Jardiance®
(empagliflozin) tablets
10 mg/25 mg

The Value of JARDIANCE Within Health Systems

for Adult Patients With Established Cardiovascular (CV) Disease and Type 2 Diabetes (T2D)

INDICATIONS 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 indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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

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 throughout. Please see accompanying Prescribing Information and Medication Guide for JARDIANCE.

Boehringer Ingelheim

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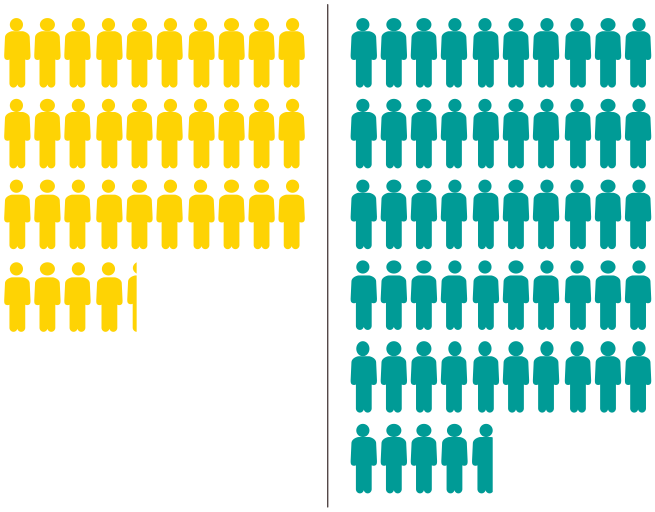
The Prevalence of Diabetes[a] Is Increasing at an Alarming Rate

2018

34.2 MILLION
people with diagnosed and undiagnosed diabetes[1]

10.5%
of population[1]



by 2030

~54.9 MILLION
people predicted with diagnosed and undiagnosed diabetes[2]

15.3%
of population[2]

= 1 million people

Direct medical costs for diagnosed diabetes[a] are

$237 billion

accounting for >2/3 of the total cost of care[3]

The largest contributors to the cost of diabetes in 2017 were

$71 Billion
Prescription medications beyond antihyperglycemic medications

$70 Billion
Hospital inpatient services

$34 Billion
Medication and supplies to directly treat diabetes

$30 Billion
Office visits to physicians and other health providers

[a]In adults, T2D accounts for about 90% to 95% of all diagnosed cases of diabetes.

Comorbid CV Disease Adds to the Complexity and Costs of Care for Patients With T2D

People with diabetes are 2-4x more likely to develop CV disease, which includes heart attacks and strokes, than people without diabetes.[4a]

4x	5x	5x	9x	5x
higher myocardial infarction (MI)[5]	higher stroke[5]	higher unstable angina[5]	higher admissions due to heart failure[5]	higher coronary revascularization procedures[5]

CV disease accounts for 28% of the cost of treating T2D and its complications[6]

Comorbid Acute MI or Acute Ischemic Stroke Creates Major Challenges[5,7]

Patients with T2D and comorbid acute MI or acute ischemic stroke pose a significant burden on health systems and add to the complexity of managing population health outcomes.

Compared with patients without diabetes, patients with T2D and comorbid acute MI or acute ischemic stroke are associated with poorer clinical outcomes, higher utilization of healthcare resources, and higher costs of care

24% to 43% more inpatient and outpatient visits, including higher medication expenditures per inpatient stay, per inpatient night, and per outpatient visit

CV-related events such as these make up 36% the total commercial cost of CV events

[a]In adults, T2D accounts for about 90% to 95% of all diagnosed cases of diabetes.

Urgent Need for Health Systems to Implement New Standards of Care in the Management of T2D and Established CV Disease

ONLY
~50%

Lack of Evidence-Based Care

of eligible patients receive the guideline-recommended preventative, chronic disease, and acute care services[8]

Vast Variability in Care Delivery

2020 American Diabetes Association (ADA) Standards of Care[9]:

Persistent variability in quality of diabetes care across providers and practice settings indicates that substantial system-level improvements are greatly needed

New Treatment Options

Guidelines Recommend[9-12]:

Inclusion of agents, such as GLP-1RAs or SGLT2 inhibitors, that address CV disease risk factors in patients with T2D and established CV disease

GLP-1RA=glucagon-like peptide 1 receptor agonist; SGLT2=sodium-glucose co-transporter 2.

