Budget Impact and Clinical Outcomes of a Molecular Signature to Inform TNFi Treatment Selection in Commercial Patients with Rheumatoid Arthritis

Martin Bergman, MD[1]; Erin Connolly-Strong, PhD[2]; Alyssa Guidoboni, MScM; Alix Arnaud, MsC[2] 1. Drexel University College of Medicine, Philadelphia, PA, USA. 2. Scipher Medicine, Waltham, MA.

AMCP 2022 Chicago, Il Mar 29-Apr 1, 2022

INTRODUCTION

- Rheumatoid arthritis (RA) is a systemic autoimmune disease characterized by chronic inflammation.[1]
- With no established preference for one class of drug over the other after failure of conventional csDMARDs, current treatment strategy for RA consists of a trial-and-error approach.[2]
- Cycling between ineffective drug treatments can lead to delays in reaching treat-to-target goals in turn risking disease progression.[2-3]
- Rapid achievement of treat-to-target goals is significantly associated with lower healthcare costs[4], slowed disease progression[2], lower mortality rate[5], improved work function[6], decreased disability[6], decreased pain[2] and improved quality of life.[2]

PrismRA is a clinically validated and commercially available blood-based molecular signature response classifier (MSRC) that predicts non-response to TNFi therapies.[7-9]

OBJECTIVE

This analysis evaluated the budget and clinical impact of integrating MSRC testing in the treatment decision making for adults with RA who are considering starting, switching, or dose escalating with a TNFi.

CONCLUSION

- The integration of the MSRC precision medicine tool in the treatment of RA benefits patients and results in meaningful net savings between $11,871 and $21,188 per patient tested.
- MSRC-informed treatment improves population level response rates, decreases pharmacy spend by shifting patients away from likely ineffective and expensive therapy classes, decreases total cost of care, and decreases workplace costs for patients with RA.

METHODS

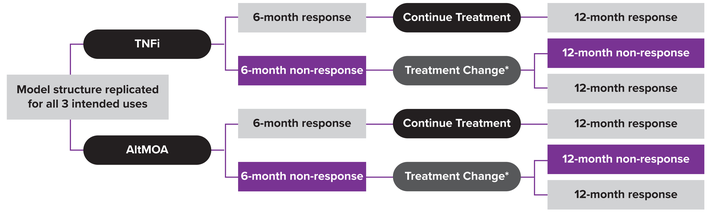
- The model uses a decision tree structure over a one-year time horizon with a (A) 6-month cycle length and (B) a 12-month cycle length.
- The model evaluates outcomes for a hypothetical US health plan with 1 million (M) commercial covered lives.
- Two treatment strategies are compared: treatment with TNFi therapies as usual (without MSRC testing) vs. treatment selection informed by MSRC testing.

MODEL KEY INPUTS

VARIABLE	INPUT VALUES	REFERENCE
Testable patients per 1M (commercial lives)*	879	Calculated
% of patients with test result signal detected	50%	9
Adherence to test results with signal detected	90%	8
6-month response rates by MSRC test result and line of therapy		
Unstratified response rate at 6 months on 1st line TNFi	27%	7
Unstratified response rate after TNFi dose escalation	13%	10
OR efficacy of AltMOAs vs. TNFis (unstratified)	1.0	11
Treatment efficacy decrease in 2nd line TNFi after failure of first line	0.84	12
2021 USD COSTS		
TNFi annual WAC cost 1st line/2nd line	$72,949 / $71,006	13-14
TNFi dose escalated annual WAC cost	$150,374	13-14
AltMOA annual WAC cost 1st line (exclude JAK)/2nd line (include JAK)	$45,667 / $48,193	13-14
Annual medical costs – response/non-response	$11,215 / $18,577	13-14
Annual workplace savings of response (vs. non-response)	$11,820	6,15

* Epidemiology estimates are not generalizable to the entire US population as medicare, medicaid, and un-insured populations have different underlying prevalence, incidence and treatment patterns

FIGURE 1: MODEL STRUCTURE



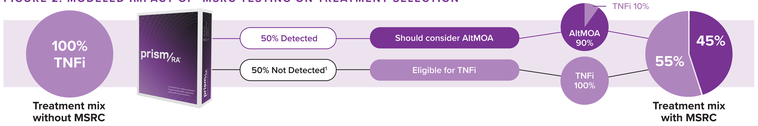
*In Scenario B 100% of patients continued on the same treatment for the full 12 months. Treatment patterns analyses show that patients who don't respond adequately to TNFi treatment stay on treatment for a median of 279 days (IQR: 200-370) Curtis.

RESULTS

1 Treatment patterns impact

- A combined 879 members per 1 million covered commercial lives are eligible for MSRC testing either as targeted treatment naïve or TNFi exposed.
- Approximately half are expected to receive a signal of non-response.
- 395 patients (45% of those tested) would change treatment selection from TNFi therapies to an AltMOAs after having received a test result of 'signal of non-response detected'.
- The number needed to test (NNT) to avoid likely ineffective therapy is 3.

FIGURE 2. MODELED IMPACT OF MSRC TESTING ON TREATMENT SELECTION



2 Modeled clinical benefits

The shift in treatment selection is estimated to result in an 37% (from 22% to 30%) increase in ACR50 response rate at 6 months (all 3 intended uses combined).

