

Prevalence and Cost of Autoimmune Specialty Drug Use by Indication in a 4.4 Million Member Commercially Insured Population Continuously Enrolled Four Years, 2012 to 2015

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Background

A set of more than 15 drugs commonly grouped as autoimmune specialty drugs has been a key pharmacy benefit and medical benefit drug cost driver. The number of different drugs in this set has increased steadily, with three drugs newly approved by the Food and Drug Administration (FDA) during the time interval studied and a fourth (Ixekizumab [Taltz[™]]) approved in March 2016, along with two new biosimilar agents (Infliximab biosimilar [Inflectra[™]] and Etanercept-szsz [Erelzi[™]]). Many individual drugs in this set have

also steadily accumulated FDA approvals for additional indications.

- Autoimmune specialty drugs share many of the same indications. This presents an opportunity for managed care plans to encourage the most cost effective treatments through formulary and utilization management programs.
- The autoimmune drugs' heterogeneity of indications and the substantial indication overlap among many products also provides an opportunity to explore indication-based pricing.

Objective

- To estimate autoimmune specialty drug cost and utilization trends among a continuously enrolled commercially insured population, from 2012 to 2015, by year and by indications deduced from integrated pharmacy and medical claims data.

Methods

- Among 12 clients with a total average of 13.8 million commercially insured members per month, all members continuously enrolled from 2012 to 2015 were identified along with all of their medical and pharmacy benefit claims.
- Autoimmune drugs were defined as the set of 15 drugs shown in Table 1. Claims for these drugs were identified by National Drug Code (NDC) on pharmacy benefit claims and Healthcare Common Procedure Coding System (HCPCS) codes on medical claims.
- The study members consisted of all individuals continuously enrolled from 2012 to 2015 with at least one claim for an autoimmune drug.
- All ICD-9 and 10 diagnosis codes on any medical claim for the study members were reviewed. Those for FDA approved or plausible off-label indications were grouped into indication categories. Claims for rituximab were limited to medical claims with a diagnosis code for rheumatoid arthritis.
- Each member with autoimmune specialty drug use was assigned to a single indication category by a hierarchical algorithm that selects the most frequently coded indication category for each member on:
 - All medical benefit claims for an autoimmune specialty drug, or if none (or ties), then
 - All medical claims for which the servicing provider National Provider Identifier code(s) (NPI) matched the NPI(s) of prescriber(s) of autoimmune specialty drug pharmacy benefit claims for the member, or if none (or ties), then
 - All medical claims incurred between January 2012 and December 2015.
- The number of users (i.e., utilizers) and sum of plan plus member payments (i.e., allowed costs) without adjustment for rebates or coupons was calculated by year, by claim bill type (i.e., pharmacy benefit, medical claim for professional services, or medical claim for facility services), by indication, and by drug.

Results

- The four year retrospective cohort study consisted of 4.4 million continuously enrolled commercially insured members with a mean age of 38.8 years.
- A total of 27,341 (0.6 percent) of 4.4 million members used an autoimmune specialty drug during the four years. Autoimmune specialty drug users increased 38.8 percent from 16,247 members in 2012 to 22,543 in 2015 (365.5 to 507.1 per 100,000 members). Autoimmune specialty drug payments increased 102.7 percent from \$360 million in 2012 to \$729 million in 2015 (\$6.74 to \$13.66 per member per month).
- Autoimmune specialty drugs accounted for 8.1 percent of total combined drug costs processed through the medical and pharmacy benefits in 2012 and 9.9 percent in 2015.

- Autoimmune specialty drugs processed through the medical benefit accounted for 31.3 percent of autoimmune specialty drug users in 2012 and 27.0 percent in 2015.
- Over four years, the mean number of different autoimmune specialty drugs per user was 1.4.
- Figure 1 shows autoimmune specialty drug costs (i.e., payments) categorized by claim bill type and year.
- Figures 2a to 2g show cost (i.e., payments) by drug, by year, for the top seven indications.
- Table 2a shows the number of members utilizing an autoimmune specialty drug per 100,000 members and Table 2b shows the mean payments per member per month (PMPM) by indication and year.

