COMMUNICATION

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PLEASE REVIEW

Drug Information

PharmPix Clinical Department

PharmPix is committed to the health and wellness of our members.

The clinical team wants to communicate the latest up-to-date drug information requested.

Drug Information:

Remember that medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that your recommendations are consistent with the most updated information.

It is our priority to offer high-quality services and support practices for health promotion and diseases prevention. If you have any questions or wish to have more information regarding this document, you can call us directly or view PharmPix communications online.

QUESTIONS

Call us at 787-522-5252-Clinical Department.

Access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Jardiance™ for chronic kidney disease

On September 22, 2023, the FDA approved Jardiance™ (empagliflozin) to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease (CKD) at risk of progression.

Background:

CKD affects 850 million people worldwide, including over 35 million in the United States. The approval of this expanded indication is based on the EMPA-KIDNEY, a study that included over 6,000 adults with CKD with and without type 2 diabetes. The primary study outcome was the time to a first event of either cardiovascular death or kidney disease progression, defined as end-stage kidney disease, a sustained decline in eGFR to <10mL/min/1.73m^2, kidney death, or a sustained decline of ≥40% in eGFR from the time of randomization. Key secondary outcomes included cardiovascular death or hospitalization for heart failure, all-cause hospitalization, and all-cause mortality.

Treatment with Jardiance™ 10mg resulted in a 28% relative risk reduction compared with placebo for the composite primary endpoint of kidney disease progression or cardiovascular death.

In addition, EMPA-KIDNEY is the first trial evaluating the effects of sodium-glucose cotransporter-2 (SGLT2) inhibitors on CKD to demonstrate a statistically significant decrease in the risk of first and recurrent hospitalization with a 14% relative risk reduction.

This is the fourth FDA approval for Jardiance™ associated with the EMPOWER clinical program. With this approval, it will compete directly with Farxiga™ (dapagliflozin) in patients with CKD with or without T2D.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252-Clinical Department. Our pharmacists will help you. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

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REFERENCES:

1. Eli Lilly. (2023, September). *US FDA approves Jardiance® for the treatment of adults with chronic kidney disease*. PR Newswire: press release distribution, targeting, monitoring and marketing. https://www.prnewswire.com/news-releases/us-fda-approves-jardiance-for-the-treatment-of-adults-with-chronic-kidney-disease-301936176.html
2. Empagliflozin in patients with chronic kidney disease. (2023). *New England Journal of Medicine*, 388(2), 117–127. https://doi.org/10.1056/nejmoa2204233

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