Real-World Clinical Outcomes of an Adalimumab Biosimilar Transition Program

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BACKGROUND[1-5]

- Adalimumab biosimilars offer a significant cost-saving opportunity for the US healthcare system and are the first major biosimilar adoption facing pharmacy benefit managers.
- Early biosimilar adoption is a crucial avenue for healthcare savings, promoting a more diverse drug mix, and further incentivizing additional manufacturers to enter the market.
- Uptake of adalimumab biosimilars has remained low nationwide (23%) despite plan and patient financial incentives.
- The real-world patient effects of a mandated biosimilar formulary transition, besides monetary savings, are poorly understood.

OBJECTIVES

- Evaluate the effect of a mandated formulary change to adalimumab biosimilars three months after implementation.
  - Compare adalimumab biosimilar utilization before and after the transition.
  - Analyze attrition patterns and alternative specialty treatment use.
  - Assess plan savings, gap in therapy, change in out-of-pocket expenses, adverse events, satisfaction score change, pharmacist interventions, and copay assistance enrollment.

METHODS

DESIGN

- This was a retrospective cohort study where pharmacy claims were compared between three commercial plans utilizing an in-network or select out-of-network specialty pharmacy.
- Patient impact data was extracted from the affiliated in-network specialty pharmacy database when outcomes were available.
- Included patients were established on reference adalimumab for at least six consecutive months prior to the mandated biosimilar transition on June 1, 2024.
- Patients were excluded if they had a gap in therapy greater than three months, change in plan eligibility during study period, used a third specialty pharmacy, or had biosimilar claims only.

ENDPOINTS

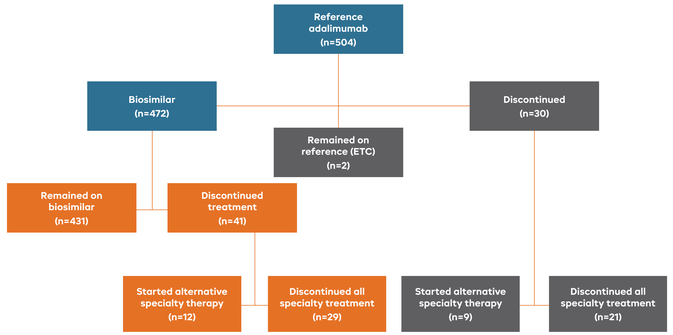
- Primary: Proportion of biosimilar utilization three months after the intervention.
- Secondary: Attrition analysis, alternative specialty treatment utilization, plan savings, gap in therapy, out-of-pocket expenses, adverse events, satisfaction score change, pharmacist interventions, and copay assistance (CPA) enrollment.

STATISTICAL ANALYSIS

- Differences in outcomes including occurrence of attrition, adverse events, and CPA enrollment were determined using Pearson's chi-squared test.
- Outcomes such as gap in therapy, satisfaction score change, pharmacist interventions, and out-of-pocket expenses were tested for statistical significance between specialty pharmacies or plans using repeated measures ANOVA.
- Following a statistically significant ANOVA result targeting an alpha value of 0.05, all relevant pairwise comparisons were completed using Tukey's HSD.

RESULTS

FIGURE 1: FLOWCHART TRANSITION SUMMARY OF ELIGIBLE INCLUDED PATIENTS INITIALLY ON REFERENCE ADALIMUMAB



ETC = Exception to coverage

FIGURE 2: PERCENTAGE OF PATIENTS SWITCHED TO AN ADALIMUMAB BIOSIMILAR THREE MONTHS AFTER THE INTERVENTION

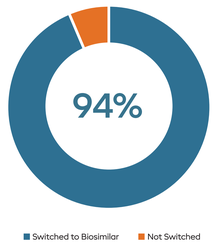


TABLE 1: DOCUMENTED REASON FOR TREATMENT DISCONTINUATION BY COMMERCIAL PLAN

Reason for Discontinuation	Plan A	Plan B	Plan C	Total
Changed Therapy	9	7	6	22
Cost or Holding Therapy	6	9	NA	15
Patient/Provider Preference	1	6	NA	7
Side Effects	1	0	NA	1
No Documentation	0	5	21	26