Table 1. Autoimmune Drugs Included in this Analysis

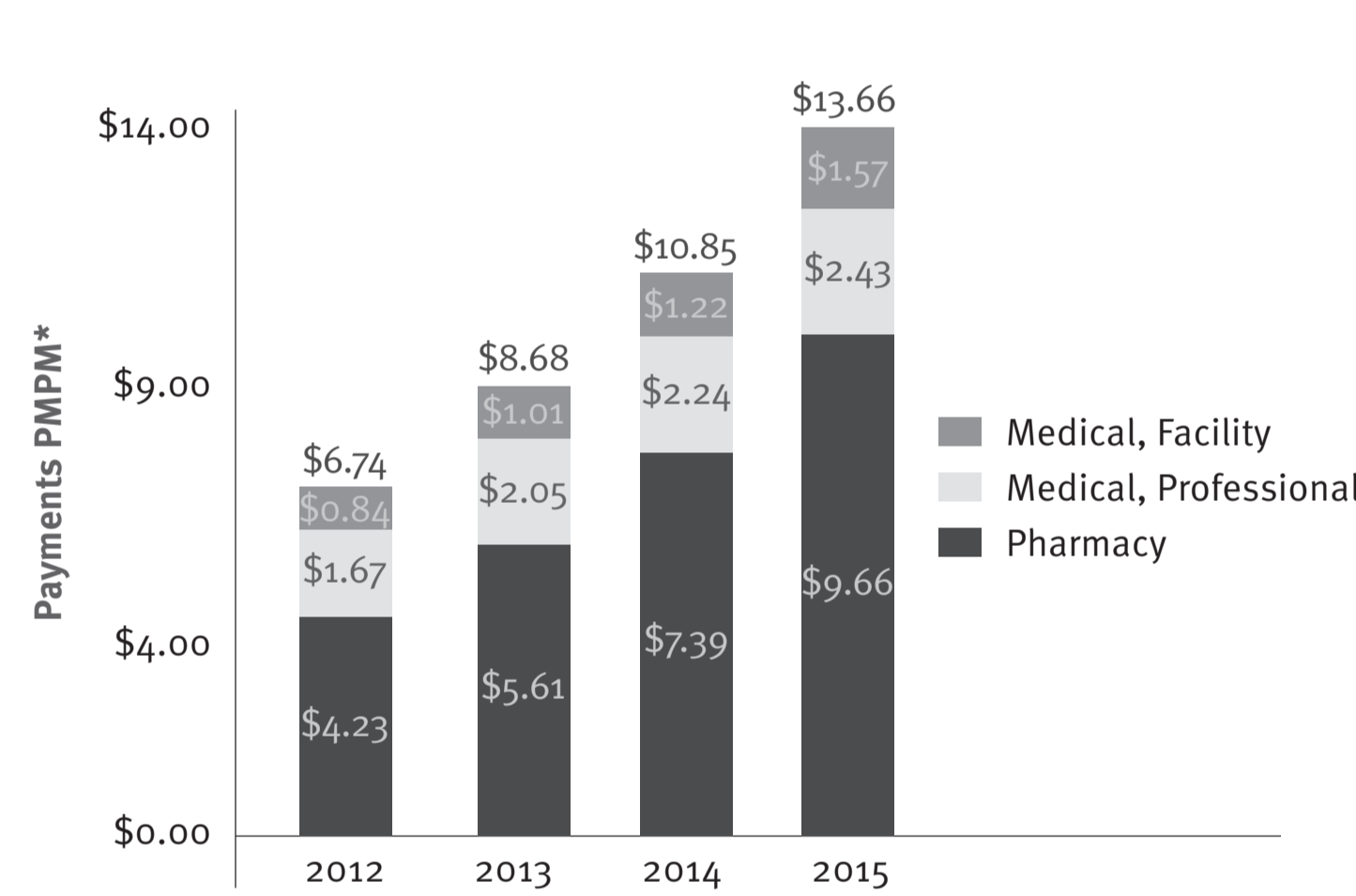
Proper Name	Brand Name	Route of Administration
Abatacept	Orencia [®] IV, Orencia [®] SC	Intravenous, Subcutaneous
Adalimumab	Humira [®]	Subcutaneous
Anakinra	Kineret [®]	Subcutaneous
Apremilast	Otezla [®]	Oral
Canakinumab	Ilaris [®]	Subcutaneous
Certolizumab	Cimzia [®]	Subcutaneous
Etanercept	Enbrel [®]	Subcutaneous
Golimumab	Simponi [®] , Simponi [®] Aria	Subcutaneous, Intravenous
Infliximab	Remicade [®]	Intravenous
Rituximab	Rituxan [®]	Intravenous
Secukinumab	Cosentyx [®]	Subcutaneous
Tocilizumab	Actemra [®]	Intravenous
Tofacitinib	Xeljanz [®]	Oral
Ustekinumab	Stelara [®]	Subcutaneous
Vedolizumab	Entyvio [®]	Intravenous

