Sodium-glucose Co-transporter (SGLT) Inhibitors and Combinations Step Therapy with Quantity Limit Program Summary

This program applies to Medicaid.

Step Therapy only applies to the MN Medicaid Preferred Drug List (PDL) preferred drugs: Farxiga, Invokana, and Jardiance.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
04-01-2024	11-01-2018

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Brenzavvy®, Bexagliflozin Tablet	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitation of Use: Not recommended in patients with type 1 diabetes mellitus. May increase the risk of diabetic ketoacidosis in these patients.		19
Farxiga® (dapagliflozin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factor To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and either established cardiovascular disease or multiple cardiovascular risk factors. To reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression Limitations of Use: • Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. • Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 45 mL/min/1.73 m^2. Farxiga is likely to be ineffective in this setting based upon its mechanism of action • Not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for the treatment of kidney disease. Farxiga is not expected to be effective in these populations.		2

Agent(s)	FDA Indication(s)	Notes	Ref#
Glyxambi® (empagliflozin /linagliptin) Tablet	To improve glycemic control in adults with type 2 diabetes mellitus. To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. Limitations of Use: • Not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. Has not been studied in patients with a history of pancreatitis. • Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2.	DPP-4 Inhibitor Combinations	14
Inpefa™ (sotagliflozin) Tablet	To reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: • heart failure or • type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors		18
Invokamet® (canagliflozin/ metformin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease Canagliflozin is indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus		3
Invokamet XR® (canagliflozin/ metformin ER) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Canagliflozin is indicated to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease Canagliflozin is indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria Limitations of Use: Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus		3
Invokana® (canagliflozin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus To reduce the risk of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease		1

Agent(s)	FDA Indication(s)	Notes	Ref#
	To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria Limitations of Use: • Not recommended in patients with type 1 diabetes mellitus • Not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2		
Jardiance® (empagliflozin) Tablet	To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure. To reduce the risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression. To reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease. As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: • Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. • Not recommended for use to improve glycemic control in patients with type 2 diabetes mellitus with an eGFR less than 30 mL/min/1.73 m^2. • Not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of intravenous immunosuppressive therapy or greater than 45 mg of prednisone or equivalent for kidney disease.		4
Qtern® (dapagliflozin/saxagliptin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitation of use: Not recommended for patients with type 1 diabetes mellitus.	DPP-4 Inhibitor Combinations	15
Segluromet® (ertugliflozin/metformin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitation of use: Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis		9
Steglatro®	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus		8

Agent(s)	FDA Indication(s)	Notes	Ref#
(ertugliflozin) Tablet	Limitation of Use: Not recommended in patients with type 1 diabetes mellitus		
Steglujan® (ertugliflozin/sitagliptin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of Use: • Not recommended for patients with type 1 diabetes mellitus • Has not been studied in patients with a history of pancreatitis.	DPP-4 Inhibitor Combinations	16
Synjardy® (empagliflozin/metformin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus Empagliflozin, when used as a component of Synjardy or Synjardy XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of: • Cardiovascular death in adults with established cardiovascular disease. • Cardiovascular death and hospitalization for heart failure in adults with heart failure. Limitations of Use: • Not recommended for use in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. • Because of the metformin component, Synjardy and Synjardy XR are not recommended for use in patients with heart failure without type 2 diabetes mellitus.		6
Synjardy®XR (empagliflozin/metformin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Empagliflozin, when used as a component of Synjardy or Synjardy XR, is indicated in adults with type 2 diabetes mellitus to reduce the risk of: • Cardiovascular death in adults with established cardiovascular disease. • Cardiovascular death and hospitalization for heart failure in adults with heart failure. Limitations of Use: • Not recommended for use in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients. • Because of the metformin component, Synjardy and Synjardy XR are not recommended for use in patients with heart failure without type 2 diabetes mellitus.		7

