

FOR ADULTS WITH TYPE 2 DIABETES AND ESTABLISHED CV DISEASE

EMPAGLIFLOZIN IS RECOMMENDED BY THE

**2019 ADA® STANDARDS OF CARE
AND THE
2018 ACC EXPERT CONSENSUS DECISION PATHWAY**

TO REDUCE THE RISK OF CV DEATH^{1,2}

Leading societies recommend initiating empagliflozin
for its proven CV benefit

- ▶ **American College of Cardiology**
- ▶ **American Diabetes Association®**

INDICATION AND LIMITATIONS OF USE

JARDIANCE is indicated to reduce the risk of cardiovascular (CV) death in adults with type 2 diabetes mellitus and established CV disease.

JARDIANCE is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

ACC=American College of Cardiology; ADA=American Diabetes Association;
CV=cardiovascular.

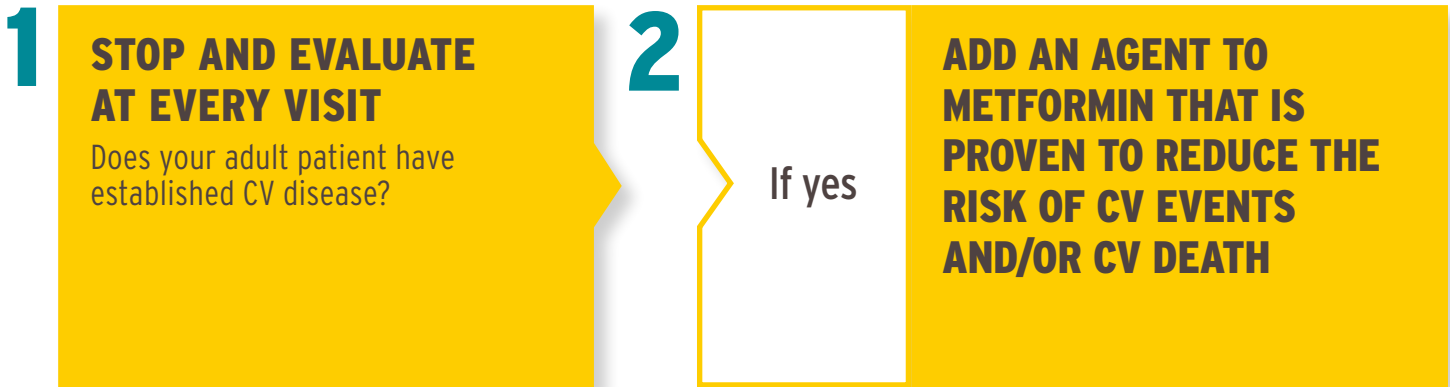
IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS: History of serious hypersensitivity to empagliflozin or any of the excipients in JARDIANCE; severe renal impairment, end-stage renal disease, or dialysis.

Please see additional Important Safety Information on the following pages. Please see [Prescribing Information](#) and [Medication Guide](#).

FOR ADULTS WITH TYPE 2 DIABETES AND ESTABLISHED CV DISEASE

The **2019 ADA® Standards of Care** treatment algorithm urges HCPs to **prioritize CV risk¹**



THE 2019 ADA® STANDARDS OF CARE RECOMMENDS EMPAGLIFLOZIN
for its proven benefit to reduce the risk of CV death when adding an agent to metformin¹

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

Hypotension: Empagliflozin causes intravascular volume contraction and symptomatic hypotension may occur. Before initiating JARDIANCE, assess and correct volume status in the elderly, and in patients with renal impairment, low systolic blood pressure, or on diuretics. Monitor for hypotension.

Ketoacidosis: Ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, has been identified in patients with type 1 and type 2 diabetes mellitus receiving SGLT2 inhibitors, including empagliflozin. Fatal cases of ketoacidosis have been reported in patients taking empagliflozin. Patients who present with signs and symptoms of metabolic acidosis should be assessed for ketoacidosis, even if blood glucose levels are less than 250 mg/dL. If suspected, discontinue JARDIANCE, evaluate, and treat promptly. Before initiating JARDIANCE, consider risk factors for ketoacidosis. Patients may require monitoring and

temporary discontinuation in situations known to predispose to ketoacidosis.

