 30, 2024.
5. Farxiga Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. January 2024.
6. Invokana Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals, Inc. July 2023.
7. Jardiance Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. September 2023.
8. Steglatro Prescribing Information. Rahway, NJ. Merck Sharp & Dohme Corp. September 2023.
9. Invokamet Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals, Inc. January 2024.
10. Invokamet XR Prescribing Information. Titusville, NJ. Janssen Pharmaceuticals, Inc. January 2024.
11. Segluromet Prescribing Information. Whitehouse Station, NJ. Merck Sharp & Dohme Corp. September 2023.
12. Synjardy Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. October 2023.
13. Synjardy XR Prescribing Information. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc. October 2023.
14. Xigduo XR Prescribing Information. Wilmington, DE. AstraZeneca Pharmaceuticals LP. November 2023.
15. American Diabetes Association. Standards of Care in Diabetes-2023. Diabetes Care 2023;46(S1).

16. 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
07/27/2018	<ul style="list-style-type: none"> <li>Initial publication and presentation of the SGLT2i combination agents to the DUR Board</li> </ul>
03/29/2019	<ul style="list-style-type: none"> <li>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 <a href="http://TxVendorDrug.com/formulary/formulary-search">TxVendorDrug.com/formulary/formulary-search</a>.) on each 'Drug Requiring PA' table</li> </ul>
04/26/2019	<ul style="list-style-type: none"> <li>Initial presentation of the SGLT2i single entity agents to the DUR Board</li> </ul>
05/01/2019	<ul style="list-style-type: none"> <li>Addition of single entity agents to the criteria as approved by the DUR Board on April 26, 2019</li> </ul>
03/25/2021	<ul style="list-style-type: none"> <li>Added approval diagnosis of heart failure for Farxiga to criteria logic</li> </ul>
07/22/2022	<ul style="list-style-type: none"> <li>Added approval diagnosis of heart failure for Farxiga and Jardiance to criteria logic</li> <li>Added approval diagnosis of chronic kidney disease for Farxiga to criteria logic</li> <li>Updated the contraindication for clients with a history of dialysis for Farxiga in criteria logic</li> <li>Added check for kidney transplant</li> <li>Updated references</li> </ul>
07/25/2022	<ul style="list-style-type: none"> <li>Updated lookback for kidney transplant to 730 days as requested by the DUR Board</li> </ul>
08/01/2022	<ul style="list-style-type: none"> <li>For SGLT2 combination agents, removed diagnosis code N18.4 (chronic kidney disease, stage 4 [severe]; eGFR 30-44) from Table 4 (corresponds to question 4)</li> </ul>
02/01/2023	<ul style="list-style-type: none"> <li>Updated ICD-10 codes for dialysis in supporting tables</li> </ul>
08/01/2023	<ul style="list-style-type: none"> <li>Updated age to 10 years and older for Jardiance, Synjardy and Synjardy XR in criteria logic and diagram</li> </ul>
09/12/2023	<ul style="list-style-type: none"> <li>Added criteria for Inpefa</li> </ul>
02/22/2024	<ul style="list-style-type: none"> <li>Annual review by staff</li> <li>Added diagnosis of chronic kidney disease for Invokana and Jardiance</li> <li>Updated references</li> </ul>