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*Original Research Article*

# Biological Treatments in Rheumatology After the Introduction of an Etanercept Biosimilar

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***Abstract***: The landscape of rheumatology has been fundamentally transformed by biological disease-modifying antirheumatic drugs (bDMARDs). The arrival of etanercept biosimilars marked a new era for cost-effective, widely accessible biological treatment in rheumatic diseases. This research article reviews the impact of etanercept biosimilars, the current status of biological treatments, their clinical effectiveness, safety, and the resulting shifts in rheumatology practice patterns. Graphs and data from large-scale trials and registries are included to illustrate outcome trends and cost benefits.

***Keywords***: Etanercept Biosimilars, Biological Disease-Modifying Antirheumatic Drugs (bDMARDs), Rheumatic Diseases, Clinical Effectiveness, Cost-Effectiveness.

## INTRODUCTION

Rheumatic diseases, including rheumatoid arthritis (RA), psoriatic arthritis, and ankylosing spondylitis, are chronic, immune-mediated conditions. The advent of bDMARDs, particularly TNF inhibitors like etanercept, dramatically improved disease control and patient quality of life. However, the high costs limited accessibility until the approval of biosimilars such as SB4 (Benepali™) and GP2015, which offered comparable efficacy at lower prices, enabling broader adoption and reshaping treatment guidelines[1][2][4].

## THE IMPACT OF ETANERCEPT BIOSIMILARS

### Approval and Indications

Etanercept biosimilars have been authorized for all reference product indications, including RA, psoriatic arthritis, axial spondyloarthritis, and juvenile idiopathic arthritis. Since the first approvals in 2015–2016, their global uptake has been robust.

### Cost Reduction and Access

- Introduction of biosimilars resulted in a marked decrease in the average cost per patient treated with biologics, fostering greater access and the ability to treat more patients under constrained healthcare budgets[4].
- Real-world data from European and UK registries demonstrate up to 30% cost savings for health systems[2][4].

### Widened Access to bDMARDs

- Increased affordability led to expanded use among biologic-naïve patients, earlier intervention in the disease course, and improved equity in access to advanced therapies[2][4].

## EFFICACY AND SAFETY: BIOSIMILAR VS. ORIGINATOR ETANERCEPT

### Clinical Outcomes

- Comparative clinical trial and real-world registry data, encompassing over 13,000 patients, confirm that etanercept biosimilars and their originators yield nearly identical outcomes for efficacy and safety[1][2][5].
- Response rates (ACR20/50/70), remission rates at 6 and 12 months, and functional measures (HAQ, DAS28) are on par between biosimilars and the reference drug[2][3][10][6].

**Table 1. Efficacy Outcomes in Biologic-Naïve RA Patients (6–12 Months)[2][3]**

| Treatment Arm | DAS28 Remission (12m) | EULAR Response (12m) | 1-year Drug Survival |
|---|---|---|---|
| Etanercept Originator | 48% | 73% | 71% |
| Etanercept Biosimilar | 51% | 75% | 76% |

### Immunogenicity and Safety

- No meaningful differences in rates of anti-drug antibody development or treatment-emergent adverse events have been observed[1][3].
- Real-world switching data reveal that transitioning from originator to biosimilar is safe and well tolerated, without loss of efficacy[1][5].

### Continued Real-World Effectiveness and Persistence

- Retention (persistence) rates at 1 year for biosimilars are comparable to or slightly higher than originator—reaching 72–76%[4][11].
- Biosimilar SB4 and GP2015 show equivalent drug survival and low discontinuation rates for inefficacy or adverse events.

**Graph 1: Drug Survival of Etanercept Biosimilar vs. Originator (RA Cohorts, 1-year)** [image:1]
*The graph displays near-identical survival curves (drug retention) for both biosimilar and originator arms.*

### The Broader Biological Arsenal After Biosimilars

### Expanding the Treatment Landscape

- Biological treatments now include several TNF inhibitors (infliximab, adalimumab, golimumab, certolizumab), IL-6 inhibitors (tocilizumab, sarilumab), IL-1 inhibitors (anakinra), B-cell targeting (rituximab), co-stimulation modulators (abatacept), and biologic biosimilars, as well as small molecule JAK inhibitors[9][8][12].
- Head-to-head trials report only minor differences in efficacy and safety among the established bDMARDs, but cost and patient-specific considerations (comorbidities, administration route, previous failures) guide selection[13][9].

### Emerging Biologics

- Recent and upcoming agents feature novel mechanisms, including inhibitors of IL-12, IL-23, and Th17 pathways; B-cell depletion with novel antibodies; and oral targeted synthetic DMARDs (tsDMARDs) like JAK inhibitors[7][8][9].
- Personalized therapy, combination regimens, and early biologic introduction are altering practice in favor of remission as the treatment goal[7][9].

**Table 2. Examples of Current and Emerging Biological Therapies in Rheumatology**

| Type of Agent | Examples | Mechanism |
|---|---|---|
| TNF inhibitors | Etanercept, Adalimumab, Infliximab | Block TNF-α interaction |
| IL-6 inhibitors | Tocilizumab, Sarilumab | IL-6 receptor blockade |
| IL-1 inhibitors | Anakinra | IL-1 receptor blockade |

 

| | | |
|---|---|---|
| B-cell depleters | Rituximab | Anti-CD20 |
| T-cell modulators | Abatacept | CTLA4-Ig co-stimulation |
| JAK inhibitors | Tofacitinib, Baricitinib, Upadacitinib | JAK pathway blockade |

**Patient-Centered and Economic Implications**

- Cost savings from biosimilars mean more patients can start or switch to advanced therapies, reducing delay and progression of joint damage[2][4].
- Evidence supports similar patient satisfaction and preference for biosimilar delivery devices (such as SB4 autoinjector), further improving adherence and outcomes[14].

## CONCLUSION

The introduction of etanercept biosimilars has made biological therapy more accessible and affordable in rheumatology, without compromising efficacy or safety. Expanded use, earlier intervention, and ongoing innovation now characterize the biological treatment era. The current therapeutic arsenal includes a broad array of biologics and new small molecules, and further advancements are expected to personalize and optimize care for those with inflammatory rheumatic diseases.
[image:1]

Graph depicting comparable drug retention rates over 1 year (originator vs. biosimilar) in rheumatoid arthritis patients.

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