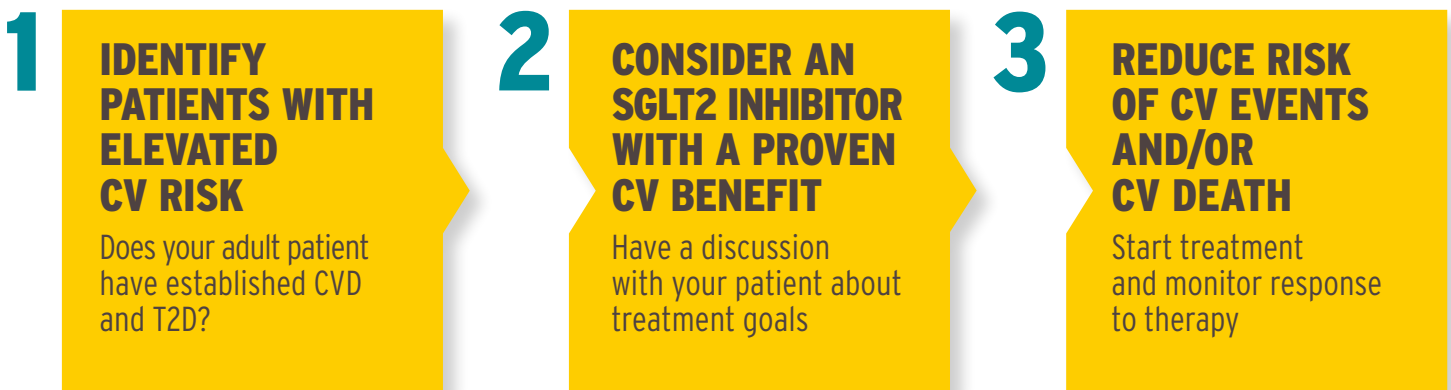
Acute Kidney Injury and Impairment in Renal Function: Empagliflozin causes intravascular volume contraction and can cause renal impairment. Acute kidney injury requiring hospitalization and dialysis have been identified in patients taking SGLT2 inhibitors, including empagliflozin; some reports involved patients younger than 65 years of age. Before initiating JARDIANCE, consider factors that may predispose patients to acute kidney injury. Consider temporary discontinuation in settings of reduced oral intake or fluid losses. Monitor patients for signs and symptoms of acute kidney injury. If it occurs, discontinue JARDIANCE and treat promptly.

(continued on next page)

Please see additional Important Safety Information on the following pages. Please see [Prescribing Information](#) and [Medication Guide](#).

The 2018 ACC Expert Consensus Decision Pathway focuses on the need to reduce the risk of CV death in T2D²

PRACTICAL CONSIDERATIONS FROM THE EXPERT CONSENSUS DECISION PATHWAY^{2,3}:



THE 2018 ACC EXPERT CONSENSUS DECISION PATHWAY RECOMMENDS JARDIANCE AS THE PREFERRED SGLT2i for adults with T2D and established CVD to reduce the risk of CV death²

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Empagliflozin increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Before initiating JARDIANCE, evaluate renal function and monitor thereafter. More frequent monitoring is recommended in patients with eGFR <60 mL/min/1.73 m². Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 m².

Urosepsis and Pyelonephritis: Serious urinary tract infections including urosepsis and pyelonephritis requiring hospitalization have been identified in patients receiving SGLT2 inhibitors, including empagliflozin. Treatment with SGLT2 inhibitors increases the risk for urinary tract infections. Evaluate for signs and symptoms of urinary tract infections and treat promptly.

Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious, life-threatening cases have occurred in both females and males. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

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FOR ADULTS WITH TYPE 2 DIABETES AND ESTABLISHED CV DISEASE

THE STANDARD OF CARE HAS CHANGED^{1,2}

THE 2019 ADA® STANDARDS OF CARE AND THE 2018 ACC EXPERT CONSENSUS DECISION PATHWAY RECOMMEND EMPAGLIFLOZIN

for its proven benefit to reduce the risk of CV death
when adding an agent to metformin^{1,2}

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

Hypoglycemia: The use of JARDIANCE in combination with insulin or insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or the insulin secretagogue may be required.

Necrotizing Fasciitis of the Perineum (Fournier's Gangrene): Serious, life-threatening cases have occurred in both females and males. Assess patients presenting with pain or tenderness, erythema, or swelling in the genital or perineal area, along with fever or malaise. If suspected, institute prompt treatment and discontinue JARDIANCE.

Genital Mycotic Infections: Empagliflozin increases the risk for genital mycotic infections, especially in patients with prior infections. Monitor and treat as appropriate.

Hypersensitivity Reactions: Discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

Increased Low-Density Lipoprotein Cholesterol (LDL-C): Monitor and treat as appropriate.

References: 1. American Diabetes Association. Standards of Medical Care in Diabetes—2019. *Diabetes Care*. 2019;42(Suppl 1):S1-S193. 2. Das SR, Everett BM, Birtcher KK, et al. *J Am Coll Cardiol*. 2018;72(24):3200-3223. 3. Zinman B, Wanner C, Lachin JM, et al; EMPA-REG OUTCOME Investigators. *N Engl J Med*. 2015;373(22):2117-2128.

MOST COMMON ADVERSE REACTIONS (≥5%): Urinary tract infections and female genital mycotic infections.

DRUG INTERACTIONS: Coadministration with diuretics may enhance the potential for volume depletion.

USE IN SPECIAL POPULATIONS

Pregnancy: JARDIANCE is not recommended, especially during the second and third trimesters.

Lactation: JARDIANCE is not recommended while breastfeeding.

Geriatric Use: JARDIANCE is expected to have diminished efficacy in elderly patients with renal impairment. Renal function should be assessed more frequently in elderly patients. The incidence of volume depletion-related adverse reactions and urinary tract infections increased in patients ≥75 years treated with empagliflozin.

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