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Category: Drug-Use Evaluation

Title: Association of severe hypoglycemic risk with package insert recommended renal dose adjustments for oral anti-diabetic drug treatments among commercially insured patients with type 2 diabetes

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Purpose: Purpose: To assess the risk of severe hypoglycemic events associated with use of oral anti-diabetic (OAD) treatments that are not concordant with package inserts (PIs) among commercially-insured patients with type 2 diabetes mellitus (T2DM) and chronic kidney disease (CKD).

Methods: Methods: Medical, pharmacy claims and laboratory findings dated 2005-2010 from a U.S. commercially-insured population were analyzed. T2DM patients (identified based on two claims with associated ICD-9-CM code of 250.xx) aged 18-64 with stage 3-5 CKD (identified based on at least one medical claims with associated ICD-9-CM code of 585.3-585.6 or dialysis procedures or lab findings with glomerular filtration rate less than 60; the date of the first CKD indication denoted as the index date) were included in this study. Patients who filled prescriptions of OAD within 6 months (baseline period) following the index date were included and concordance of use based on the Pis recommendations for renal impairment was determined. Patients were considered not concordant if OADs were prescribed when recommended to be avoided, or without recommended dose adjustments. Severe hypoglycemic events identified from medical claims using a published algorithm following the 6 months baseline period were evaluated until loss of follow-up. Cox proportional hazards regression was used to estimate the risk of severe hypoglycemic events associated with OAD treatment according to PIs recommendations, adjusting for patient demographic and clinical characteristics. Data analyzed were encrypted and compliant with the Health Insurance Portability and Accountability Act; the study was exempted from institutional review board review.

Results: Results: The final study sample included 3,300 T2DM patients with stage 3-5 CKD (mean age: 56.0; 37.9% female; 83.2% stage 3 CKD), of which 74.4% had OAD utilization outside of PI recommendations. The rate of non-concordant use was 97.3% for glyburide, 94.4% for glipizide, 94.0% for glimepiride, 12.5% for acarbose, 28.6% for miglitol, 78.7% for metformin, 15.5% for repaglinide, and 35.8% for sitagliptin. After adjustment for patient

characteristics, non-PI-concordant patients had 35% higher risk of severe hypoglycemic events (hazard ratio: 1.35, 95 % CI: 1.10-1.67).

Conclusion: Conclusion: These findings suggest a higher risk of severe hypoglycemic events associated with OAD treatments not concordant with PI recommendations for renal impairment among T2DM patients with stage 3-5 CKD. Efforts should be made to monitor OAD treatments when managing these patients in clinical practice.