Practical Considerations From the American College of Cardiology (ACC) Expert Consensus Decision Pathway

The ACC Expert Consensus Decision Pathway
recognizes the need for comprehensive CV risk reduction in patients with type 2 diabetes[12]

Addressing 3 Key Areas In The Management of Patients With T2D

1. **SCREENING PATIENTS WITH CV DISEASE FOR T2D**
2. **AGGRESSIVELY TREATING CV RISK**
3. **PRESCRIBING AN ANTIHYPERGLYCEMIC AGENT WITH EVIDENCE TO IMPROVE CV PATIENT OUTCOMES**

Integrating JARDIANCE Into Protocols to Reduce the Risk of CV Death in Adult Patients With Established CV Disease and T2D[13]

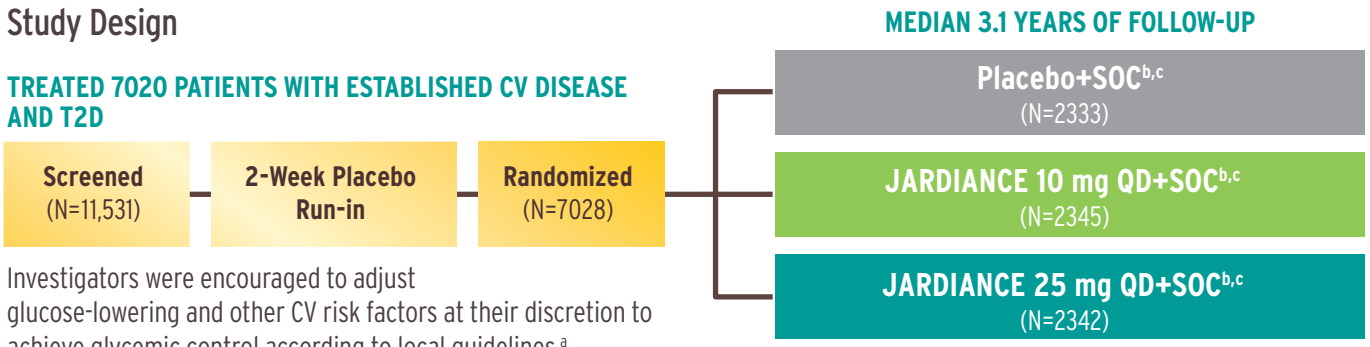
EMPA-REG OUTCOME Trial

- The EMPA-REG OUTCOME was a landmark CV outcome trial of JARDIANCE, with the breakthrough data from this study published in the *New England Journal of Medicine*.
- This was the first large, randomized CV outcome trial in patients with established CV disease and type 2 diabetes that showed a reduction in the risk of CV death.
- JARDIANCE, when added to standard of care[b], improved survival of patients with established CV disease and type 2 diabetes by significantly reducing the risk of CV death.

EMPA-REG OUTCOME Trial: Study Design

- The EMPA-REG OUTCOME Trial was a multicenter, multinational, randomized, double-blind, placebo-controlled study.
- The EMPA-REG OUTCOME Trial aimed to assess the effect of JARDIANCE versus placebo, in addition to standard of care, on time to first occurrence of CV death, nonfatal MI, or nonfatal stroke in adults with established CV disease and type 2 diabetes.
- All patients had to have established atherosclerotic CV disease and insufficient glycemic control at baseline (A1C 7%-10%).
- This was an event-driven trial, thus the duration of treatment was not predefined. The trial continued until at least 691 patients experienced an adjudicated primary outcome event. The primary endpoint was time to the first occurrence of any of the following adjudicated components of the 3-point major adverse CV events (MACE) composite index: CV death (including fatal stroke and fatal MI), nonfatal MI (excluding silent MI), or nonfatal stroke.