IV = intravenous, SC = subcutaneous

Table 2a. Autoimmune Drug Utilizers per 100,000 Members; Integrated Medical and Pharmacy Benefits

Indication	Utilizers per 100,000 Members				Utilization Change per 100,000 Members			
	2012	2013	2014	2015	2012 to 2013	2013 to 2014	2014 to 2015	2012 to 2015
Rheumatoid arthritis	146.8	163.7	182.8	187.1	11.5%	11.7%	2.3%	27.4%
Psoriasis	65.6	73.2	84.5	101.0	11.6%	15.5%	19.5%	53.9%
Crohn's disease	55.3	62.2	70.0	78.2	12.4%	12.6%	11.8%	41.5%
Psoriatic arthritis	50.1	56.0	62.7	65.2	11.7%	11.9%	4.1%	30.1%
Ulcerative colitis	17.7	21.3	26.7	32.8	20.4%	25.0%	22.9%	85.0%
Ankylosing spondylitis	17.9	20.6	23.6	23.7	15.5%	14.5%	0.3%	32.6%
Juvenile idiopathic arthritis	6.7	7.8	8.7	8.6	16.5%	11.3%	-0.3%	29.3%
Behçet's syndrome/noninfectious uveitis	1.0	1.4	1.7	2.3	38.6%	26.2%	35.1%	136.4%
Sarcoidosis	0.6	0.5	0.6	0.9	-4.0%	16.7%	35.7%	52.0%
Hidradenitis suppurativa	0.2	0.2	0.4	1.2	37.5%	72.7%	184.2%	575.0%
Other	1.6	2.1	2.6	3.1	31.4%	25.0%	20.9%	98.6%
Unassigned	2.1	1.9	2.1	2.9	-6.5%	10.5%	36.8%	41.3%
Total	365.5	411.0	466.5	507.1	12.5%	13.5%	8.7%	38.8%

Figure 1. Autoimmune Drug Payments per Member per Month (PMPM) by Claim Billing Type in a 4.4 Million Commercially Insured Continuously Enrolled Members, 2012 – 2015



