Adherence, Persistence, and Switching Patterns of a Newer Oral Direct Thrombin Inhibitor, Dabigatran Etxilate

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Background: Dabigatran, an oral direct thrombin inhibitor, was approved by the FDA in October 2010 to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation. Dabigatran does not share warfarin’s potential limitations of having a variable response, food and drug interactions, lab monitoring requirements, and narrow therapeutic index concerns. However, dabigatran is dosed twice daily and is likely to have an increased prescription cost burden to patients.

Objective and Purpose: To investigate adherence, persistence, and switching patterns for patients initiating dabigatran therapy, stratified by those with or without prior warfarin use, using large prescription claims databases.

Methods: This will be a descriptive cohort analysis using electronic pharmacy claims databases housing Medicare Part D, Medicaid, and Commercial claims. Patients with a claim for dabigatran and continuously enrolled for the duration of the study period (six months pre- and six months post-initiation of dabigatran) will be identified and stratified into two groups based on the presence or absence of warfarin claims prior to dabigatran initiation. Various demographic and clinical characteristics, such as age, sex, concurrent medications, and concomitant disease states, will be assessed for each group. Additionally, persistence and adherence to dabigatran as well as switching patterns between dabigatran and warfarin will be described.

Results: The proportion of patients persistent to dabigatran therapy over six months will be reported. Of patients who are non-persistent to dabigatran therapy, time to discontinuation or time to switch from dabigatran to warfarin will be reported. Adherence will be measured using the Proportion of Days Covered (PDC) methodology.

Conclusions: The results of this study are expected to reveal characteristics of patients who initiated dabigatran therapy in the first six months of market availability. It is expected to identify differences between those who are new to oral anticoagulation and those who were previously on warfarin. Lack of patient persistence, adherence, and the presence of switching to warfarin could suggest tolerability issues. Lastly, this study may show whether adherence is optimal for this twice-daily oral anticoagulant, and whether there is a need for patient education on the importance of adherence to anticoagulation therapy.