CHAPMAN UNIVERSITY
SCHOOL OF PHARMACY

EE287

Annual Treatment Cost of Biologic Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis

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Background

Rheumatoid arthritis (RA) treatment has been revolutionized by the development of biologic disease-modifying antirheumatic drugs (bDMARDs), which are increasingly used. The high cost of bDMARDs is the major cost driver in RA management that affects RA treatment.

Objectives

- To assess the annual cost of bDMARDs used in rheumatoid arthritis treatment
- To evaluate the factors explaining their annual cost at market entry
- To examine the impact of biosimilar authorization on the annual cost of bDMARDs

Methods

The annual bDMARDs cost was calculated using wholesale acquisition cost prices (IBM Micromedex) at market entry and the FDA-recommended doses. Costs were adjusted to 2023 US dollars using the consumer price index. Descriptive statistics and regression analysis were performed. We standardized costs to the year level to assess trends in annual treatment costs across pharmacological classes and bDMARDs with and without FDA biosimilar authorization.

Results

Ten biologic DMARDs (bDMARDs) were available for RA treatment and were approved by the FDA as of December 2023 in US. Five bDMARDs are classified in TNFi classification, and five in non-TNFi classification (Table1). Among these bDMARDs recommended for RA treatment, the FDA has approved a total of 19 biosimilars for five of them as of December 2023. All nine biosimilars for adalimumab were marketed in 2023, and biosimilars for etanercept and tocilizumab had not yet entered the market in the US.

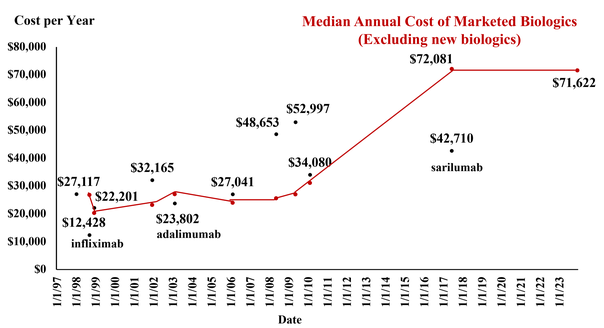
Table 1. Biologic DMARDs indicated for Rheumatoid Arthritis Approved by the FDA

Classification	Approval Date	Number of Biosimilar	Orphan Status	Priority Review	Warning Box	Usage in RA Treatment	RA Activity	Indications rheumatic disorders
TNFi								
infliximab	8/24/1998	4	1	1	1	Combination	Moderate to Severe	RA, AS, PsA
etanercept	11/2/1998	2	0	1	1	Monotherapy/ combination	Moderate to Severe	RA, JIA, PsA, AS
adalimumab	12/31/2002	9	1	0	1	Monotherapy/ combination	Moderate to Severe	RA, JIA,PsA, AS
certolizumab pegol	4/22/2008	0	0	0	1	Monotherapy/ combination	Moderate to Severe	RA , PsA, AS,axSpA
golimumab	4/24/2009	0	0	0	1	Combination	Moderate to Severe	RA, PsA, AS
Non- TNFi								
rituximab	11/26/1997	3	1	1	1	Combination	Moderate to Severe	RA
anakinra	11/14/2001	0	1	0	0	Monotherapy/ combination	Moderate to Severe	RA
abatacept	12/23/2005	0	0	1	0	Monotherapy/ combination	Moderate to Severe	RA, JIA,PsA, AS
tocilizumab	1/8/2010	1	0	0	1	Monotherapy/ combination	Moderate to Severe	RA, JIA
sarilumab	5/22/2017	0	0	0	1	Monotherapy/ combination	Moderate to Severe	RA, PMR

Rheumatoid Arthritis (RA), Ankylosing Spondylitis (AS), Psoriatic Arthritis (PsA), Juvenile Idiopathic Arthritis (JIA), Axial Spondylarthritis (axSpA), Polymyalgia Rheumatica (PMR)

The inflation-adjusted median biologic annual treatment cost at market entry was $29,677 (IQR=$15,873) for all bDMARDs, among these, the lowest was infliximab ($12,394) and the highest was golimumab ($52,854).