		WITHOUT MSRC		WITH MSRC	
		N PATIENTS	% OF TOTAL	N PATIENTS	% OF TOTAL
Considering 1st TNFi start	Responders at 6 months	109 / 389	28%	138 / 389	36%
	Responders at 12 months[1]	185 / 389	47%	206 / 389	53%
	Avg time to response for responders (months)[1]	8.46		7.97	
Considering dose escalation	Responders at 6 months	30 / 232	13%	50 / 232	22%
	Responders at 12 months[1]	85 / 232	36%	99 / 232	43%
	Avg time to response for responders (months)[1]	9.86		8.97	
Considering switch	Responders at 6 months	53 / 258	21%	75 / 258	29%
	Responders at 12 months[1]	108 / 258	42%	124 / 258	48%
	Avg time to response for responders (months)[1]	9.07		8.38	

[1] Outcomes at 6 months are the same in scenario A and B, outcomes are 12 months and time to response are only for scenario A.

3 Net savings across pharmacy, medical, and employer costs

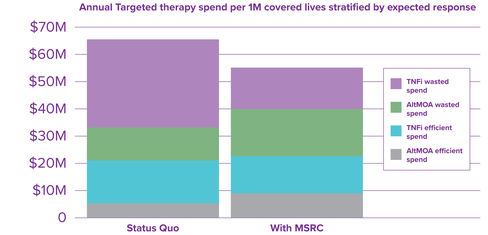
Annual savings were estimated at between $10.0M and $18.0M in biologic pharmacy spend, between $452,914 and $523,600 in medical spend from reduced other medical costs and between $703,529 and $813,328 in reduced workplace costs if employed for Scenarios A and B respectively. This translates to between $0.87 and $1.55 in net direct cost savings per member per month not including cost of testing.

	SCENARIO A non-responders change treatment after 6 months				SCENARIO B patients stay on treatment full year			
	WITHOUT MSRC		WITH MSRC		WITHOUT MSRC		WITH MSRC	
	Total spend	Total spend per patient	Total spend	Total spend per patient	Total spend	Total spend per patient	Total spend	Total spend per patient
Total targeted therapy drug WAC costs	**$ 65.7M**	**$ 74,732**	**$ 55.7M**	**$ 63,376**	**$ 81.6M**	**$ 92,835**	**$ 63.5M**	**$ 72,244**
Spend on TNFi	$ 49.1M		$ 29.0M		$ 81.6M		$ 44.9M	
Spend on AltMOA	$ 16.6M		$ 26.7M		-		$ 18.6M	
Total medical costs	**$ 14.2M**	**$ 16,191**	**$ 13.8M**	**$ 15,676**	**$ 14.9M**	**$ 16,968**	**$ 14.3M**	**$ 16,372**
TOTAL (excluding cost of testing)	**$ 79.9M**	**$ 90,923**	**$ 69.5M**	**$ 79,052**	**$ 96.5M**	**$ 109,803**	**$ 77.9M**	**$ 88,616**

4 Overall improvement in efficiency of spend

- Without MSRC, 68 cents of every dollar spent on drug did not result in a clinically meaningful response.
- MSRC informed care resulted in a 12% decrease in inefficient spend (from 68 to 60 cents per dollar).
- Net $11,314,526 decrease in inefficient spend (WAC) per 1 million commercial covered lives.

Annual Targeted therapy spend per 1M covered lives stratified by expected response



Inefficient spend was defined as targeted therapy spend that does not result in a meaningful clinical response (ACR50)

REFERENCES: 1. Rheumatoid Arthritis (RA) CDC. (2022). Retrieved 1 February 2022. **2.** Fraenkel L, et al. 2021 Arthritis & Rheumatology, 73(7), 1108-1123. **3.** Acosta-Herrera M, et al. 2019 Journal of Clinical Medicine, 8(6), 826. **4.** Bergman MJ, et al. 2020 Rheumatology and Therapy, 7(4):775-92. **5.** Birnbaum, H., et al. 2010 Current medical research and opinion, 26(1), 77-90. **6.** Strand V, et al. 2018 Journal of managed care & specialty pharmacy 2018; 24(4), 344-352. **7.** Cohen, S., et al. 2021 Rheumatology and therapy, 8(3), 1159-1176. **8.** Strand V., et al. 2021 Expert Review of Molecular Diagnostics, 22:1, 101-109. **9.** Jones A., et al 2021 Expert review of molecular diagnostics, 21(11), 1235-1243. **10.** Ariza-Ariza, R., 2007 Rheumatology, 46(3), 529-532. **11.** ICER (2017). Targeted immune modulators for RA: effectiveness & value. Evidence report. **12.** Incerti, D., & Jansen, J., 2018 A description of the IVI-RA model. **13.** MicroMedex Redbook. Greenwood Village (CO): IBM Corporation. **14.** Yip 2018 Datamonitor Healthcare, informa pharma intelligence. **15.** Osterhaus, J. T., et al. 2009Arthritis research & therapy, 11(3), 1-12.

SUPPORT AND DISCLOSURES: This study was sponsored by Scipher Medicine. **AUTHOR DISCLOSURES:** AA, ECS, and AG are employees of Scipher Medicine, and may hold stock or stock options. MB has a consulting agreement with Scipher Medicine