THERAPEUTIC DRUG MONITORING (TDM) OF INFLIXIMAB IS ASSOCIATED WITH LOWER BIOLOGIC SWITCH & EXPENDITURES COMPARED TO NO-TDM COHORT OF IBD PATIENTS BASED ON 12- TO 48-MONTH REAL WORLD OUTCOMES FROM A US COMMUNITY GI PRACTICE

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Objective

To assess the practical implications and costs associated with biologic switching, by comparing IFX dose-optimized patients who utilized Anser® TDM with those who did not, within a large community-based gastroenterology specialty group.

Background

Infliximab (IFX), an anti-TNF biologic, is pivotal in treating inflammatory bowel disease (IBD).

Optimal Start: The initial biologic therapy is crucial to minimize future adverse patient outcomes and therapy failures.

Challenges: Up to 40% may face primary non response (PNR), and 50% could encounter secondary lose of response (SLR) within the first year, often due to suboptimal dosing that does not achieve sufficient therapeutic levels.

Strategic Monitoring: TDM is key in enhancing treatment outcomes and health care cost saving.

Antibody Detection: Identifying antibodies against anti-TNFs is vital for managing PNR and preventing SLR, potentially averting the need to switch biologics.

Methods

Data Source: De-identified patient charts (ages 8-89 treated with Infliximab (IFX) from 2016 to 2022) from a US community-based gastroenterology specialty group were analyzed.

Study design: Records were matched to test results from Prometheus Laboratories and tokenized. Two cohorts: TDM and non-TDM, were matched based on propensity score, baseline disease, demographics, and comorbidities.

Analysis: Biologic switch (discontinuation of IFX and start of a different biologic/advanced therapy) and corresponding mean biologic expenditures (aggregate reference wholesale acquisition cost per EMR data for specific duration) were analyzed. Data was accessible via Lynx.MD.

Patient Stratification: Analysis was conducted for **all patients** and those **naïve to anti-TNFs (TNF-N)** across different time periods.

Statistical Methods: Chi-squared tests for biologic switch analysis and two-sample t-tests for expenditure analysis.

Table 1. Demographics IFX-Treated IBD Patients (All Patients)

	Cohorts	Male	Crohn's disease	Median Age (min-max)	Observation Period	Cohort size (n)
12-months	Anser TDM	51%	64%	39 (7-87)	1.25k	337
	No TDM	50%	66%	37 (9-83)	1.43k	321
24-months	Anser TDM	50%	64%	36 (7-87)	1.45k	267
	No TDM	46%	68%	39 (12-83)	1.62k	265
36-months	Anser TDM	45%	64%	37 (7-87)	1.64k	200
	No TDM	44%	66%	41 (12-83)	1.79k	204
48-months	Anser TDM	46%	64%	38 (9-87)	1.82k	137
	No TDM	43%	67%	42 (12-83)	1.91k	157

Table 2. Demographics IFX-Treated IBD Patients (Anti-TNF Naïve Patients)

	Cohorts	Male	Crohn's disease	Median Age (min-max)	Observation Period	Cohort size (n)
12-months	Anser TDM	55%	65%	35 (7-87)	1.26k	296
	No TDM	51%	65%	36 (9-83)	1.31k	281
24-months	Anser TDM	54%	65%	35 (7-87)	1.47k	235
	No TDM	47%	67%	38 (12-83)	1.57k	233
36-months	Anser TDM	49%	64%	35 (7-87)	1.65k	178
	No TDM	45%	65%	39 (12-83)	1.74k	176
48-months	Anser TDM	50%	63%	35 (7-87)	1.84k	123
	No TDM	44%	66%	39 (12-83)	1.91k	131

Table 3. Biologic Switch Rates & Biologic Expenditures (All Patients)

		Anser TDM	No TDM	Total Savings	p-value
12-months	Biologic Switch	**58 (17.2%)**	**81 (25.2%)**	**8%**	**0.015**
	Mean Biologic Expenditures	$32,565	$35,238	$2,673.19	0.082
24-months	Biologic Switch	**64 (24%)**	**94 (35.5%)**	**12%**	**0.005**
	Mean Biologic Expenditures	$70,777	$76,478	$5,701.48	0.16
36-months	Biologic Switch	**60 (30%)**	**98 (48%)**	**18%**	**<0.001**
	Biologic Expenditures	**$110,642**	**$128,380**	**$17,738.12**	**0.025**
48-months	Biologic Switch	**48 (35%)**	**85 (54.1%)**	**19%**	**0.002**
	Mean Biologic Expenditures	**$149,943**	**$188,583**	**$38,640.26**	**0.003**

P-values that were found statistically significant are bolded

Table 4. Biologic Switch Rates & Biologic Expenditures (Anti-TNF Naïve Patients)

		Anser TDM	No TDM	Total Savings	p-value
12-months	Biologic Switch	**42 (14.2%)**	**57 (20.3%)**	**6%**	**0.067**
	Mean Biologic Expenditures	$31,424	$33,112	$1,689	0.226
24-months	Biologic Switch	**48 (20.4%)**	**72 (30.9%)**	**11%**	**0.013**
	Mean Biologic Expenditures	$67,038	$70,307	$3,269	0.36
36-months	Biologic Switch	**43 (24.2%)**	**73 (41.5%)**	**17%**	**0.001**
	Mean Biologic Expenditures	**$100,491**	**$113,836**	**$13,346**	**0.044**
48-months	Biologic Switch	**37 (30.1%)**	**61 (46.6%)**	**17%**	**0.01**
	Mean Biologic Expenditures	**$139,365**	**$161,906**	**$22,541**	**0.042**

P-values that were found statistically significant are bolded

Results

All patients: Rates of biologic switching was significantly lower for those that had TDM testing incorporated into their treatment plan compared to those without TDM testing at all time periods. There was an 8%, 12%, 18%, and 19% difference at 12-, 24-, 36- and 48-months, respectively. (Table 3)

TNF-N patients: Rates of biologic switching was significantly lower for TDM for all durations except at 12-months with a difference of 11%, 17%, and 17% at 24-, 26-, and 48-months, respectively. (Table 4)

The monetary costs were lower due to the reduced switch rates for TDM at all time points in all patients and TNF-N patients, with the difference being significant at 36- and 48-months.

Conclusions

Results indicate that **Anser® TDM significantly reduced the rate of biologic switching in pediatric and adult IBD patients**, suggesting it may be an effective strategy for optimizing treatment with biologics.

The impact of Anser® TDM on outcomes became more evident over time, with switch rates decreasing and expenditures savings increasing from 12-months to 48-months as compared to the no-TDM group. This implies that the TDM outcome benefit may be sustained and possibly increase overtime.

The health economic benefits of incorporating TDM to reduce risks of biologic switching indicates potential cost savings over time. With a **mean biologic expenditure savings of $22,541 and $38,640 per patient, respectively at 48-months for anti-TNF naïve and all biologic patients.**