Impact of Prescription Drug Benefit Design on Access to Autoimmune Medications in Michigan

Manasvini Singh
Kenneth E. Thorpe, Ph.D.

Emory University
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BACKGROUND

Health plans and pharmacy benefit managers (PBMs) deploy a variety of utilization management tools to control spending on prescription drugs. These include increasing the amount the patient pays through coinsurance and co-pays and combining medical and drug deductibles that require a higher level of spending than separate drug deductibles. Plans also develop and use tiered formularies to encourage the use of generic and preferred drugs within a therapeutic area. The tiers within formularies (generally 5) require higher patient out-of-pocket spending per tier to provide economic incentives to choose medicines associated with lower out-of-pocket costs. Plans often require additional conditions be met before they cover newer, often higher cost medicines. Those additional conditions include requiring physicians to obtain prior authorization for coverage and requiring patients to try one or more other medicines without success first before covering the medicine prescribed—often called "step therapy."

These spending control mechanisms have raised concerns among patients and providers. Specifically, these mechanisms can present significant barriers to accessing medicines selected as best for the patient and add administrative burden on providers. These concerns are particularly acute for people living with serious autoimmune diseases known to be heterogenic in their presentation, progression, severity level, and response to treatment.[2] Also, an analysis of commercial plans' utilization of step therapy and other restrictions on access found that medicines for autoimmune diseases were often the subject of restrictions, with significant variations by plan noted.[6]

Autoimmune diseases result from a dysfunctional immune system that attacks healthy cells, tissue, and organs. These chronic diseases can manifest in different systems of the body, vary in symptomology, be difficult to diagnose, and involve multiple providers for treatment.[8] According to the American Autoimmune Related Diseases Association (AARDA), researchers have identified 80-100 different autoimmune diseases.[9] Autoimmune diseases are debilitating to the human immune system and require a lifetime of treatment. Though individually rare, autoimmune diseases collectively are among the most prevalent diseases in the U.S.[8]

This study examines the extent to which the largest private and Medicare health plans in Michigan[1] utilize coverage limitations on medications in their outpatient pharmacy benefits for five autoimmune diseases: Crohn's disease, multiple sclerosis, psoriasis, psoriatic arthritis, and rheumatoid arthritis. To allow comparisons between plans and conditions, we calculated average scores for each plan's formulary based on the structure and content of the formulary and usage of prior authorization and step therapy for each disease.

1 Michigan is home to the American Autoimmune Related Diseases Association which commissioned this study.

KEY FINDINGS

People living with autoimmune diseases in Michigan face substantial hurdles in accessing medicines whether insured by commercial insurance or through Medicare, with few exceptions.

- Across all five autoimmune diseases studied, the vast majority of private and Medicare health plans impose significant to austere restrictions on access to medicines indicated for the disease.
    - In covering medicines for multiple sclerosis, all of the largest Medicare plans and 20 of the largest private plans the accumulated high scores for imposing restrictions on access.
        - » Of the autoimmune diseases studied, multiple sclerosis had the most plans with fewer access restrictions.
    - For all other conditions studied, 24 of the 25 largest plans and PBMs had significant restrictions limiting access to medicines.
        - » For the autoimmune diseases studied, people with psoriatic arthritis had the most plans with the highest level of access restrictions.
- Medicare plans impose far greater access restrictions on medicines than private, commercial coverage.
    - Within Medicare, every one of the 25 most popular plans impose austere access restrictions for psoriasis, psoriatic arthritis, and rheumatoid arthritis.
    - For Crohn's disease and multiple sclerosis, 24 out of 25 plans severely limit access to prescription medicines.
    - People with autoimmune diseases living in Michigan have few options for Medicare coverage. Only for multiple sclerosis, among all conditions considered, did two Medicare plans achieve scores representing less than a significant number of restrictions on access.
- The largest Medicare plan by lives covered achieved better scores on access relative to the scores of other large Medicare plans across all five conditions. That plan, however, imposed greater access restrictions than the largest commercial plan across all five conditions.
- Among employers, plans covering federal employees imposed far greater access restrictions than other private and public employers in Michigan for all five autoimmune diseases. Often the federal employee plans scored a full point (magnitude) higher than other employers in terms of the restrictions on access imposed.
- For all five autoimmune conditions, the three largest commercial plans tended to have better access scores relative to other plans.
    - None of these large plans, however, achieved the best scores for access. Instead, coverage offered by private employers with fewer lives covered achieved the best scores for access. (See table below for examples.)