Agent(s)	FDA Indication(s)	Notes	Ref#
Trijardy XR™ (empagliflozin/linagliptin/metformin) Tablet	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes mellitus and established cardiovascular disease Limitations of Use: • Not recommended in patients with type 1 diabetes. • Has not been studied in patients with a history of pancreatitis	DPP-4 Inhibitor Combinations	17
Xigduo® XR (dapagliflozin/metformin) Tablet	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Dapagliflozin is indicated to reduce: • The risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established cardiovascular disease or multiple cardiovascular risk factors. • The risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (NYHA class II-IV) with reduced ejection fraction. • The risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death and hospitalization for heart failure in adults with chronic kidney disease at risk of progression. Limitations of Use: • Not recommended for use to improve glycemic control in patients with type 1 diabetes mellitus. • Because of the metformin component, the use of Xigduo XR is limited to adults with type 2 diabetes mellitus for all indications. • Not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent history of immunosuppressive therapy for the treatment of kidney disease. Xigduo XR is not expected to be effective in these populations.		5

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Overview	The American Diabetes Association (ADA) recommends the following guidelines:(10,11) • Healthy lifestyle behaviors, diabetes self-management education and support, avoidance of clinical inertia, and social determinants of health should be considered in the glucose-lowering management of type 2 diabetes. Pharmacologic therapy should be guided by person-centered treatment factors, including comorbidities and treatment goals. • In adults with type 2 diabetes and established/high risk of atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease, the treatment regimen should include agents that reduce cardiorenal risk.

	• Pharmacologic approaches that provide adequate efficacy to achieve and maintain treatment goals should be considered, such as metformin or other agents, including combination therapy. • Weight management is an impactful component of glucose-lowering management in type 2 diabetes. The glucose-lowering treatment regimen should consider approaches that support weight management goals. • Metformin should be continued upon initiation of insulin therapy (unless contraindicated or not tolerated) for ongoing glycemic and metabolic benefits. A Early combination therapy can be considered in some individuals at treatment initiation to extend the time to treatment failure. • The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when A1C levels (>10% [86 mmol/mol]) or blood glucose levels (greater or equal to 300 mg/dL) are very high. • A person-centered approach should guide the choice of pharmacologic agents. Consider the effects on cardiovascular and renal comorbidities, efficacy, hypoglycemia risk, impact on weight, cost and access, risk for side effects, and individual preferences. • Among individuals with type 2 diabetes who have established atherosclerotic cardiovascular disease or indicators of high cardiovascular risk, established kidney disease, or heart failure, a sodium–glucose cotransporter 2 inhibitor and/or glucagon-like peptide 1 receptor agonist with demonstrated cardiovascular disease benefit is recommended as part of the glucose-lowering regimen and comprehensive cardiovascular risk reduction, independent of A1C and in consideration of person-specific factors. • In adults with type 2 diabetes, a glucagon-like peptide 1 receptor agonist is preferred to insulin when possible. Healthy lifestyle behaviors, diabetes self-management, education, and support, avoidance of clinical inertia, and social determinants of health should be considered in the glucose-lowering management of type 2 diabetes. Pharmacologic therapy should be guided by person-centered treatment factors, including comorbidities and treatment goals. Pharmacotherapy should be started at the time type 2 diabetes is diagnosed unless there are contraindications. Pharmacologic approaches that provide the efficacy to achieve treatment goals should be considered, such as metformin or other agents, including combination therapy, that provide adequate efficacy to achieve and maintain treatment goals. In adults with type 2 diabetes and established/high risk of atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), and/or chronic kidney disease (CKD), the treatment regimen should include agents that reduce cardiorenal risk.(11) Pharmacologic approaches that provide the efficacy to achieve treatment goals should be considered, specified as metformin or agent(s), including combination therapy, that provide adequate efficacy to achieve and maintain treatment goals. In general, higher-efficacy approaches have greater likelihood of achieving glycemic goals, with the following considered to have very high efficacy for glucose lowering: the GLP-1 RAs dulaglutide (high dose) and semaglutide, the gastric inhibitory peptide (GIP) and GLP-1 RA tirzepatide, insulin, combination oral therapy, and combination injectable therapy. Weight management is an impactful component of glucose-lowering management in type 2 diabetes. The glucose-lowering treatment regimen should consider approaches that support weight management goals, with very high efficacy for weight loss seen with semaglutide and tirzepatide.(11) Metformin is effective and safe, is inexpensive, and may reduce risk of cardiovascular events and death. Metformin is available in an immediate-release form for twice-daily dosing or as an extended-release form that can be given once daily. Compared with sulfonylureas, metformin as first-line therapy has beneficial effects on A1C, weight, and cardiovascular mortality. For people with type 2 diabetes and established ASCVD or indicators of high ASCVD risk, HF, or CKD, an SGLT2 inhibitor and/or GLP-1 RA with demonstrated CVD benefit is recommended as part of the glucose-lowering regimen independent of A1C, independent of metformin use and in consideration of person-specific factors. For people without established ASCVD, indicators of high ASCVD risk,

