Trends in Specialty Pharmacy Use among US Medicare Beneficiaries: Implications for Part D Policy

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BACKGROUND

- Specialty drugs are innovative, high-cost agents used to treat complex chronic conditions such as rheumatoid arthritis (RA), multiple sclerosis (MS), and chronic myeloid leukemia (CML).
- Evidence suggests adherence to specialty drugs is suboptimal, particularly among Medicare beneficiaries.
- Relative to traditional retail pharmacies, specialty pharmacies offer several additional services that may help patients initiate and maintain adherence to their specialty medications.
  - Assistance completing prior authorizations
  - Financial assistance to help with cost sharing
  - Detailed instructions for administration
  - Warning about side effects and strategies for management
  - Prescription reminders and physician alerts
- Prior studies have shown specialty pharmacy use to be associated with better adherence across a variety of conditions.
- While Medicare beneficiaries have unique circumstances that make them more susceptible to specialty drug non-adherence, plans cannot require them to use specialty pharmacy services due to the Any Willing Pharmacy (AWP) provision under Medicare Part D.

OBJECTIVE

- To examine the use of specialty pharmacy and associated factors among Medicare beneficiaries receiving Part D specialty drugs for rheumatoid arthritis (RA), multiple sclerosis (MS), and chronic myeloid leukemia (CML)

METHODS

- Data Source
  - 2014 and 2019 Chronic Conditions Warehouse (CCW) 100% fee-for-service Medicare Part A, B, and D national claims data available from the Centers for Medicare and Medicaid Services
- Study Samples
  Annual cross-sectional study samples of RA, MS, and CML specialty drugs users in 2014 and 2019 based on the following selection criteria:
  - ≥1 Part D specialty drug fill for one of the conditions of interest in the calendar year
  - Continuous fee-for-service Medicare Parts A, B, and D coverage in the calendar year
  - ≥1 claim with an ICD-9 or ICD-10 code for RA, MS, or CML in the calendar year
- Outcome
  - Specialty pharmacy (vs. retail or other pharmacy) use for any Part D specialty drug prescription filled for the condition of interest in the calendar year
- Analyses
  - Trends in specialty pharmacy use across 2014 and 2019 were reported descriptively for the RA, MS, and CML samples.
  - Factors associated with specialty pharmacy use were assessed using logistic regression using the latest available year of data prior to the COVID-19 pandemic (2019).
  - Covariates included age, sex, race/ethnicity, metropolitan status, census region, Part D plan type, Part D low-income subsidy (LIS) status, and Charlson comorbidity score.

RESULTS

- Between 2014 and 2019, the rate of specialty pharmacy use increased among Medicare beneficiaries using specialty drugs across all three s (**Figure 1**):
  - RA: 14.4% to 31.2%, p<0.001
  - MS: 25.1% to 48.9%, p<0.001
  - CML: 21.1% to 34.8%, p<0.001

- **Table 1** presents the characteristics of the 45,747 beneficiaries filling RA drugs, 38,822 beneficiaries filling MS drugs, and 9,458 beneficiaries filling CML specialty drugs in 2019.
  - RA: mean age 65.9 years, 22.0% male, 75.0% White, 62.8% full low-income subsidy
  - MS: mean age 59.6 years, 23.0% male, 79.8% White, 55.5% full low-income subsidy
  - CML: mean age 70.8 years, 48.8% male, 79.5% White, 40.4% full low-income subsidy

Table 1. Sample Characteristics in 2019

	RA (N=45,747)	MS (N=38,822)	CML (N=9,458)
Age, mean (SD)	65.9 (12.0)	59.6 (11.5)	70.8 (12.1)
<65 years	38.4%	59.5%	22.1%
65 to 69 years	19.2%	19.6%	16.3%
70 to 74 years	19.2%	14.1%	21.1%
75 to 79 years	12.5%	5.2%	17.7%
≥80 years	10.7%	1.6%	22.8%
Sex			
Male	22.0%	23.0%	48.8%
Female	78.0%	77.0%	51.2%
Race/Ethnicity			
White	75.0%	79.8%	79.5%
Black	12.1%	14.7%	10.9%
Hispanic	5.8%	2.2%	3.5%
Other	7.1%	3.3%	6.2%
Metropolitan status			
Urban	78.2%	79.2%	79.4%
Rural	21.8%	20.8%	20.6%
Region			
Northeast	20.8%	22.9%	20.4%
Midwest	19.8%	26.8%	22.6%
South	38.9%	33.1%	39.6%
West	20.6%	17.2%	17.5%
Part D drug benefit type			
Enhanced alternative	19.2%	29.1%	32.2%
Standard or other alternatives*	80.8%	70.9%	67.8%
Low-income subsidy (LIS) status			
Non-LIS	36.7%	43.3%	58.7%
Full LIS	62.8%	55.5%	40.4%
Partial LIS	0.5%	1.2%	0.9%
Charlson comorbidity score, mean (SD)	2.7 (2.1)	1.5 (1.9)	2.8 (2.5)

* Includes defined standard benefit, actuarially equivalent standard benefit, & basic alternative benefit

- **Table 2** presents the results of the logistic regressions that identified several factors associated with specialty pharmacy use across the three conditions.
  - Across all three samples of RA, MS, and CML specialty drug users:
    - Older age was associated with lower odds of specialty pharmacy use
    - Higher comorbidity score was associated with lower odds of specialty pharmacy use
    - Residence in the Midwest relative to Northeast was associated with lower odds of use
  - Among RA drug users, Hispanic and Other race/ethnicity, full and partial low-income subsidy status, and rural residence were associated with lower odds of specialty pharmacy use.
  - Among MS specialty drug users, male sex, Black race, partial low-income subsidy status, and rural residence were associated with lower odds of specialty pharmacy use.
  - Among CML drug users, full low-income subsidy status and standard or other alternative Part D drug benefit type were associated with lower odds of specialty pharmacy use.