For Top 25 Health Plans/PBMs by Size

Number with Significant to Austere Restrictions on Access to Outpatient Medications

Autoimmune disease	Medicare Coverage Degree of Access Limits		Commercial Coverage Degree of Access Limits	
	Significant to Austere	Austere	Significant to Austere	Austere
Crohn's Disease	25 out of 25	24 out of 25	25 out of 25	6 out of 25
Multiple sclerosis	24 out of 25	24 out of 25	20 out of 25	3 out of 25

Psoriasis	25 out of 25	25 out of 25	24 out of 25	5 out of 25
Psoriatic arthritis	25 out of 25	25 out of 25	24 out of 25	8 out of 25
Rheumatoid arthritis	25 out of 25	25 out of 25	24 out of 25	8 out of 25

A list of the specific health plans and PBMs included among the largest 25 by enrollment in this analysis is provided in the Appendix.

Variations in Employer Coverage Scores by Condition

Compared to Federal Employee Benefit Plan Coverage

Employer/ Plan Name	Level of Access Restrictions in Pharmacy Benefit for Prescription Medicines by Condition (Score = Magnitude of Restrictions on Access)				
	Crohn's Disease	Multiple Sclerosis	Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis
Federal Employees: Blue Care Network of Michigan FEHBP	3.65	3.05	3.60	3.59	3.65
Federal Employees: BCBS FEP Standard	4.00	3.57	3.91	3.88	3.83
UAW Retiree Medical Benefit Trust	2.70	1.88	2.64	3.00	2.63
Microsoft – A2	2.50	1.84	2.18	2.32	2.29
University of Michigan	3.20	1.95	2.91	2.87	2.73
Chrysler Group LLC	3.00	2.32	2.68	3.03	3.09
State of Michigan Employees	2.17	2.94	2.52	2.37	2.39
DOW Corning	1.60	1.18	2.00	2.32	1.71
General Motors	1.80	1.12	2.27	2.36	1.84
Memorial Healthcare	1.60	1.18	2.00	2.32	1.71
Genesee County	1.80	1.12	2.27	2.36	1.84
Calhoun, Newaygo & Sanilac Counties	1.60	1.18	2.00	2.32	1.71

Higher scores represent greater restrictions on access

DEFINITIONS AND METHODS

Prior Authorization

Prior authorization of prescription drugs requires prescribers to first obtain approval from insurers or PBMs for the patient to qualify for coverage under his or her insurance. These restrictions are supposed to encourage responsible prescriber behavior by instituting an added administrative barrier to prescribing medicines. Reasons for using prior authorization are often economic, including generic availability and cost of the medicine; but it can be used for drugs with a high potential for abuse, misuse, or other safety concerns. For example, a prior authorization policy for select antibiotics decreased antimicrobial resistance without affecting clinical outcomes or increasing health service use.[18]

Step therapy

Step therapy is a specific type of prior authorization endorsed by some health plans and PBMs as a cost-constraining measure to be used in the process of treating an illness. Step therapy requires physicians and patients to try one or more older, typically lower cost (often generic) drugs and document that the drug was ineffective or insufficient for treating the illness. These "steps" are required before a plan will approve coverage of higher-cost, typically newer, brand name drugs. These steps are required for medicines even though a drug is listed on a plan's formulary.

Evidence about the overall cost and health impacts of prior authorization and step therapy for prescription drugs is mixed[1]. Research shows that such methods of direct drug control can reduce pharmacy spending[2], from estimates of $0.03 in savings per member per month to $0.83 per member per month.[3,4] Moreover, research shows that using generics over branded drugs - as is often the "fail-first" requirement of step therapy protocols - is cost-effective.[5]

Studies assessing how access restrictions affect overall care utilization and costs indicate that restricting access can increase overall costs by increasing utilization of other health care services, particularly with conditions requiring a personalized approach to optimize therapeutic benefit. For example, instituting a step therapy requirement for schizophrenia medications reduced pharmacy costs for Georgia Medicaid by $20 a month but raised outpatient services costs by $32 a month.[15] Similarly, a literature review examining the impact of access restrictions on antipsychotic medication usage found that savings on medication costs were countered by increases in overall healthcare utilization and costs in a majority of studies.[14] Other studies have documented significant increases in general inpatient/ ED utilization and spending, as well as increases in outpatient visits for patients subjected to step therapy and other variations of preferred drug lists protocol.[10-13,22]

For PBMs and stand-alone Medicare prescription drug plans, higher medical spending does not affect the plans as they are responsible for managing drug costs alone and seldom have visibility or accountability for the impact of medication access restrictions on health outcomes or overall medical spending.

