VANDERBILT HEALTH | Specialty Pharmacy

Clinical Outcomes and Medication Switches Following Adalimumab Biosimilar Initiation in Pediatric Patients

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Background

Despite the established use of adalimumab biosimilars in adult populations, there remains a critical gap in the literature regarding their safety, efficacy, and long-term outcomes in pediatric patients

Purpose

Evaluate clinical outcomes and patterns of medication switches among pediatric patients transitioned from adalimumab originator to biosimilar

Methods

Study Design and Setting

Single center, retrospective cohort study at Vanderbilt Health

Primary Outcome

Number of patients who experience an adverse event on adalimumab biosimilar

Patient Population

Inclusion criteria: Patients prescribed an adalimumab biosimilar from January 2024 – June 2025 from a Vanderbilt Health System pediatric provider in the Rheumatology or IBD pediatric clinic

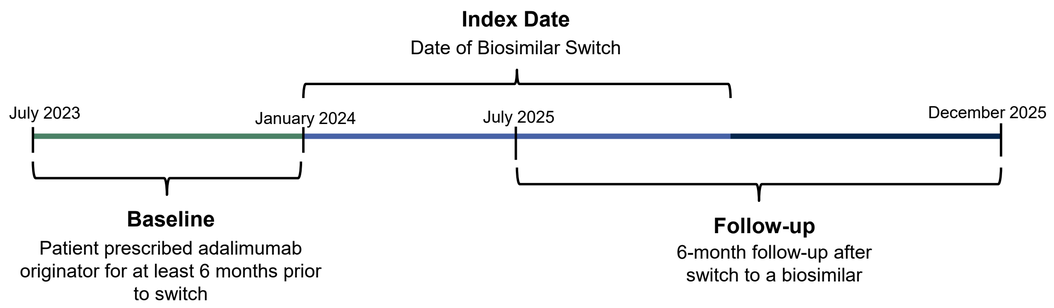
Patients prescribed an adalimumab biosimilar should have been on the Humira originator product for at least 6 months prior.

Exclusion criteria: Biosimilar prescribed by a non-VUMC provider; Patients lost to follow up – defined as no clinical evaluation within 6 months of switching

Secondary Outcomes

- Side effects at follow-up
- Biosimilar switched to
- Patients required to change pharmacies for biosimilar
- Patients who switch back to the originator product, another adalimumab biosimilar, or non-adalimumab product
- Reasons for medication switches post-biosimilar initiation

Study Timeline



CONCLUSION

- Biosimilar transitions in pediatric patients were generally well tolerated
- After biosimilar initiation, 26% of patients switched to another biosimilar, non-adalimumab product, or Humira originator

Results

Table 1. Patient Characteristics

Characteristic	N=144 n(%)
Age at first biosimilar fill, Median [IQR]*	16 years [13-18]
Sex, Female	83 (58%)
Race, White	131 (91%)
Medical Insurance, Commercial	138 (96%)
Clinic Adalimumab Biosimilar was Prescribed	
Pediatric IBD	50 (35%)
Pediatric Rheumatology	94 (65%)
Diagnosis	
Juvenile idiopathic arthritis	76 (53%)
Crohn's disease	42 (29%)
Ulcerative colitis	11 (8%)
Off-label use	7 (5%)
Uveitis	5 (3%)
Rheumatoid arthritis	2 (1%)
Ankylosing spondylitis	1 (<1%)
Required to Change Pharmacy for Biosimilar, Yes	13 (9%)

*Interquartile Range (IQR)

Figure 1. Medication Switches Post-Biosimilar Initiation

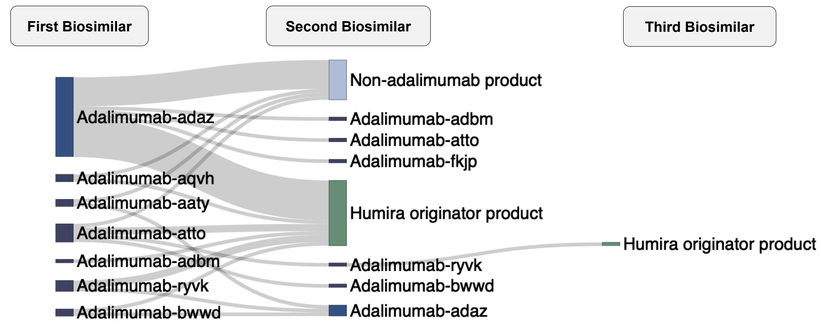
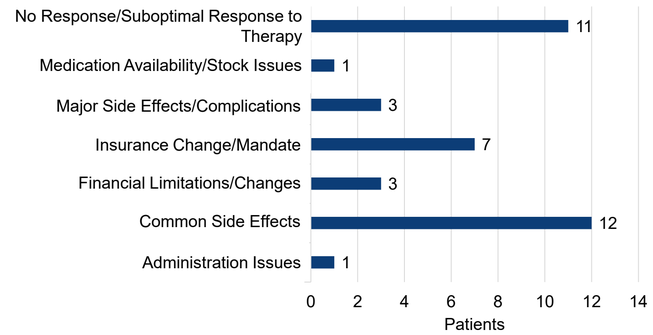


Figure 2. Reasons for Biosimilar Switches Post-Biosimilar Initiation



Median time from biosimilar initiation to another medication switch: **5.5 months [IQR 2.6-8.9]**

Table 2. Adverse Events (AE) Reported 6-months Post-Biosimilar Initiation

13% reported an AE

Median time from biosimilar switch to AE: **3.7 months [IQR 1.4-5.5]**

10% experienced a **flare or worsening of symptoms**

AE Experienced	Overall n=23 n (%)	IBD Clinic n=10	Rheumatology Clinic n=13
Injection site pain/reaction	7 (30%)	2 (20%)	5 (39%)
Nausea	4 (17%)	2 (20%)	2 (15%)
Headache	3 (13%)	2 (20%)	1 (8%)
Dermatologic reaction/rash	3 (13%)	1 (10%)	2 (15%)
Infection	2 (9%)	1 (10%)	1 (8%)
Other	2 (9%)	1 (10%)	1 (8%)
Vomiting	1 (0.4%)	0 (0%)	1 (8%)
Fatigue	1 (0.4%)	1 (10%)	0 (0%)

* AEs are not mutually exclusive