The EMPA-REG OUTCOME Trial Was Placebo-Controlled; All Patients Received SOC Medications



A1C was not an outcome of the study; the study was designed to determine the impact of JARDIANCE on MACE outcomes independent of A1C. To do this, prescribers were asked to treat to goal in both the JARDIANCE and placebo arms.

SOC=standard of care.
[a]Modifications to glucose-lowering medication(s) or CV medication(s) were at the physician's discretion.
[b]CV medications (eg, ACEIs/ARBs, statins) and glucose-lowering agents (eg, metformin, sulfonylureas, insulin).
[c]Active management of CV risk factors by adjusting therapies throughout the study was encouraged. Background antidiabetic therapy was to remain unchanged for first 12 weeks.

IMPORTANT SAFETY INFORMATION (continued)

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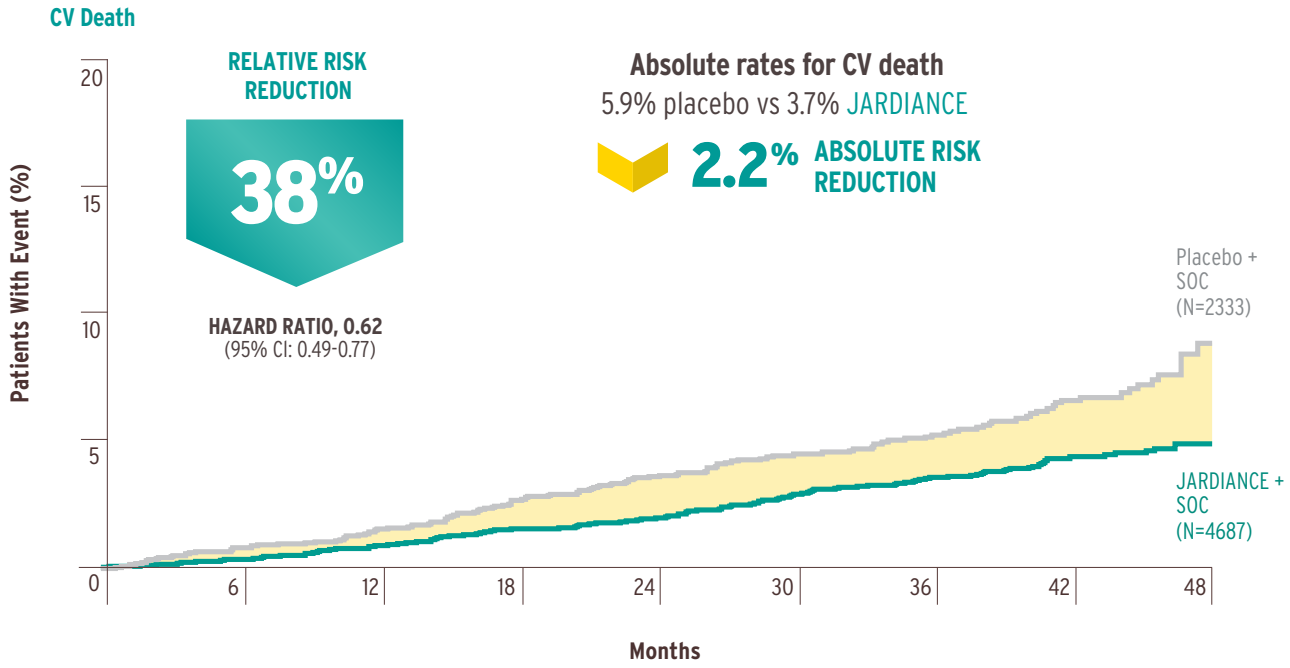
JARDIANCE Significantly Reduced the Risk of CV Death[a] on Top of SOC[13b]



Reductions in the risk of CV death with JARDIANCE were early and sustained over the study period

[a]CV death was a prespecified and adjudicated endpoint.
[b]CV medications (eg, ACEIs, ARBs, statins) and glucose-lowering agents (eg, metformin, sulfonylureas, insulin).
CI=confidence interval.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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. For patients who undergo scheduled surgery, consider temporarily discontinuing JARDIANCE for at least 3 days prior to surgery.

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 has 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.

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 m^2. Discontinue JARDIANCE in patients with a persistent eGFR <45 mL/min/1.73 m^2.

