Estimation of Budget Impact With the Substitution of Biologic Reference Product for Biosimilars in Patients With Rheumatoid Arthritis From the Perspective of Medium Size Healthcare Insurance in Brazil

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INTRODUCTION

According to the information provided by Polaris Market Research, the global rheumatoid arthritis market was valued at USD 22.77 billion in 2021 and is anticipated to expand at a Compound Annual Growth Rate (CAGR) of 4.5% throughout the forecast period Figure 1. The principal factors contributing to the market's growth encompass the increasing incidence of rheumatoid arthritis, heightened demand for rheumatoid arthritis therapeutics, growing acceptance of traditional Disease-Modifying Antirheumatic Drugs (DMARDs), and governmental initiatives aimed at raising awareness regarding rheumatoid arthritis symptoms [1].

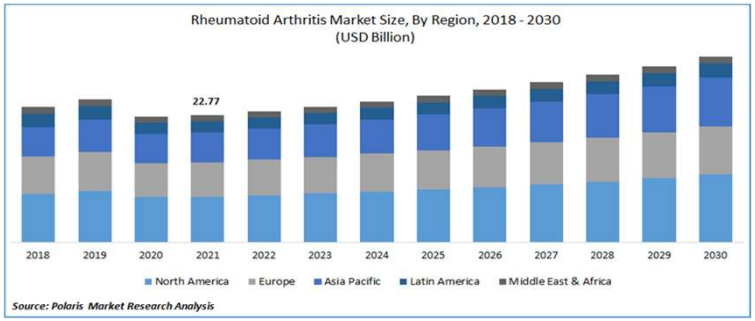

Figure 1: Forecast of the rheumatoid arthritis market according to the 2022-2030 industry analysis report. The image shows market share and trends by therapy, distribution channel, drug type, and region. Source: Rheumatoid Arthritis Market Insights."[9]

The World Health Organization (WHO) delineates a biosimilar as a "biotherapeutic product exhibiting likeness in terms of quality, safety, and efficacy to an already licensed reference biotherapeutic product" [2,3].

Regulatory agencies in various countries and regions have sanctioned multiple biosimilar agents, leading to a growing availability of these products. Replicas of biologic agents, including several tumor necrosis factor (TNF) inhibitors, rituximab, and other therapeutic molecules, have been marketed and are under development for use in treating rheumatic diseases [4].

Commercially available products designated as biosimilars (e.g., infliximab, etanercept, adalimumab, and rituximab) in the United States, Canada, and select other countries, are detailed in the drug information monograph provided within UpToDate for the original (originator) biologic agent [5-7]. Concerning equivalence with bio-originators, The American College of Rheumatology (ACR) has released a "white paper" advocating for the utilization of biosimilars among patients with rheumatic diseases [8].

OBJECTIVE

This study seeks to evaluate the financial impact arising from the substitution of Adalimumab, Infliximab, and Etanercept reference products with their biosimilar counterparts among patients diagnosed with rheumatoid arthritis (RA) within a Brazilian private health insurer catering to 100,000 beneficiaries.

METHODS

The impact analysis draws upon medication values outlined by the Chamber of Market Regulation of Medicines (CMED), a regulatory benchmark for drug pricing in Brazil. The RA patient population is estimated based on a national study, indicating an approximate 0.5% prevalence, of which 25% may experience a moderate or severe condition justifying the use of this medication class. The analysis exclusively focuses on medication costs for patients in the maintenance phase, projecting three scenarios for each medication across the entire eligible population over a one-year.

RESULTS

Prevalence data reveals the portfolio comprises around 500 RA beneficiaries, with 125 having an indication for biologic therapy. An individualized analysis for each agent, considering recommended dosages, estimates the impact of substitution for therapy-indicated patients: Adalimumab (3,000 doses/year) – reference cost $5,287,755.10 versus biosimilar cost $1,436,493.47, resulting in a saving of $3,851,261.63; Infliximab (patients ≅70kg – 1,500 doses/year) – reference cost $1,322,888.78 versus biosimilar cost $499,591.84, resulting in a saving of $823,296.94; and Etanercept (6,500 doses/year) – reference cost $10,458,144.49 versus biosimilar cost $3,400,664.29, resulting in a saving of $7,057,480.20 – Figure 2. Implementing the switch among 125 beneficiaries diagnosed with moderate or severe RA yields significant savings of approximately 72%, 62%, and 67%, respectively.

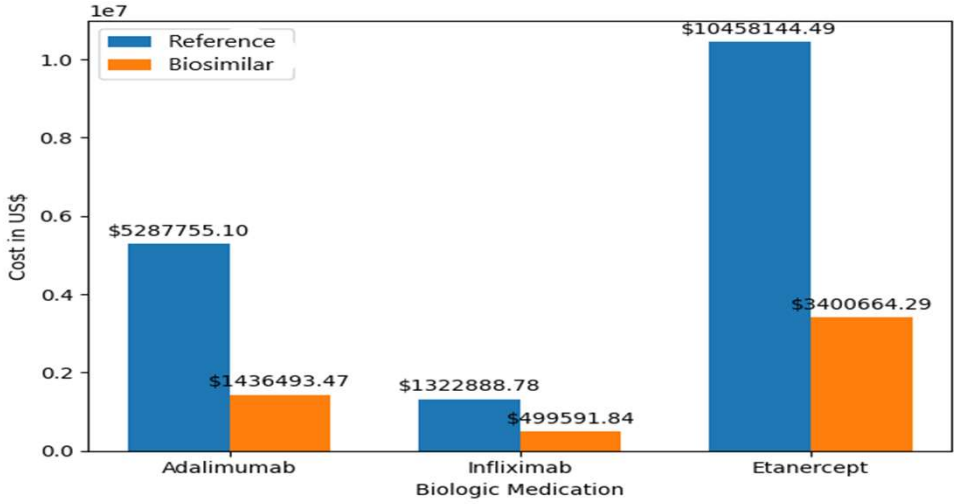

Figure 2: Cost reference vs. Biossimilars

CONCLUSION

Prescribing biosimilar agents in Brazil's private healthcare sector remains challenging. Economic studies play a crucial role in raising awareness within the medical community amid a progressively resource-scarce landscape. The imperative for resource optimization is evident in RA management, where studies affirm no efficacy differences between agents, enabling prescribers to choose agents with an optimal cost-effectiveness ratio.

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