Aside from the cost impact, these figures raise ethical concerns about compromising patient welfare in the pursuit of pharmacy cost savings.[5] The process of trying medicines for a sufficient time to know they are not working can take months to complete and, with serious illnesses, over that time the person's health could deteriorate. Providers have expressed concerns that these policies delay patients from getting essential medications[19] or inhibit drug regimen initiation entirely.[20]

In a recent American Medical Association survey, 78 percent of doctors reported that prior authorization "sometimes, often or always" leads to patients' abandoning a recommended course of treatment.[16] More than 90 percent of doctors indicated that prior authorization requirements had negatively affected patients' clinical outcomes.[17] A separate systematic review examining the health impacts of such access restrictions found that limiting or delaying treatment for economic reasons was negatively associated with 130 patient outcomes, approximately half of all outcomes studied.[7]

Prior authorization and step therapy are also associated with increased administrative burden and uncompensated costs incurred by physician offices, pharmacists, and patients themselves. According to the AMA survey referenced above, physician offices receive an average of 29.1 prior authorization requests a week and spend 14.6 hours handling them,[16] leading to an AMA effort to establish principles on prior authorization. Retail pharmacists have also reported dissatisfaction with the added burden of filing prior authorization paperwork and drug rejection resolutions.[23]

METHODOLOGY AND ANALYSIS

Calculating Pharmacy Benefit Restrictions on Access Scores

Managed Markets Insights and Technology, Inc. (MMIT) provided data on formulary design, step therapy, and other prior authorization requirements for all medicines indicated for each of five autoimmune diseases studied for all formularies offered under each plan or PBM. MMIT also provided the relative size of each plan based on the number of covered lives, allowing us to focus on the top 25 plans in the commercial market, Medicare market, and overall. The five autoimmune conditions examined were: Crohn's disease, multiple sclerosis, psoriasis, psoriatic arthritis, and rheumatoid arthritis.

Based on the MMIT data, we evaluated overall access to the medicines indicated for each condition based on: formulary status, tier placement, prior authorization requirements, and step therapy requirements.

We developed a point system based on the criteria for each medicine indicated for a condition and averaged those scores across medications to arrive at a score for each formulary. We then assigned the formulary-disease category score to each health plan using that specific formulary.

We assigned a point if the plan had a step therapy requirement and another point for a prior authorization restriction. For step therapy, we gave a single point whether the protocol required one or multiple steps before covering the medicine. We also assigned points based on MMIT's Universal Status Coverage: Generic = 0; Preferred = 1 point; Covered = 2 points; Specialty = 3 points; and Not Covered/ not Listed/ Unknown = 4 points.

Lower scores reflect fewer access restrictions and higher scores reflect multiple access restrictions. Across both commercial and Medicare plans, access scores ranged from 0-1 (few access restrictions) to 3-4 (significant to austere access restrictions). Each point increase in score represents a magnitude of difference in terms of limitations on access.

The results for the largest 25 plans by enrollment in Michigan for Medicare and for commercial health plans are shown in the following tables.

Level of Access Restrictions on Prescription Medicines by Condition

For Largest Commercial Plans in Michigan by Enrollment

Plan Name	Enrollment	Type of Plan	Level of Access Restrictions in Pharmacy Benefit for Prescription Medicines by Condition (Score = Magnitude of Restrictions on Access)				
			Crohn's Disease	Multiple Sclerosis	Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis
Blue Cross Blue Shield of Michigan PPO 3 Tier	843890	PPO	2.40	1.83	2.23	2.35	2.40
Express Scripts National Preferred with Advantage Plus	288269	PBM Offering	2.36	1.88	2.46	2.68	2.46
Express Scripts National Preferred with Advantage	235188	PBM Offering	2.36	1.82	2.46	2.68	2.46
Priority Health Michigan PPO	231100	PPO	3.81	3.14	3.72	3.81	3.69
UAW Retiree Medical Benefit Trust	228322	Employer	2.70	1.88	2.64	3.00	2.63
UnitedHealthCare Advantage 3 Tier PPO	163594	PBM Offering	2.25	2.56	2.39	2.48	2.54
Department of Veterans Affairs	150055	Other Insurer	2.80	2.23	2.83	2.91	2.84
Health Alliance Plan Michigan PPO Three Tier	128877	PPO	3.29	2.95	3.18	3.29	3.13
Blue Care Network of Michigan FEHBP	126136	Employer	3.65	3.05	3.60	3.59	3.65
CHE Trinity Health Employees	124722	Employer	3.00	2.32	2.68	3.03	3.09
University of Michigan	108513	Employer	3.20	1.95	2.91	2.87	2.73
Chrysler Group LLC	104767	Employer	3.00	2.32	2.68	3.03	3.09
BCN Blue Essentials	88004	Employer	2.78	2.26	2.30	2.49	2.52
Blue Care Network of Michigan HMO 3 Tier	88004	HMO	2.82	2.26	2.40	2.47	2.51
State of Michigan Employees	87574	Employer	2.17	2.94	2.52	2.37	2.39
CVS Caremark Performance Standard Control w/Exclusions & Adv Specialty Control	82729	PBM Offering	3.00	2.32	2.68	3.03	3.09
BCBS Michigan PPO 2 Tier Closed	77422	PPO	2.93	2.50	2.35	3.65	1.95
BCBS MI PPO 2 Tier Clinical	77422	PPO	2.25	2.95	1.89	1.98	2.59
BCBS Michigan PPO 5 Tier	77422	PPO	3.75	2.11	3.65	2.59	3.71
OptumRx Premium Highly Managed with UM	76563	PBM Offering	2.42	2.72	2.73	2.74	2.67
TRICARE East	74669	HMO	2.55	2.32	2.33	2.44	2.57
UnitedHealthCare Traditional 3 Tier PPO	71919	PPO	2.25	2.50	2.38	2.48	2.53
BCBS FEP Standard	70877	Employer	4.00	3.57	3.91	3.88	3.83
OptumRx Select Covered	69398	PBM Offering	2.17	2.83	2.16	2.29	2.06
CVS Caremark Performance Standard Opt-Out Formulary	68887	PBM Offering	2.67	2.32	2.55	2.60	2.60