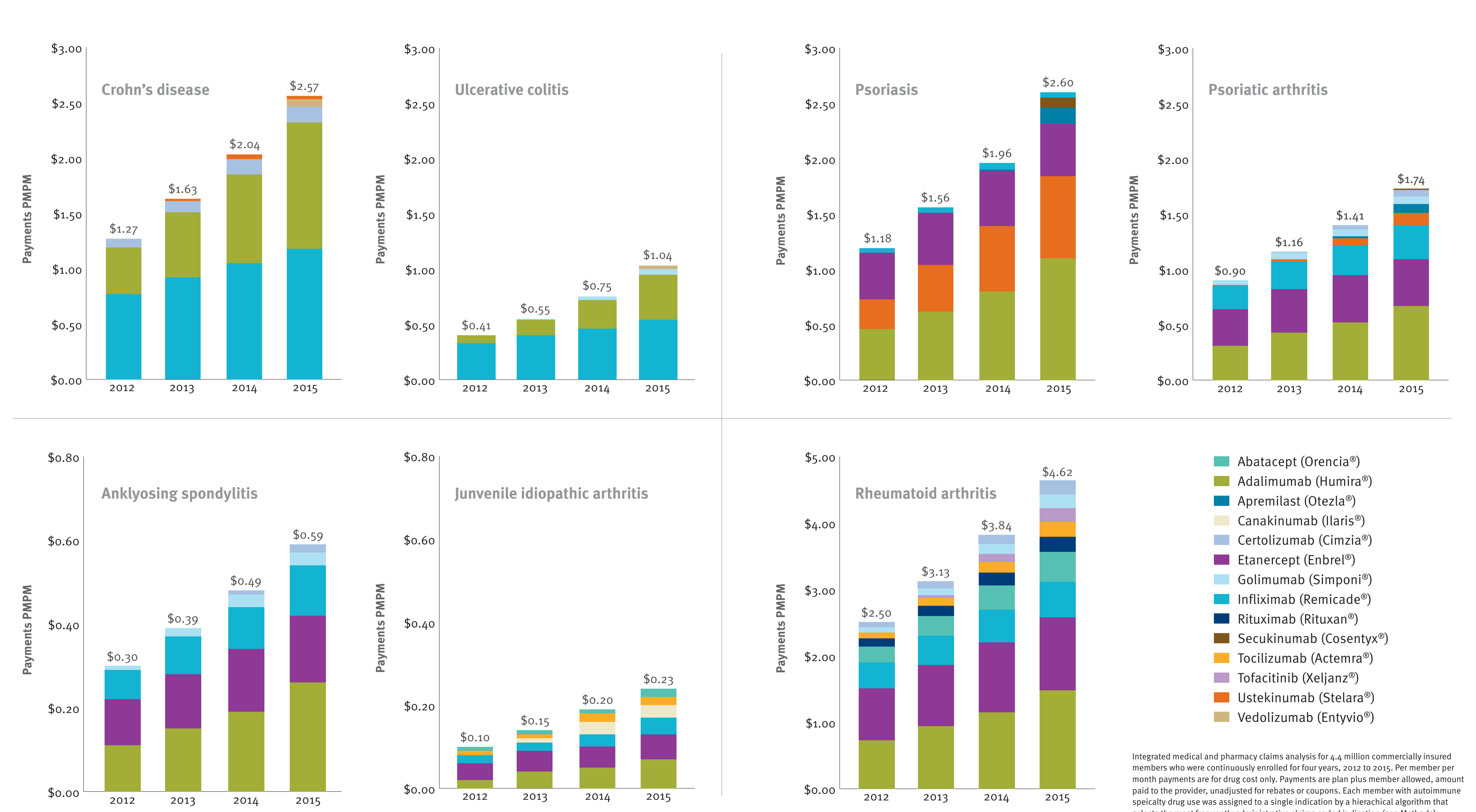
*Payments are allowed costs, i.e., plan plus member payment

Table 2b. Autoimmune Drug Payments per Member per Month (PMPM) by Indication and Year; Integrated Medical and Pharmacy Benefits

