DEVELOPMENT OF A BIOSIMILAR ADOPTION PROGRAM FOR RITUXIMAB BIOSIMILAR IN A COMMUNITY HOSPITAL

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Learning objective: Identify barriers to adopting a biosimilar product in a community hospital during a pandemic.

Background: Biosimilars are complex macromolecules that are highly similar to and have no clinically meaningful differences from an existing Food and Drug Administration (FDA) approved originator. To establish a biosimilars' clinical efficacy and safety, including immunogenicity, it must undergo a similar developmental process to biologics. Regulated agencies scrutinize these products to demonstrate that any potential biological product differences are not clinically meaningful concerning quality, safety, and efficacy. Rituximab-abbs, one of the rituximab biosimilars, was approved in 2018, and many institutions are still facing many internal and external challenges implementation into the health system. The purpose of this study is to develop a biosimilar adoption process and provide clarity to any unknown potential barriers.

Methods: A retrospective, descriptive cohort quality improvement analysis was conducted to evaluate the rate of biosimilar adoption, infusion-related reactions, and financial impact. After gaining the P&T approval for rituximab to rituximab-abbs substitution in the inpatient setting, four months of data were collected from November 2020 to February 2020. Data points collected included patients receiving rituximab or rituximab-abbs at one of CoxHealth locations. Laboratory values, signs, and symptoms of rituximab adverse events during and post infusions were analyzed. Then a financial report was calculated per the institution revenue cycle team.

Results: 50 patient visits were reviewed, and 14 distinctive patients met the inclusion criteria, and one was excluded (clinical trial). After evaluating these patients, six stayed on rituximab-abbs after discharged, six were in the loss to follow-up cohort (4 deceased, 2 transferred to a different facility), and two did not switch due to payer restriction. The adoption rate for both new starts and patients established on rituximab originator to the biosimilar is 75% (6/8). Infusion-related adverse drug reactions (ADRs) occurred in 7% (1/14) of patients during infusion (rituximab: 1, rituximab-abbs: 0) and 21% (3/14) for post-infusion (rituximab: 2, rituximab-abbs: 1). The calculated savings for the health system is $61,600. In comparison, a lost opportunity is $13,600 due to using the originator instead of the biosimilar.

Conclusions: As seen in this study, switching to a biosimilar at a community hospital saved over $60,000 in four months for inpatient. This study's limitations are the retrospective design, the small sample size, single-center, exclusion of outpatient data due to the institution unable to obtain a pre-certification technician at this time, and the short time turnaround after implementing rituximab biosimilar at this institution. The institution will address barriers and perfect a process for future implementation of additional biosimilar products.