August 26, 2020 **COM-2020-062**

DRUG SAFETY NOTIFICATION

DATE: August 26, 2020

DRUG NAME:

- **Invokana™ (Canagliflozin)**
- **Invokamet™ (Canagliflozin & Metformin HCl)**
- **Invokamet XR™ (Canagliflozin & Metformin HCl XR)**

SAFETY TOPIC: Removal of box warning related to risk of leg and foot amputation

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. It is for this reason that we are notifying you that on August 26, 2020 the US Food and Drug Administration (FDA) published a safety communication for **Invokana™ (canagliflozin), Invokamet™(canagliflozin & Metformin HCL) and Invokamet XR™ (canagliflozin & Metformin**) indicating the removal of the boxed warning about the risk of leg and foot amputations related to the use of products containing canagliflozin.

According to the new clinical trials results, the risk of leg and feet amputations is lower than the previously described. The benefits of using the therapy including reduced risk of major heart-related events, reduced risk of worsening renal function and heart failure may outweigh the risk of amputations, specifically when the patient receives appropriate monitoring and counseling.

Recommendations for healthcare professionals:

- Patients should recognize the importance of preventive foot care and monitor for pain, ulcers, sores or tenderness that might be related to a possible infection. If a patient suspects of infection, should contact their healthcare provider as soon as possible.
- Patients should continue their current treatment unless otherwise specified by the healthcare provider.
- Health care professionals should recognize the importance of preventive foot care and monitoring. In addition, health care professionals must provide counseling to patients regarding these topics.

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- Report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:
    - Complete and submit the MedWatch Online Voluntary Reporting Form online.
    - Download FDA Form 3500 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

Additional information can be found at:

- https://www.fda.gov/drugs/drug-safety-and-availability/fda-removes-boxed-warning-about-risk-leg-and-foot-amputations-diabetes-medicine-canagliflozin

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- U.S. Food and Drug Administration. (2020). Invokana, Invokamet, Invokamet XR (canagliflozin): MedWatch Safety -Boxed Warning about Risk of Leg and Foot Amputations Removed. Retrieved from https://www.fda.gov/safety/medical-product-safety-information/invokana-invokamet-invokamet-xr-canagliflozin-medwatch-safety-alert-boxed-warning-about-risk-leg-and?utm_campaign=FDA%20MedWatch%20%20Invokana%2C%20Invokamet%2C%20Invokamet%20XR%20%28canagliflozin%29%3A%20MedWatch%20Safety%20Alert&utm_medium=email&utm_source=Eloqua

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