

Diabetes Drug Linked to Increased Risk of Amputations



[Healthcare Recovery Solutions \(HRS\)](#) has added the drug Canagliflozin and its name brands to its list of searchable and potential recovery opportunities for healthcare payers. On May 16, 2017, the FDA issued a [safety announcement](#) about the drug, which is sold under the names Invokana, Invokamet and Invokamet XR. Canagliflozin is a sodium-glucose cotransporter-2 inhibitor that lowers blood sugar by causing the kidneys to remove sugar from the body through urination. All three drugs are manufactured by Janssen Pharmaceuticals, a Johnson & Johnson's subsidiary.

Increased Risk of Amputations

Two clinical trials found that the medication caused an increased risk of leg and foot amputations, nearly twice as high for patients who took the drug in comparison those who received a placebo. The [FDA's announcement](#) states that amputations of the toe and middle of the foot were more common but amputations of the leg, below and above the knee also occurredⁱ. Data from [the FDA Adverse Event Reporting System](#) collected by Advera Health reports twenty-five cases of toe amputations of patients taking Invokanaⁱⁱ. This number is significantly higher when compared to only two reported amputations on one competitor medication and no reported amputations on another widely used competitor medication.



The FDA reports that the risk of amputation affects approximately 6 to 8 out of 1,000 individuals on the medication. As a result, the FDA is forcing Janssen Pharmaceuticals to place a black box warning on the packaging of Canagliflozin products. A black box warning is the highest level warning for drugs manufactured and sold in the U.S. without being removed from the market.

Payers Can Recover Expenses

Healthcare payers have expended thousands of dollars in amputation surgeries and after-care treatment for individuals who had a toe, foot or limb amputation as a result of taking Invokana. According to the *Journal of the American Podiatric Medical Association*, a foot or leg amputation costs between \$30,000 and \$60,000 in initial medical costs, and between \$43,000 and \$60,000 in after-care for up to three yearsⁱⁱⁱ. Healthcare Recovery Solutions (HRS) has the ability to identify these paid claims and recover expenses incurred by healthcare payers. Those that do not take affirmative action, risk losing thousands of dollars in recoveries.

ⁱ Center for Drug Evaluation and Research. "Drug Safety and Availability - FDA Drug Safety Communication: FDA Confirms Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin." *U.S. FDA*. Center for Drug Evaluation and Research.

ⁱⁱ EP Vantage Newsletter Provider, Biotech, HealthcareEP Vantage. "Amputation Risk Adds Another Cut To Invokana." *Seeking Alpha*.

ⁱⁱⁱ Phillips, Quinn. "Costs of Amputation." *Diabetes Self-Management*.