FIGURE 3: PERCENT UTILIZATION OF ALTERNATIVE SPECIALTY TREATMENT OPTIONS BASED ON CLASSIFICATION OF MECHANISM OR MEDICATION

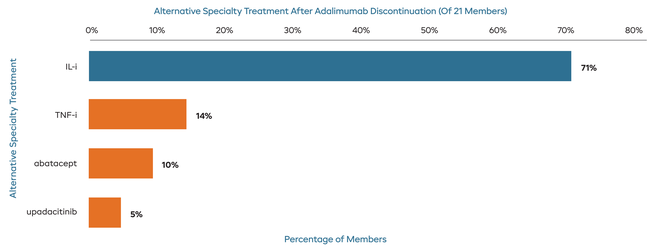
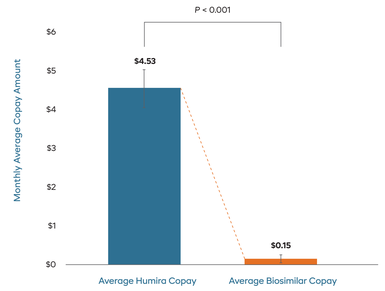


FIGURE 4: CHANGE IN AVERAGE PATIENT OUT-OF-POCKET COST AFTER COPAY ASSISTANCE BEFORE AND AFTER THE TRANSITION TO A BIOSIMILAR



$14,189
saved in annual out-of-pocket costs for 269 members

$20.79
saved in PMPM plan spending before rebates

FIGURE 5: DISTRIBUTION OF GAP IN THERAPY BASED ON DAY SUPPLY AND DIFFERENCE BETWEEN DATE OF PROCESSED CLAIMS

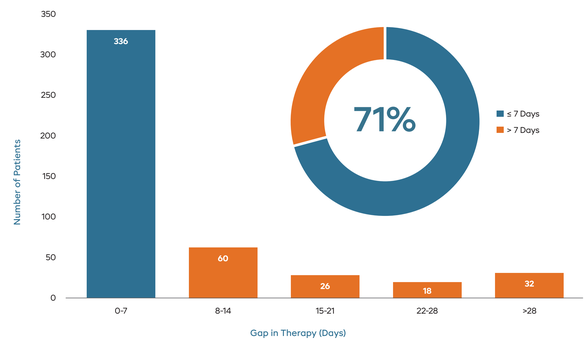
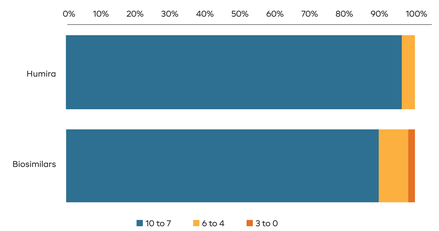


FIGURE 6: PERCENT DISTRIBUTION OF SATISFACTION SCORES FOR THE SAME GROUP OF PATIENTS ESTABLISHED ON REFERENCE ADALIMUMAB BEFORE AND AFTER THE TRANSITION TO A BIOSIMILAR



91%
of members satisfied with biosimilars

LIMITATIONS

- Limited study period after the formulary transition may not reflect long-term outlook.
- Claim dates may not accurately reflect when the patient is administering the medication so they may misestimate the true gap in therapy.
- Small sample size limits generalizability in several patient impact outcomes and a larger study should be performed to fully characterize adalimumab biosimilar use.
- Patient impact data was only available for clients utilizing the in-network specialty pharmacy so comparison to an outside specialty pharmacy was not fully possible.

CONCLUSIONS

This research suggests that biosimilar formulary preference is effective in promoting high utilization of lower net cost alternatives. It was also associated with minimal biosimilar attrition (8.7%) and low alternative specialty treatment use (4.2%) after three months. Additionally, the average patient gap in therapy during the transition was under seven days. Adalimumab biosimilars generated patient copay and plan savings as well as fewer reported injection site reactions compared to reference adalimumab.

DISCLOSURE

This research was conducted by Navitus Health Solutions, Madison, WI without external funding.

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