(Higher scores indicate greater restrictions on access, with each point representing a magnitude of difference in access)

Level of Access Restrictions on Prescription Medicines by Condition

For Largest Medicare Part D and Medication Advantage-Part D Plans in Michigan by Enrollment

Plan Name	Enrollment	Type of Plan	Level of Access Restrictions in Pharmacy Benefit for Prescription Medicines by Condition (Score = Magnitude of Restrictions on Access)				
			Crohn's Disease	Multiple Sclerosis	Psoriasis	Psoriatic Arthritis	Rheumatoid Arthritis
Express Scripts EGWP High Performance 3 Tier	200465	PDP	2.89	2.00	3.29	3.28	3.15
SilverScript Choice	93530	PDP	3.80	3.45	3.87	3.83	3.88
PriorityMedicare Value	75587	MA-PD	3.94	3.05	3.88	3.92	3.82
AARP MedicareRx Preferred	69765	PDP	4.00	3.50	4.00	4.00	4.00
Humana Walmart Rx Plan	69327	PDP	3.87	3.78	3.81	3.85	3.84
Aetna Medicare Rx Saver	52737	PDP	3.93	3.64	3.93	3.89	3.88
Humana Preferred Rx Plan	45137	PDP	3.87	3.78	3.81	3.85	3.84
EnvisionRxPlus PDP	41487	PDP	3.67	3.70	3.76	3.48	3.52
WellCare Classic PDP	40336	PDP	3.93	3.22	3.93	3.90	3.88
Medicare Plus Blue PPO Signature	39292	MA-PD	3.80	3.43	3.67	3.88	3.70
Cigna-HealthSpring Rx Secure	38357	PDP	3.87	3.48	3.88	3.93	3.84
Express Scripts EGWP Premier Access 4 Tier	32811	PDP	3.95	3.24	3.88	3.95	3.81
Symphonix Value Rx	30710	PDP	4.00	3.67	4.00	4.00	4.00
Prescription Blue Option B	26254	PDP	3.80	3.43	3.77	3.87	3.69
Humana Enhanced (PDP)	23978	PDP	3.87	3.73	3.81	3.85	3.84
BCN Advantage HMO-POS Basic	23104	MA-PD	3.93	3.50	3.87	3.93	3.76
PriorityMedicare Merit	22944	MA-PD	3.94	3.05	3.88	3.92	3.82
First Health Part D Value Plus PDP	22107	PDP	3.85	3.65	3.84	3.81	3.65
BCN Advantage HMO-POS Classic	19766	MA-PD	3.93	3.50	3.87	3.93	3.76
HumanaChoice - National-5	19175	MA-PD	3.87	3.73	3.81	3.85	3.84
PriorityMedicare	18641	MA-PD	3.94	3.05	3.88	3.92	3.82
AARP MedicareRx Walgreens	17777	PDP	4.00	3.72	4.00	4.00	4.00
Medicare Plus Blue PPO Essential	17765	MA-PD	3.80	3.43	3.67	3.88	3.70
AARP MedicareRx Saver Plus	17515	PDP	4.00	3.67	4.00	4.00	4.00
Medicare Plus Blue PPO Vitality	15017	MA-PD	3.80	3.43	3.67	3.88	3.70

(Higher scores indicate greater restrictions on access, with each point representing a magnitude of difference in access)

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