	HF, or CKD, medication choice is guided by efficacy in support of individualized glycemic and weight management goals, avoidance of side effects (particularly hypoglycemia and weight gain), cost/access, and individual preferences.(11) Dapagliflozin and empagliflozin have been shown to significantly reduce the risk of worsening heart failure or cardiovascular death independently of diabetes status.(2,4) Angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), funny current channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine are all medications commonly used for heart failure with reduced ejection fraction (HFrEF).(12,13)
Safety	Invokamet, Invokamet XR, Segluromet, Synjardy, Synjardy XR, Trijardy XR, and Xigduo XR all have a black box warning for lactic acidosis due to their metformin component:(3,5-7,9,17) • Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. Symptoms included malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Laboratory abnormalities included elevated blood lactate levels, anion gap acidosis, increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL. • Risk factors include renal impairment, concomitant use of certain drugs, age more than 65 years old, radiological studies with contrast, surgery and other procedures, hypoxic states, excessive alcohol intake, and hepatic impairment. Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided in the Full Prescribing Information. • If lactic acidosis is suspected, discontinue the medication and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended. Brenzavvy, Farxiga, Invokana, Jardiance, Steglatro, and Glyxambi are contraindicated in patients on dialysis.(1,2,4,8,14,19) Inpefa is contraindicated in history of serious hypersensitivity reaction to Inpefa.(18) Invokamet and Invokamet XR are contraindicated in patients with severe renal impairment, acute or chronic metabolic acidosis, including diabetic ketoacidosis.(3) Segluromet, Synjardy, Synjardy XR, Xigduo XR, and Trijardy XR are contraindicated in patients with severe renal impairment, end stage renal disease (ESRD), patients on dialysis, and patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis.(5-7,9,17) Steglujan and Qtern are contraindicated in patients with severe renal impairment, end stage renal disease (ESRD), or on dialysis.(5-7,9,17)

REFERENCES

Number	Reference
1	Invokana prescribing information. Janssen Pharmaceuticals, Inc. July 2023.
2	Farxiga prescribing information. Astra Zeneca. September 2023.
3	Invokamet and Invokamet XR prescribing information. Janssen Pharmaceuticals, Inc. July 2023.
4	Jardiance prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc. September 2023.
5	Xigduo XR prescribing information. AstraZeneca Pharmaceuticals LP. September 2023.
6	Synjardy prescribing information. Boehringer Ingelheim. March 2022.
7	Synjardy XR prescribing information. Boehringer Ingelheim. March 2022.
8	Steglatro prescribing information. Merck & Co, Inc. March 2022.

Number	Reference
9	Segluromet prescribing information. Merck Sharp & Dohme Corp. May 2022.
10	American Diabetes Association. Standards of Medical Care in Diabetes-2022. Available at: https://care.diabetesjournals.org/content/45/Supplement_1.
11	Nuha A. ElSayed, et. al, American Diabetes Association, 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S140–S157. https://doi.org/10.2337/dc23-S009.
12	American Diabetes Association, 10. Cardiovascular Disease and Risk Management: Standards of Care in Diabetes—2023. Diabetes Care 1 January 2023; 46 (Supplement_1): S158–S190. https://doi.org/10.2337/dc23-S010.
13	Yancy CW, Jessup M, Bozkurt B, et. al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Circulation. 2017;136:e137-e161. Available at: https://www.ahajournals.org/doi/full/10.1161/CIR.0000000000000509.
14	Glyxambi prescribing information. Boehringer Ingelheim Pharmaceuticals, Inc and Eli Lilly and Company. October 2022.
15	Qtern prescribing information. Astra Zeneca. September 2023.
16	Steglujan prescribing information. Merck & Co., Inc. June 2022.
17	Trijardy XR prescribing information. Boehringer Ingelheim International GmbH. October 2022.
18	Inpefa Prescribing Information. Lexicon Pharmaceuticals, Inc. May 2023.
19	Brenzavvy prescribing information. TheracosBio, LLC. September 2023.

