BlueCross BlueShield
Federal Employee Program

SGLT2 STEP POLICY

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Synjardy, Synjardy XR (empagliflozin/metformin), Xigduo XR (dapagliflozin/metformin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Synjardy, Synjardy XR (empagliflozin/metformin), and Xigduo XR (dapagliflozin/metformin) are oral sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. They should not be used to treat type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis. They work by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in patients with diabetes who have elevated blood glucose levels. Farxiga and Jardiance are also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure (HF). In addition, Farxiga and Jardiance are indicated to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization in adult patients with chronic kidney disease (1-7).

Regulatory Status

FDA-approved indications for Farxiga, Glyxambi, Jardiance, Qtern, Synjardy, Synjardy XR, and Xigduo XR: They are sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1-7).

Farxiga is also indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure, and 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 (2).

Jardiance is also indicated to reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure, and 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 (1).

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Synjardy and Synjardy XR are also indicated in adults with type 2 diabetes mellitus to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure (5-6).

Limitations of Use for Farxiga and Jardiance for CKD: (1-2)
Farxiga and Jardiance are not recommended for the treatment of chronic kidney disease in patients with polycystic kidney disease or patients requiring or with a recent of history of immunosuppressive therapy for the treatment of kidney disease. Farxiga and Jardiance are not expected to be effective in these populations.

The safety and effectiveness of Farxiga, Glyxambi, Qtern, Synjardy, Synjardy XR, and Xigduo XR in pediatric patients less than 18 years of age have not been established (2-7).

The safety and effectiveness of Jardiance in pediatric patients less than 10 years of age have not been established (1).

Summary

Farxiga (dapagliflozin), Glyxambi (empagliflozin/linagliptin), Jardiance (empagliflozin), Qtern (dapagliflozin/saxagliptin), Synjardy, Synjardy XR (empagliflozin/metformin), and Xigduo XR (dapagliflozin/metformin) are oral sodium-glucose co-transporter 2 (SGLT2) inhibitors indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. They should not be used to treat type 1 diabetes; in those who have increased ketones in their blood or urine (diabetic ketoacidosis); or in those with severe renal impairment, end stage renal disease, or in patients on dialysis. They work by blocking the reabsorption of glucose by the kidney, increasing glucose excretion, and lowering blood glucose levels in patients with diabetes who have elevated blood glucose levels. Farxiga and Jardiance are also indicated to reduce the risk of cardiovascular death and hospitalization for heart failure (HF). In addition, Farxiga and Jardiance are indicated to reduce the risk of kidney function decline, kidney failure, cardiovascular death, and hospitalization in adult patients with chronic kidney disease. The safety and effectiveness of Farxiga, Glyxambi, Qtern, Synjardy, Synjardy XR, and Xigduo XR in pediatric patients less than 18 years of age have not been established. The safety and effectiveness of

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Jardiance in pediatric patients less than 10 years of age have not been established (1-7).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Farxiga, Glyxambi, Jardiance, Qtern, Synjardy, Synjardy XR, and Xigduo XR while maintaining optimal therapeutic outcomes.

References

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