# Prevalence and Cost of Autoimmune Specialty Drug Use by Indication in a Commercially Insured Population, January 2019 through June 2020



K. Bowen, MD, MBA<sup>1</sup>, C.I. Starner, PharmD<sup>1,2</sup>, P.P. Gleason, PharmD<sup>1,2</sup>. <sup>1</sup>Prime Therapeutics LLC, Eagan, MN, United States; <sup>2</sup>University of Minnesota College of Pharmacy, Minneapolis, MN, United States.

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#### BACKGROUND

- A set of 29 specialty drugs commonly termed autoimmune (AI) drugs currently accounts for almost 20% of total commercially insured pharmacy plus medical benefit drug cost with approximately a quarter of the AI drugs primarily processed via the medical benefit and the majority processed via the pharmacy benefit.1
- Although Al drugs represent approximately \$1 in every \$5 in drug expenditures through the pharmacy and medical benefits, less than 1% of commercially insured members use an Al drug.<sup>1</sup>
- Many Al drugs have overlapping indications, presenting an opportunity for managed care plans to encourage the most cost-effective treatments through indication-based formularies and pricing.
- Al drugs used for the same indication may have significantly different average costs per user.
- Some AI drugs may have significantly different average costs when used for different indications.
- Medical drug claims are submitted with International Classification of Diseases, Tenth Revision (ICD-10) diagnosis (Dx) codes. However, these may not always specify drug indication, if this is not required for reimbursement.
- Pharmacy claims lack Dx codes. Health plans may have indication information from utilization management (UM), such as prior authorization and step therapy. However, this information may only be available for a fraction of Al drug claims.
- The Institute for Clinical and Economic Review (ICER) has assessed the price to value of AI drugs for rheumatoid arthritis, psoriasis and ulcerative colitis and has found many of the AI drugs are over-priced to the value they provide.<sup>2-4</sup>
- As AI drugs represent a disproportionate portion of all drug expenditures, it is important to understand AI drugs by condition utilization trends, expenditure trends and observed cost per treated member.

## **OBJECTIVE**

- To determine the number of members using and the cost of AI drugs in a commercially insured population by quarter, January 2019 through June 2020, by indications deduced from integrated pharmacy and medical claims data and available UM information.
- To illustrate the potential value of deduced indication in tracking and reporting observed treatment cost by drug for two sets of indications: Crohn's disease and plaque psoriasis.

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#### **METHODS**

- Integrated pharmacy and medical claims and UM data were queried for an average of 15 million commercially insured members per month.
- We identified all pharmacy and medical claims January 2019 to June 2020 for AI drugs (29 different drugs) (Table 1) and, for these members, all medical claims January 2018 to June 2020 for any goods or services that had a Dx code for any of the 12 FDA-approved indications for any of these drugs and all available UM information in which the provider had specified a Dx.
- Each member with AI drug use was assigned to a single indication category based on UM information, if available, or the member's most frequently coded Dx among the set of FDAapproved indications consistent with all the AI drugs the member used. Members with a UM Dx indicating on plausible indication not FDA-approved were assigned as off-label, but we did not attempt to deduce off-label indications for users where this was not specified by the provider in UM information. Those with no UM diagnosis who had no medical claim diagnosis, or more than one claim diagnosis with the same frequency, were categorized as not deduced.
- The number of users and sum of plan plus member payments without adjustment for rebates or coupons was calculated by quarter, type of claim, indication and drug, and normalized to users per 100,000 members and payments per member per month (PMPM). The mean cost of therapy by indication by drug by quarter was estimated as the sum of payments divided by the number of users.