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Brenzavvy	bexagliflozin tab	20 MG	M ; N ; O	M		
Farxiga	dapagliflozin propanediol tab	10 MG ; 5 MG	M ; N ; O	M		
Glyxambi	empagliflozin-linagliptin tab	10-5 MG ; 25-5 MG	M ; N ; O ; Y	N		
Inpefa	sotagliflozin tab	200 MG ; 400 MG	M ; N ; O	N		
Invokamet	canagliflozin-metformin hcl tab	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	M ; N ; O ; Y	N		
Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	M ; N ; O	N		
Invokana	canagliflozin tab	100 MG ; 300 MG	M ; N ; O ; Y	N		
Jardiance	empagliflozin tab	10 MG ; 25 MG	M ; N ; O	N		
Qtern	dapagliflozin-saxagliptin tab	10-5 MG ; 5-5 MG	M ; N ; O	N		
Segluromet	ertugliflozin-metformin hcl tab	2.5-1000 MG ; 2.5-500 MG ; 7.5-1000 MG ; 7.5-500 MG	M ; N ; O	N		
Steglatro	ertugliflozin l-pyroglutamic acid tab	15 MG ; 5 MG	M ; N ; O	N		
Steglujan	ertugliflozin-sitagliptin tab	15-100 MG ; 5-100 MG	M ; N ; O	N		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG ; 5-1000 MG ; 5-500 MG	M ; N ; O	N		
Synjardy xr	empagliflozin-metformin hcl tab er	10-1000 MG ; 12.5-1000 MG ; 25-1000 MG ; 5-1000 MG	M ; N ; O	N		
Xigduo xr	dapagliflozin prop-metformin hcl tab er	10-1000 MG ; 10-500 MG ; 2.5-1000 MG ; 5-1000 MG ; 5-500 MG	M ; N ; O	M ; N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Brenzavvy	bexagliflozin tab	20 MG	30	Tablets	30	DAYS			
Farxiga	dapagliflozin propanediol tab	10 MG ; 5 MG	30	Tablets	30	DAYS			
Glyxambi	empagliflozin-linagliptin tab	10-5 MG ; 25-5 MG	30	Tablets	30	DAYS			
Inpefa	sotagliflozin tab	200 MG	30	Tablets	30	DAYS			
Inpefa	sotagliflozin tab	400 MG	30	Tablets	30	DAYS			
Invokamet	canagliflozin-metformin hcl tab	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS			
Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	60	Tablets	30	DAYS			
Invokana	canagliflozin tab	100 MG ; 300 MG	30	Tablets	30	DAYS			
Jardiance	empagliflozin tab	10 MG ; 25 MG	30	Tablets	30	DAYS			
Qtern	Dapagliflozin-Saxagliptin Tab 10-5 MG	10-5 MG	30	Tablets	30	DAYS			
Qtern	Dapagliflozin-Saxagliptin Tab 5-5 MG	5-5 MG	30	Tablets	30	DAYS			
Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	120	Tablets	30	DAYS			
Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-1000 MG	7.5-1000 MG	60	Tablets	30	DAYS			
Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-500 MG	7.5-500 MG	60	Tablets	30	DAYS			
Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 15 MG (Base Equiv)	15 MG	30	Tablets	30	DAYS			
Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 5 MG (Base Equiv)	5 MG	60	Tablets	30	DAYS			
Steglujan	ertugliflozin-sitagliptin tab	15-100 MG ; 5-100 MG	30	Tablets	30	DAYS			
Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG ; 5-1000 MG ; 5-500 MG	60	Tablets	30	DAYS			
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	60	Tablets	30	DAYS			
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 12.5-1000 MG	12.5-1000 MG	60	Tablets	30	DAYS			
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 25-1000 MG	25-1000 MG	30	Tablets	30	DAYS			
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS			
Trijardy xr	Empagliflozin-Linaglip-Metformin Tab ER 24HR 12.5-2.5-1000MG	12.5-2.5-1000 MG	60	Tablets	30	DAYS			
Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 10-5-1000 MG	10-5-1000 MG	30	Tablets	30	DAYS			
Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 25-5-1000 MG	25-5-1000 MG	30	Tablets	30	DAYS			
Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 5-2.5-1000MG	5-2.5-1000 MG	60	Tablets	30	DAYS			
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	30	Tablets	30	DAYS			
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-500 MG	10-500 MG	30	Tablets	30	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	60	Tablets	30	DAYS			
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	60	Tablets	30	DAYS			
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Brenzavvy	bexagliflozin tab	20 MG	Medicaid
Farxiga	dapagliflozin propanediol tab	10 MG ; 5 MG	Medicaid
Glyxambi	empagliflozin-linagliptin tab	10-5 MG ; 25-5 MG	Medicaid
Inpefa	sotagliflozin tab	200 MG ; 400 MG	Medicaid
Invokamet	canagliflozin-metformin hcl tab	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	Medicaid
Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	Medicaid
Invokana	canagliflozin tab	100 MG ; 300 MG	Medicaid
Jardiance	empagliflozin tab	10 MG ; 25 MG	Medicaid
Qtern	dapagliflozin-saxagliptin tab	10-5 MG ; 5-5 MG	Medicaid
Segluromet	ertugliflozin-metformin hcl tab	2.5-1000 MG ; 2.5-500 MG ; 7.5-1000 MG ; 7.5-500 MG	Medicaid
Steglatro	ertugliflozin l-pyroglutamic acid tab	15 MG ; 5 MG	Medicaid
Steglujan	ertugliflozin-sitagliptin tab	15-100 MG ; 5-100 MG	Medicaid
Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG ; 5-1000 MG ; 5-500 MG	Medicaid
Synjardy xr	empagliflozin-metformin hcl tab er	10-1000 MG ; 12.5-1000 MG ; 25-1000 MG ; 5-1000 MG	Medicaid
Xigduo xr	dapagliflozin prop-metformin hcl tab er	10-1000 MG ; 10-500 MG ; 2.5-1000 MG ; 5-1000 MG ; 5-500 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Brenzavvy	bexagliflozin tab	20 MG	Medicaid
Farxiga	dapagliflozin propanediol tab	10 MG ; 5 MG	Medicaid
Glyxambi	empagliflozin-linagliptin tab	10-5 MG ; 25-5 MG	Medicaid
Inpefa	sotagliflozin tab	200 MG	Medicaid
Inpefa	sotagliflozin tab	400 MG	Medicaid
Invokamet	canagliflozin-metformin hcl tab	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	Medicaid
Invokamet xr	canagliflozin-metformin hcl tab er	150-1000 MG ; 150-500 MG ; 50-1000 MG ; 50-500 MG	Medicaid
Invokana	canagliflozin tab	100 MG ; 300 MG	Medicaid
Jardiance	empagliflozin tab	10 MG ; 25 MG	Medicaid