Figure 1. Specialty Pharmacy Use among Medicare Beneficiaries using Specialty Drugs for MS, RA, and CML in 2014 and 2019
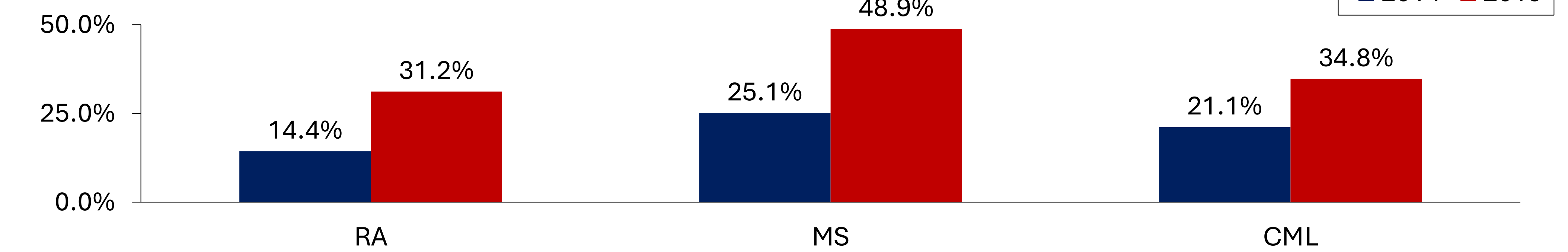

Legend: 2014, 2019

RA: 14.4% (2014), 31.2% (2019); MS: 25.1% (2014), 48.9% (2019); CML: 21.1% (2014), 34.8% (2019)

Table 2. Factors Associated with Specialty Pharmacy Use in 2019

	RA			MS			CML		
	OR	95% CI	p-value	OR	95% CI	p-value	OR	95% CI	p-value
Age									
<65 years	REF			REF			REF		
65 to 69 years	1.13	1.06 1.20	<.0001	1.03	0.97 1.09	0.405	0.96	0.83 1.12	0.595
70 to 74 years	0.98	0.92 1.05	0.581	0.86	0.80 0.92	<.0001	0.86	0.74 1.00	0.043
75 to 79 years	0.89	0.83 0.96	0.002	0.73	0.66 0.81	<.0001	0.83	0.71 0.97	0.019
≥80 years	0.88	0.82 0.95	0.001	0.69	0.59 0.82	<.0001	0.80	0.69 0.93	0.004
Sex									
Male	REF			REF			REF		
Female	1.02	0.97 1.07	0.536	1.07	1.02 1.12	0.005	0.95	0.87 1.03	0.222
Race/Ethnicity									
White	REF			REF			REF		
Black	1.03	0.97 1.10	0.317	0.92	0.86 0.97	0.004	0.94	0.81 1.09	0.405
Hispanic	0.82	0.75 0.90	<.0001	0.95	0.82 1.09	0.438	1.11	0.86 1.42	0.430
Other	0.81	0.75 0.88	<.0001	1.02	0.91 1.14	0.761	1.17	0.98 1.40	0.088
Metropolitan status									
Urban	REF			REF			REF		
Rural	0.82	0.78 0.87	<.0001	0.92	0.88 0.97	0.002	1.04	0.94 1.16	0.433
Region									
Northeast	REF			REF			REF		
Midwest	0.71	0.67 0.76	<.0001	0.85	0.80 0.90	<.0001	0.76	0.66 0.86	<.0001
South	0.77	0.73 0.81	<.0001	1.04	0.99 1.10	0.124	0.93	0.82 1.04	0.205
West	0.89	0.84 0.95	0.000	0.99	0.93 1.05	0.735	1.00	0.87 1.15	0.956
Part D drug benefit type									
Enhanced alternative	0.99	0.94 1.04	0.667	1.04	0.99 1.09	0.112	1.22	1.11 1.34	<.0001
Standard or other alternative	REF			REF			REF		
Low-income subsidy (LIS) status									
Non-LIS	REF			REF			REF		
Full LIS	0.61	0.58 0.64	<.0001	1.02	0.97 1.07	0.511	0.63	0.56 0.70	<.0001
Partial LIS	0.60	0.45 0.81	0.001	0.79	0.65 0.95	0.012	1.12	0.72 1.75	0.625
Charlson comorbidity score	0.96	0.95 0.96	<.0001	0.94	0.93 0.95	<.0001	0.98	0.97 1.00	0.042

LIMITATIONS

- Medicare data were only available for fee-for-service patients; results may not be generalizable to those enrolled in Medicare Advantage plans.
- Claims data are not developed for research purposes and may be subject to coding errors and lack information on clinical parameters.

CONCLUSION

- Specialty pharmacy use increased from 2014 to 2019 across all three conditions; however, approximately two-thirds of RA and CML patients and half of MS patients were not using a specialty pharmacy in 2019.
- Factors such as older age, minority race/ethnicity, and low-income subsidy status were associated with lower odds of specialty pharmacy use.
- Future research should examine how these disparities in specialty pharmacy use translate into differences in specialty drug adherence and clinical outcomes in the Medicare Part D population.
- Policymakers should reassess the Any Willing Pharmacy (AWP) provision under Medicare Part D, which likely drives the high rates of retail pharmacy use for specialty drug fills in this population.