## RESULTS

- Among ~15 million commercially insured members with integrated medical and pharmacy claims data, from 1Q2019 to 2Q2020, members using an Al drug increased 89.4 per 100,000 (17.0%) from 524.5 to 613.9 per 100,000, and expenditures increased \$7.70 (32.2%) from \$23.89 to \$31.59 PMPM (Figures 1a and 1b).
- The proportion of total AI users with an AI claim through the pharmacy benefit increased 0.9 percentage points from 77.3% in 1Q2019 to 78.2% in 2Q2020.
- \*\*\* The proportion of total AI drug payments through the pharmacy benefit increased 5.8 percentage points from 78.6% in 1Q2019 to 83.2% in 2Q2020.
- ••• Mean Al quarterly drug payments per user increased \$1,774 (13.0%) from \$13,662 in 1Q2019 to \$15,436 in 2Q2020.
- Of the 82,030 unique AI drug users in 1Q2019 and 95,129 in 2Q2020, UM review Dx was used to assign indication for 34,731 (42.3%) and 47,210 (49.6%), respectively. For these members, the medical claims Dx algorithm assigned the same indication as the UM review Dx for 33,916 (97.7%) and 46,064 (97.6%), respectively.
- Table 2 compares 1Q2019 and 2Q2020 Al drug payments PMPM and users per 100,000 by
- Seven indications accounted for over 95% of use: rheumatoid arthritis, psoriasis (PsO), Crohn's disease (CD), psoriatic arthritis, ulcerative colitis, ankylosing spondylitis and hidradenitis suppurativa.
- \*\* The largest PMPM drug expenditure increases were for treatment of PsO and CD: respectively, PMPM \$2.24 and \$1.57, and users per 100,000 were 28.9 and 14.1.
- Figures 2a and 2b describe 2Q2020 mean AI drug payments per user by drug for treatment of PsO and CD.
- The five most common therapies for Ps0 were: apremilast, adalimumab, secukinumab, ustekinumab SC and risankizumab. Of these, apremilast had the lowest mean per member per quarter cost and risankizumab the highest.
- The five most common therapies for CD were: adalimumab, infliximab, ustekinumab SC, vedolizumab and certolizumab pegol. Of these, infliximab had the lowest mean cost and ustekinumab SC the highest.
- The ustekinumab SC \$39,579 mean per member per quarter CD drug treatment cost was 2.3 times higher than the ustekinumab SC mean \$17,271 PsO treatment cost.
- The adalimumab \$19,779 per member per quarter mean CD drug treatment cost was 1.3 times higher than the adalimumab \$15,387 mean PsO treatment cost.

## TABLE 1

**Autoimmune Drugs Included in the Analysis and Indications Assigned** 

				X = FDA approved for indication											
<b>Generic Name</b>	<b>Trade Name</b>	Target	<b>Admin</b>	RA	Ps0										Spond
Abatacept	Orencia®	co-stim	SC/IV	Χ		Χ				Χ					•
Adalimumab	<b>Humira®</b>	TNF	SC	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ	Χ			
Anakinra	Kineret®	IL-1	SC	Χ									Χ		
Apremilast	Otezla®	PDE	PO		Χ	Χ									
Baricitnib	Olumiant®	JAK	PO	Χ											
Brodalumab	Siliq®	IL-17	SC		Χ										
Canakinumab	Ilaris <sup>®</sup>	IL-1	SC							Χ			Χ		
Certolizumab pegol	Cimzia <sup>®</sup>	TNF	SC	Χ	Χ	Χ	Χ		Χ						Χ
Etanercept	Enbrel®	TNF	SC	Χ	Χ	Χ			Χ	χ					
Golimumab	Simponi®	TNF	SC	Χ		Χ		Χ	Χ						
Golimumab IV	Simponi Aria®	TNF	IV	Χ		Χ			Χ						
Guselkumab	Tremfya <sup>®</sup>	IL-23	SC		Χ										
Infliximab	Remicade®	TNF	IV	Χ	Χ	Χ	Χ	Χ	Χ						
Infliximab-abda	Renflexis®	TNF	IV	Χ	Χ	Χ	Χ	Χ	Χ						
Infliximab-dyyb	Inflectra®	TNF	IV	Χ	Χ	Χ	Χ	Χ	Χ						
Ixekizumab	Taltz <sup>®</sup>	IL-17	SC		Χ	Χ									Χ
Risankizumab-rzaa	Skyrizi <sup>®</sup>	IL-23	SC		Χ										
Sarilumab	<b>Kevzara</b> ®	IL-6	SC	Χ											
Secukinumab	<b>Cosentyx</b> ®	IL-17	SC		Χ	Χ			Χ						
Tildrakizumab	Ilumya®	IL-23	SC		Χ										
Tocilizumab	<b>Actemra</b> ®	IL-6	SC/IV	Χ						Χ				Χ	
Tofacitinib	Xeljanz <sup>®</sup>	JAK	PO	Χ		Χ		Χ							
Upadacitinib	Rinvoq®	JAK	PO	Χ											
Ustekinumab	Stelara®	IL-12/24	SC		Χ	Χ	Χ	Χ							
Ustekinumab IV	Stelara®	IL-12/24	IV				Χ	Χ							
Vedolizumab	<b>Entyvio</b> ®	Integrin	IV				Χ	Χ							
Rituximab	Rituxan®	CD20	IV	Χ											
Rituximab-abbs	Truxima <sup>®</sup>	CD20	IV	Χ											
Natalizumab	Tysabri®	Integrin	IV				Χ								