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Qtern	Dapagliflozin-Saxagliptin Tab 10-5 MG	10-5 MG	Medicaid
Qtern	Dapagliflozin-Saxagliptin Tab 5-5 MG	5-5 MG	Medicaid
Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-1000 MG	2.5-1000 MG	Medicaid
Segluromet	Ertugliflozin-Metformin HCl Tab 2.5-500 MG	2.5-500 MG	Medicaid
Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-1000 MG	7.5-1000 MG	Medicaid
Segluromet	Ertugliflozin-Metformin HCl Tab 7.5-500 MG	7.5-500 MG	Medicaid
Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 15 MG (Base Equiv)	15 MG	Medicaid
Steglatro	Ertugliflozin L-Pyroglutamic Acid Tab 5 MG (Base Equiv)	5 MG	Medicaid
Steglujan	ertugliflozin-sitagliptin tab	15-100 MG ; 5-100 MG	Medicaid
Synjardy	empagliflozin-metformin hcl tab	12.5-1000 MG ; 12.5-500 MG ; 5-1000 MG ; 5-500 MG	Medicaid
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	Medicaid
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 12.5-1000 MG	12.5-1000 MG	Medicaid
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 25-1000 MG	25-1000 MG	Medicaid
Synjardy xr	Empagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	Medicaid
Trijardy xr	Empagliflozin-Linaglip-Metformin Tab ER 24HR 12.5-2.5-1000MG	12.5-2.5-1000 MG	Medicaid
Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 10-5-1000 MG	10-5-1000 MG	Medicaid
Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 25-5-1000 MG	25-5-1000 MG	Medicaid
Trijardy xr	Empagliflozin-Linagliptin-Metformin Tab ER 24HR 5-2.5-1000MG	5-2.5-1000 MG	Medicaid
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-1000 MG	10-1000 MG	Medicaid
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 10-500 MG	10-500 MG	Medicaid
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 2.5-1000 MG	2.5-1000 MG	Medicaid
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-1000 MG	5-1000 MG	Medicaid
Xigduo xr	Dapagliflozin-Metformin HCl Tab ER 24HR 5-500 MG	5-500 MG	Medicaid