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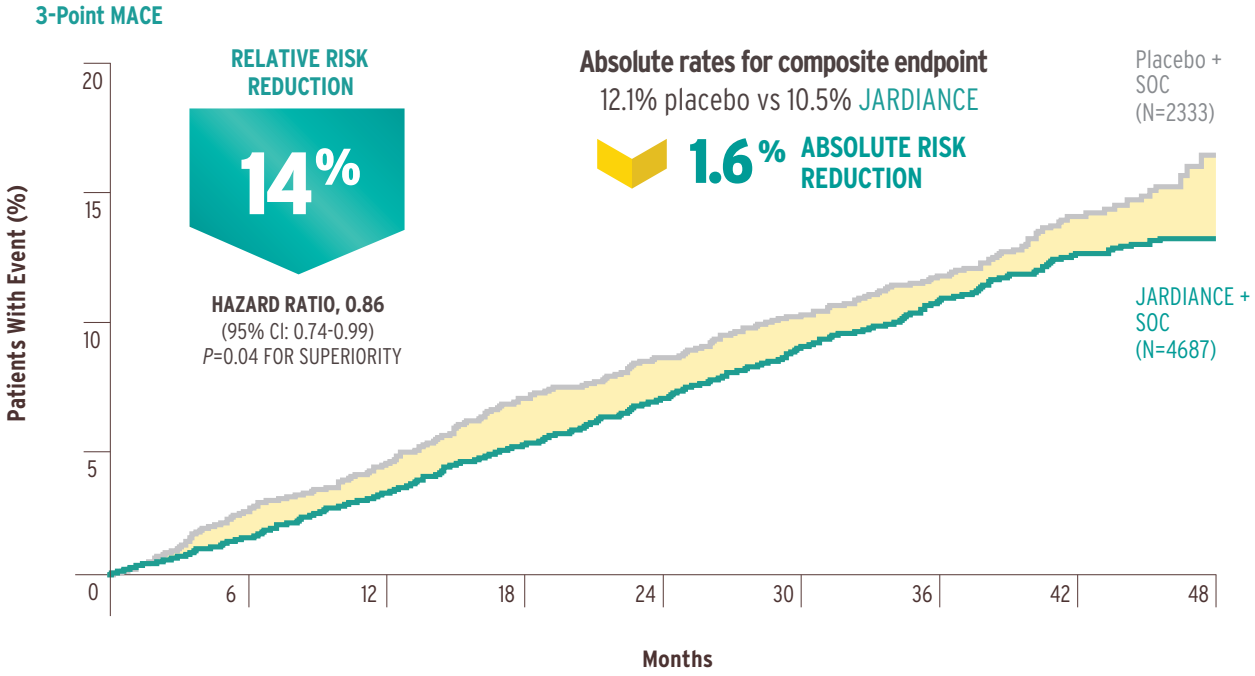
JARDIANCE on Top of SOC[a] Significantly Reduced the Risk of First Occurrence of Primary Composite Endpoint of CV Death, Nonfatal MI, or Nonfatal Stroke[13]



There was no change in risk of nonfatal MI (HR=0.87 [95% CI: 0.70-1.09]) or nonfatal stroke (HR=1.24 [95% CI: 0.92-1.67]); the 14% RRR in CV events was due to a reduction in the risk of CV death (HR=0.62 [95% CI: 0.49-0.77]).

[a]CV medications (eg, ACEIs, ARBs, statins) and glucose-lowering agents (eg, metformin, sulfonylureas, insulin).
CI=confidence interval; HR=hazard ratio; RRR=relative risk reduction.

IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS

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 requiring urgent surgical intervention have occurred in both females and males. Serious outcomes have included hospitalization, multiple surgeries, and death. 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: Serious hypersensitivity reactions have occurred with JARDIANCE (angioedema). If hypersensitivity reactions occur, discontinue JARDIANCE, treat promptly, and monitor until signs and symptoms resolve.