Indications: RA = rheumatoid arthritis, PsO = psoriasis, PsA = psoriatic arthritis, CD = Crohn's disease, UC = ulcerative colitis, Ank = ankylosing spondylitis, JIA = juvenile idiopathic arthritis, HS = hidradenitis suppurativa, Eye = non-infectious uveitis, PFS = periodic fever syndromes, GCA = Giant cell arteritis, Spond = non-radiographic axial spondylitis. Admin = method of administration, SC = subcutaneous, IV = intravenous, PO = oral.

Targets: TNF = Tumor necrosis factor-alpha antagonists, IL-12/24 = interleukin-12/24 antagonists, Integrin = Integrin receptor blockers, IL-27 = interleukin-17 antagonists, IL-23 = interleukin-23 antagonists, IL-6 = interleukin-6 receptor inhibitors, costim = T-cell co-stimulation modulators, IL-1 = interluekin-1 antagonists, CD20 = anti-CD20 (B-cell

Note: Rituximab, Rituximab-abbs and Natalizumab are also FDA-approved for other indications. Many of these agents also have off-label uses.

## TABLE 2

**Autoimmune Drug Payments Per Member Per Month and Users per 100,000 Members by Indication** 

	DAA	DAA		s per	0/ - ( = 1 -	1 202222	Change from		
	PMPM		100,	,000	% of lota	l 2Q2020	1Q2019 to 2Q2020		
Indication	1Q2019	2Q2020	1Q2019	2Q2020	PMPM	Users per <b>100,000</b>	PMPM	<b>Users per 100,000</b>	
Rheumatoid arthritis	\$6.35	\$7.81	155.4	171.3	24.7%	27.9%	\$1.46	15.9	
Psoriasis	\$4.69	\$6.93	109.5	138.4	21.9%	22.5%	\$2.24	28.9	
Crohn's disease	\$5.13	\$6.70	90.3	104.4	21.2%	17.0%	\$1.57	14.1	
Psoriatic arthritis	\$3.00	\$3.90	69.8	81.4	12.3%	13.3%	\$0.90	11.6	
Ulcerative colitis	\$2.01	\$2.63	42.0	52.0	8.3%	8.4%	\$0.62	10.0	
Ankylosing spondylitis	\$1.04	\$1.37	24.8	29.0	4.3%	4.7%	\$0.33	4.3	
Hidradenitis suppurativa	\$0.45	\$0.73	5.4	7.7	2.3%	1.3%	\$0.28	2.3	
Juvenile idiopathic arthritis	\$0.28	\$0.37	6.1	7.2	1.2%	1.2%	\$0.10	1.1	
Non-infectious uveitis	\$0.10	\$0.17	2.1	3.0	0.5%	0.5%	\$0.07	1.0	
Off-label	\$0.03	\$0.06	0.8	1.5	0.2%	0.2%	\$0.03	0.7	
Periodic fever syndromes	\$0.04	\$0.05	0.4	0.4	0.2%	0.1%	\$0.01	0.0	
Giant cell arteritis	\$0.01	\$0.02	0.4	0.5	0.1%	0.1%	\$0.01	0.2	
Not deduced	\$0.76	\$0.83	17.6	17.1	2.6%	2.8%	\$0.08	(0.5)	
Any	\$23.89	\$31.59	524.5	613.9	100.0%	100.0%	\$7.70	89.4	