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
All other target agent(s)	**TARGET AGENT(S)** **Brenzavvy, Bexagliflozin** **Glyxambi** (empagliflozin/linagliptin) **Invokana** (canagliflozin) **Invokamet** (canagliflozin/metformin) **Invokamet XR** (canagliflozin/metformin ER) **Qtern** (dapagliflozin/saxagliptin) **Segluromet** (ertugliflozin/metformin) **Steglatro** (ertugliflozin) **Steglujan** (ertugliflozin/sitagliptin) **Synjardy** (empagliflozin/metformin) **Synjardy XR** (empagliflozin/metformin ER)

Module	Clinical Criteria for Approval
	Trijardy XR (empagliflozin/linagliptin/metformin ER) **Xigduo XR** (dapagliflozin/metformin ER) **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient's medication history includes use of an agent containing metformin or insulin **OR** 2. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: 1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** 3. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 4. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The patient has an intolerance or hypersensitivity to one of the following agents: metformin or insulin **OR** 7. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulins **OR** 8. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 9. The prescriber has provided documentation that metformin AND insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Farxiga	**TARGET AGENT(S)** **Farxiga** (dapagliflozin) **Target Agent(s)** will be approved when ONE of the following is met: 1. The patient has a diagnosis of heart failure **OR** 2. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 3. The patient has a diagnosis of chronic kidney disease (CKD) **OR** 4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past **OR** 5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following: A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine was discontinued due to lack of effectiveness or an adverse event **OR**

Module	Clinical Criteria for Approval
	B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **OR** 8. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** 10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulins **OR** 11. The prescriber has provided documentation that metformin AND insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine **OR** 14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.
Jardiance and Inpefa	**TARGET AGENT(S)** **Jardiance** (empagliflozin) **Inpefa** (sotagliflozin) **Target Agent(s)** will be approved when ONE of the following is met: 1. If the requested agent is Jardiance, then BOTH of the following: A. The patient has a diagnosis of chronic kidney disease (CKD) **AND** B. The patient is at high risk for progression of CKD, including, risk of sustained decline in eGFR, end-stage kidney disease, cardiovascular death, and hospitalization **OR** 2. The patient has a diagnosis of heart failure **OR** 3. The patient has a diagnosis of type 2 diabetes with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** 4. The patient's medication history includes use of an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs),

Module	Clinical Criteria for Approval
	If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine in the past **OR** 5. The prescriber has stated that the patient has tried an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine AND ONE of the following: A. An agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over an agent containing metformin, insulin, ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 6. Information has been provided that indicates the patient is currently being treated with the requested SGLT inhibitor within the past 90 days **OR** 7. The prescriber states the patient is currently being treated with the requested SGLT inhibitor within the past 90 days AND is at risk if therapy is changed **OR** 8. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 9. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** 10. The patient has an FDA labeled contraindication to ALL of the following agents: metformin and insulin **OR** 11. The prescriber has provided documentation that metformin AND insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** 12. The patient has an intolerance or hypersensitivity to ONE of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate or hydralazine **OR** 13. The patient has an FDA labeled contraindication to ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine **OR** 14. The prescriber has provided documentation that ALL of the following agents: ACE inhibitors, angiotensin receptor blockers (ARBs), angiotensin receptor-neprilysin inhibitors (ARNIs), If channel inhibitors (e.g., Corlanor), aldosterone antagonists, beta blockers, isosorbide dinitrate and hydralazine cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **Length of Approval:** 12 months NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: A. BOTH of the following:

Module	Clinical Criteria for Approval
	1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **OR** B. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit **OR** C. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. Information has been provided to support therapy with a higher dose for the requested indication **Length of Approval**: up to 12 months