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

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

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JARDIANCE Demonstrated Consistent Reductions in CV Death Across A1C Subgroups[13,14]

A1C AT BASELINE	A1C CHANGE FROM BASELINE
<7.0% ✓	Reduction of ≥0.3% ✓
7.0% - <8.0% ✓	Reduction of <0.3% or increase ✓
8.0% - <9.0% ✓	
≥9.0%	

Post-hoc analysis: Risk of CV death was analyzed in the placebo and pooled JARDIANCE groups according to baseline A1C and change in A1C from baseline to the last value in the trial. A Cox proportional hazards model was used to assess the differences between the treatment groups. The post-hoc analysis was not designed to determine statistical significance.
Rate of CV death (%) across A1C subgroups: All values depict JARDIANCE vs placebo, respectively. <7.0%: 2.4 (N=297) vs 7.9 (N=127); 7.0%-<8.0%: 3.7 (N=2042) vs 6.1 (N=1029); 8.0%-<9.0%: 3.7 (N=1534) vs 5.4 (N=795); ≥9.0%: 4.2 (N=812) vs 5.5 (N=382).

EMPA-REG OUTCOME Trial: Adverse Events Overview

- JARDIANCE safety was assessed in >7000 patients with established CV disease and type 2 diabetes over a median follow-up of 3.1 years.

Adverse Events: Overview

	PLACEBO (N=2333)	JARDIANCE 10 mg (N=2345)	JARDIANCE 25 mg (N=2342)
≥1 AE (%)	91.7	90.1	90.4
≥1 serious AE (%)	42.3	37.4	39.0
AEs leading to discontinuation (%)	19.4	17.7	17.0

Adverse Events: Hypoglycemia

	PLACEBO (N=2333)	JARDIANCE 10 mg (N=2345)	JARDIANCE 25 mg (N=2342)
Overall[a] (%)	27.9	28.0	27.6
Requiring assistance (%)	1.5	1.4	1.3

- The incidence of genital infections was greater with JARDIANCE than placebo. The incidence rates with JARDIANCE 10 mg and 25 mg were 6.5% and 6.3%, respectively compared with 1.8% with placebo.
- The incidence of urinary tract infections was 18.2% with JARDIANCE 10 mg, 17.8% with JARDIANCE 25 mg, and 18.1% with placebo.
- Patients receiving insulin[b] at baseline had a greater incidence of hypoglycemia than those not receiving insulin.
- A lower dose of insulin/an insulin secretagogue may be required to reduce the risk of hypoglycemia when used in combination with JARDIANCE.

[a]Plasma glucose level <70 mg/dL or an event requiring assistance.
[b]48% of the study population in the combined JARDIANCE and 49% in the placebo arm.

IMPORTANT SAFETY INFORMATION (continued)

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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Based on the Landmark EMPA-REG OUTCOME Trial, Clinical Associations Include Recommendations for Adults With T2D and Established CV Disease to Reduce the Risk of CV Death

Evolving guidelines include important recommendations for the care of patients with T2D with established CV disease with clear guidance around SGLT2 inhibitor or GLP-1 RA use to reduce the risk of CV death

- **American Diabetes Association®**
- **European Association for the Study of Diabetes**
- **American Association of Clinical Endocrinologists**
- **American College of Cardiology**

CV risk continues to be prioritized in both the ACC Expert Consensus Decision Pathway and the ADA Standards of Care[9-12]

Health Systems, Providers, and Payors Are Integrating JARDIANCE Into Patient Care Processes

Over 52 health systems have established JARDIANCE on treatment formularies, pathways, and protocols[14]

JARDIANCE leads in Commercial and Medicare Part D access among all branded antidiabetic products[a]

JARDIANCE is the #1 prescribed SGLT2 inhibitor by cardiologists, endocrinologists, and primary care physicians[b]

[a]Source: Fingertip Formulary, health plan or state listed above, and/or data on file, Boehringer Ingelheim Pharmaceuticals, Inc. as of 06/01/2020. Placement on formulary does not establish clinical comparability of products, including safety and efficacy, and is not a guarantee of full or partial coverage and/or payment. Contact health plan, state, or www.medicare.gov for most current information, as it may change without notice.

[a]As measured by TRx through 07/10/2020.

IMPORTANT SAFETY INFORMATION (continued)

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REFERENCES

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