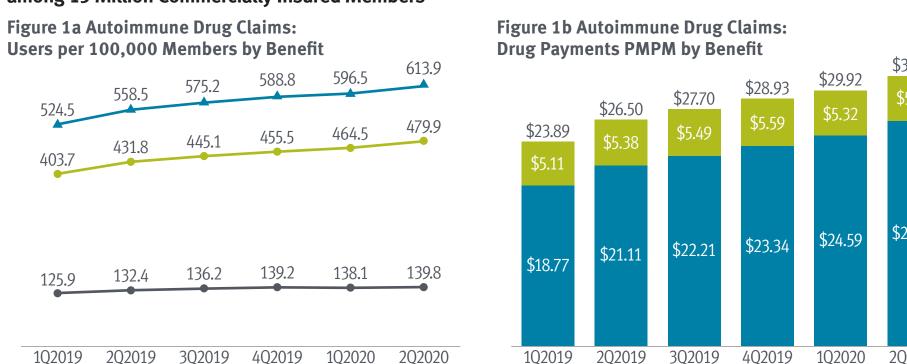
15 million member commercially insured population. PMPMs = per member per month plan plus member payments without adjustment for any rebates. See **Table 1** for list

Non-radiographic axial spondylitis AI drug utilization not shown due to PMPM < \$0.01.

Each member with AI drug use was assigned to a single indication category based on utilization management (UM) information, if available, or the member's most frequently coded Dx among the set of FDA-approved indications consistent with all of the AI drugs the member used. Off-label indication was only assigned if specified in UM information. Those with no indication determined from UM or claims information, or for whom more than one indication was scored as equally probable by claims algorithm,

# FIGURES 1a and 1b

**Autoimmune Drug Claims: Users per 100,000 Members and Drug Payments Per Member Per Month by Benefit** among 15 Million Commercially Insured Members



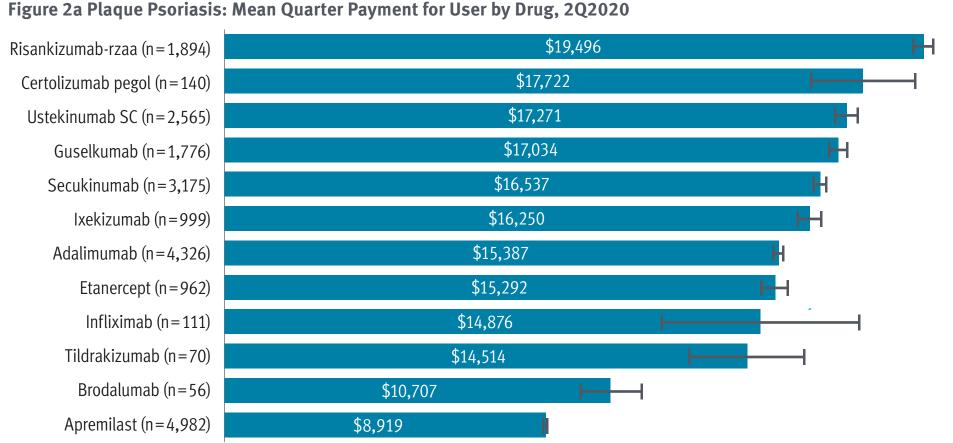
Note: Some members had AI drug claims through both pharmacy and medical benefits during PMPM = per member per month, plan plus member payments without adjustment for any rebates See **Table 1** for list of autoimmune drugs included.

# FIGURES 2a and 2b

See **Table 1** for list of autoimmune drugs included.

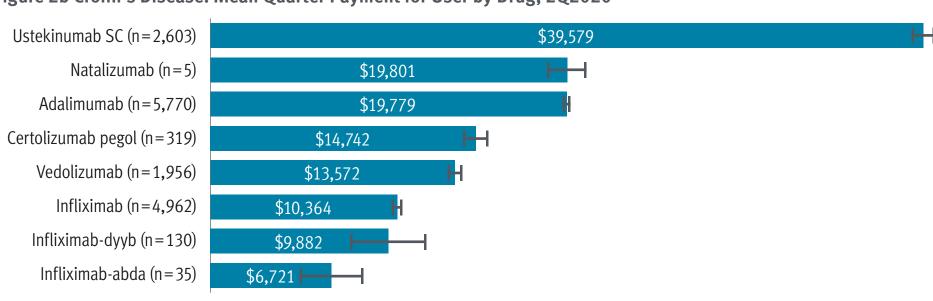
Mean Autoimmune Drug Payments per User for Three Months for Treatment of Plaque Psoriasis and Crohn's Disease

**─** Medical



15 million member commercially insured population. Mean payments = 2Q2020 plan plus member payments without adjustment for any rebates. Bars indicate 95% confidence limits of the mean. Excludes 381 members with a claim for more than one AI drug during 2Q2020. Infliximab-dyyb (n = 5) and infliximab-abda (n = 2) not shown.