Indication	Payments PMPM				Change in PMPM			
	2012	2013	2014	2015	2012 to 2013	2013 to 2014	2014 to 2015	2012 to 2015
Rheumatoid arthritis	\$2.50	\$3.13	\$3.84	\$4.62	24.9%	22.7%	20.5%	84.6%
Psoriasis	\$1.18	\$1.56	\$1.96	\$2.60	32.1%	25.7%	32.8%	120.5%
Crohn's disease	\$1.27	\$1.63	\$2.04	\$2.57	28.4%	25.4%	26.2%	103.2%
Psoriatic arthritis	\$0.90	\$1.16	\$1.41	\$1.74	29.2%	22.2%	23.0%	94.1%
Ulcerative colitis	\$0.41	\$0.55	\$0.75	\$1.04	34.3%	37.1%	37.7%	153.4%
Ankylosing spondylitis	\$0.30	\$0.39	\$0.49	\$0.59	31.4%	24.6%	22.1%	99.8%
Juvenile idiopathic arthritis	\$0.10	\$0.15	\$0.20	\$0.23	51.2%	31.6%	19.3%	137.6%
Behçet's syndrome/noninfectious uveitis	\$0.02	\$0.03	\$0.04	\$0.07	42.8%	53.1%	61.6%	253.4%
Sarcoidosis	\$0.01	\$0.02	\$0.02	\$0.03	44.2%	4.6%	38.3%	108.4%
Hidradenitis suppurativa	\$0.00	\$0.00	\$0.01	\$0.03	74.3%	76.3%	191.7%	796.0%
Other	\$0.03	\$0.04	\$0.06	\$0.08	41.4%	46.3%	35.3%	179.9%
Unassigned	\$0.02	\$0.02	\$0.03	\$0.05	16.4%	24.8%	54.5%	124.6%
Total	\$6.74	\$8.68	\$10.85	\$13.66	28.8%	25.0%	25.9%	102.7%

Integrated medical and pharmacy claims analysis for 4.4 million commercially insured members who were continuously enrolled for four years, 2012 to 2015. Members comprehensive integrated medical and pharmacy claims were analyzed. Each member with autoimmune specialty drug use was assigned to a single indication by a hierarchical algorithm that selects the most frequently administrative claims coded indication (see Methods). Per member per month payments are for drug costs only. Payments are plan plus member allowed, actually paid to provider, unadjusted are not adjusted for rebates or coupons.

Figures 2a-2g. Autoimmune Drug Payments per Member per Month (PMPM) by Indication and Drug, in a 4.4 Million Commercially Insured Continuously Enrolled Members, 2012 – 2015



Integrated medical and pharmacy claims analysis for 4.4 million commercially insured members who were continuously enrolled for four years, 2012 to 2015. Per member per month payments are for drug cost only. Payments are plan plus member allowed, amount paid to the provider, unadjusted for rebates or coupons. Each member with autoimmune specialty drug use was assigned to a single indication by a hierarchical algorithm that selects the most frequently administrative claims coded indication (see Methods).

Limitations

- These results are from a study sample of commercially insured members continuously enrolled for four years, which may not be representative of the total insured population or generalizable to other commercially insured populations. The results would not be expected to be generalizable to Medicare or Medicaid populations.
- Indications for drug use were deduced from administrative claims data only and were not validated by information such as providers' attestations for prior authorization or the members' statements about reason for therapy to specialty drug care management staff.
- Described claims payments are not adjusted for rebates paid by manufacturers or for manufacturers' coupons or patient assistance programs.

Conclusions

- Autoimmune specialty drugs now account for about 1 of every 10 dollars of drug expense through the medical and pharmacy benefits in a commercially insured population.
- The autoimmune drug class is one of the fastest growing, with this study finding a doubling in autoimmune drug expenditures and a 38 percent increase in utilization, in the most recent four years.
- With over 15 autoimmune drugs, it is essential for payers and insurers to focus utilization and cost management on this burgeoning drug class.
- Integrated analysis of medical and pharmacy claims is essential as more than 25 percent of autoimmune specialty drug use is paid through the medical benefit.
- Medical claim provider information and diagnosis coding can also be used to categorize autoimmune drug use by indication, which may be helpful in designing strategies to manage cost effective use and for indication-based pricing.