Figure 1. Annual Cost at Market Entry of New Biologic DMARDs, 1997-2023



The annual treatment cost at market entry for all new bDMARDs was higher than the median of inflation-adjusted annual treatment cost of previous bDMARDs except infliximab, adalimumab, and sarilumab (Figure1)..

Results

All TNFi bDMARDs had higher inflation-adjusted annual treatment costs at market entry than the inflation-adjusted median of previous bDMARDs' TNFi classification.

The evaluation of trends after standardizing to the cost per year of bDMARDs at the initial market entry of all bDMARDs in each group showed a significant increase in bDMARDs with TNFi classification compared to those in non-TNFi classification, which had a small increase as of December 2023 (Figures 2 and 3).

Figure 2. Trend in Annual Cost of Biologic DMARDs TNFi classification, 2010-2023

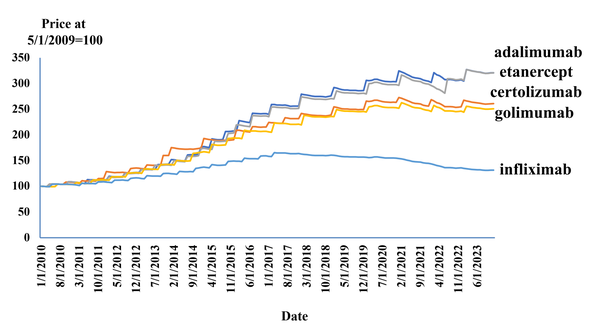
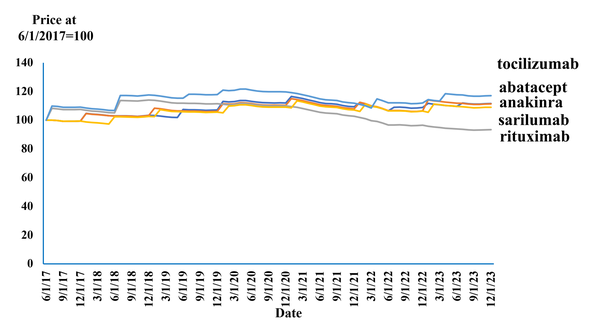


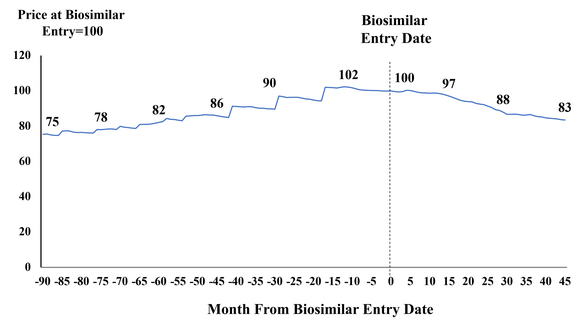
Figure 3. Trend in Annual Cost of Biologic DMARDs non-TNFi classification, 2017-2023



This evaluation among bDMARDs with biosimilars showed an increase, which is notable for adalimumab and etanercept compared to those without biosimilars.

The trend in the annual cost of bDMARDs with biosimilars both before and after the introduction of the first biosimilar by utilizing costs standardized to the cost per year of the biologic at the initial biosimilar entry revealed a considerable decrease after the biosimilar entry date for infliximab, rituximab, and adalimumab (Figures 4). However, there was no decrease in the trend of the annual cost of etanercept and tocilizumab, bDMARDs with biosimilars approved but not marketed in the US.

Figure 4. Trends in Annual Cost of rituximab Brand Before and After Biosimilar Entry



The regression analysis results indicated that the inflation-adjusted bDMARDs annual cost at market entry was associated significantly positively with FDA approval dates (p=0.002), TNFi classification (p=0.039), and negatively with the indication in other rheumatic disorders besides RA (p=0.031).

Conclusions

The annual cost of bDMARDs at market entry was associated with the approval date and pharmacological class. Moreover, the evaluation of trends revealed a significant increase in the annual treatment costs of TNFi bDMARDs. The FDA authorization of biosimilars significantly reduced the annual cost of bDMARDs used in RA treatment.