Figure 2b Crohn's Disease: Mean Quarter Payment for User by Drug, 2Q2020



15 million member commercially insured population. Mean payments = 2Q2020 plan plus member payments without adjustment for any rebates. Bars indicate 95% confidence limits of the mean. Excludes 286 members with a claim for more than one Al drug incurred during 2Q2020 and 91 members whose only Al drug claim was for ustekinumab IV. 186 of the 286 members excluded because they had claims for both ustekinumab IV and ustekinumab SC.

## **LIMITATIONS**

- This study describes utilization in one large commercially insured population comprised of many different health plans, which may not reflect utilization in other populations. Within the described population, there was considerable variation among individual health plans in the proportion of members treated by indication due to factors such as geographic variation in prevalence of the conditions and provider practice variation. However, the described methodology can be used to describe utilization within subpopulations or populations and in other time intervals.
- For slightly more than half of members described, the indication for Al drug therapy was deduced from administrative claims by an automated algorithm rather than derived from provider attestation for individual members. However, where provider attestation was available from UM data, indication deduced from claims was the same for almost 98%. supporting a high level of accuracy for this method.
- The described AI drug therapy costs represent payments unadjusted by manufacturers' rebates or coupons, which are important modifiers of the actual cost of AI drugs. However, the methodology described attaches an indication to every drug claim, which can be used to calculate fully discounted costs if rebate information is available.
- The mean per patient per quarter drug costs could be influenced by differences in drug new start rates and adherence, although the quarter (approximately 90 days) is a short time period and should alleviate new start and adherence impacts.

#### CONCLUSIONS

- In this integrated medical and pharmacy claims analysis of 15 million commercially insured members, 1 in 158 (0.63%) utilized an AI drug and these members' AI drug utilization accounted for \$31.59 PMPM, approximately 20% of all drug expenditures through the medical and pharmacy benefits.
- The autoimmune drug category PMPM increased 32.2% over 15 months from 1Q2019 to 2Q2020, one of the fastest growing drug categories.
- There were important real-world AI drug cost variances per treated individual, within a drug and by the condition treated. For example, ustekinumab SC drug cost was 2.3 times higher for Crohn's disease treatment than for plaque psoriasis.
- Integrated AI drug analysis including medical claims is essential for determining indication-based utilization.
- Assigning a member to AI drug indication can help in designing indication-based, cost-effective formulary management strategies and value-based contracting.

#### **REFERENCES**

1. Prime internal data, Prime Therapeutics LLC.

- 2. Targeted Immune Modulators for Rheumatoid Arthritis: Effectiveness & Value (Evidence Report). Institute for Clinical and Economic Review. April 7, 2017. Accessed at: http://icerorg.wpengine. com/wp-content/uploads/2020/10/NE\_CEPAC\_RA\_Evidence\_Report\_FINAL\_040717.pdf.
- 3. Targeted Immunomodulators for the Treatment of Moderate-to-Severe Plaque Psoriasis: Effectiveness and Value (Condition Update, Final Evidence Report). Institute for Clinical and Economic Review. Aug. 3, 2018. Accessed at: https://icer.org/wp-content/uploads/2020/10/ ICER\_Psoriasis\_Update\_Final\_Evidence\_Report\_10042018.pdf.
- . Targeted Immune Modulators for Ulcerative Colitis: Effectiveness and Value (Final Evidence Report and Meeting Summary). Institute for Clinical and Economic Review. Oct. 16, 2020. Accessed at: https://icer.org/wp-content/uploads/2020/08/ICER\_UC\_Final\_Evidence\_ Report\_101620.pdf.