Characteristics and Treatment Patterns of Patients Initiating Cladribine Tablets: A US Commercial and Medicare Advantage Prescription Drug Claims Analysis

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CONCLUSIONS



- Among 113 patients evaluated from the Optum database, more than half (57.5%) were ≥50 years of age
- 52.2% of the patients were insured through MAPD, and 47.8% had commercial insurance
- Most patients had moderate MS severity (46.9%), followed by low (35.4%) and high (17.7%) severity at baseline



Nearly two-thirds (65.5%) of patients indicated previous use of DMT during the 1-year period before cladribine tablets



Using a payer database, initial insights were identified on the real-world patient characteristics and treatment patterns among US patients receiving cladribine tablets



BACKGROUND

Real-world evidence for cladribine tablets in patients with MS is emerging in the US



OBJECTIVE

• To better understand the characteristics of US patients with commercial or Medicare Advantage insurance who are initiating treatment with cladribine tablets



METHODS

- Commercial and Medicare Advantage Prescription Drug (MAPD) health plan members from the Optum Research Database (ORD) were included if they had ≥1 cladribine tablets claim from 4/1/2019–09/30/2020 (day of cladribine tablets initiation=index date), ≥1 MS diagnosis from 4/1/2018–09/30/2021, continuous insurance 12 months pre- (baseline) and post- (follow-up) index, aged ≥18 years at index, and no pregnancy claims during baseline and follow-up periods
- Data were analyzed descriptively



RESULTS

Patient selection

 Among 201 enrollees with commercial or MAPD insurance with ≥1 pharmacy claim for cladribine tablets during the identification period, 113 met the inclusion criteria (**Table 1**)

Baseline demographic and clinical characteristics (n=113)

- Mean (SD) age was 52.0 (11.6) years, 75.2% of the patients were female, 52.2% had MAPD insurance, and 47.8% had commercial insurance (**Table 2**)
- Most patients had moderate MS severity (46.9%), followed by low (35.4%) and high (17.7%) severity at baseline
- Common comorbidities are shown in Figure 1

Baseline healthcare resource use, relapse, and symptoms (n=113)

- During the 1-year baseline period before cladribine tablets, 9.7% of patients used a cane/walker/hospital bed/ wheelchair, 11.5% had MS-related hospitalizations, and 39.8% had a relapse (Figure 2)
- Common MS symptoms are shown in Figure 3

DMT use prior to cladribine tablets (n=113)

- Nearly two-thirds of patients (65.5%) had a previous (non-cladribine tablets) DMT during baseline (**Table 3**)
 - The most common DMTs were dimethyl fumarate, ocrelizumab, natalizumab, teriflunomide, fingolimod, glatiramer acetate, and subcutaneous interferon-beta 1a (Figure 4)

Table 1. Patient selection

Criteria	Patients Remaining	Patients Excluded
	n (%)	n (%)
Inclusion		
Commercial or MAPD enrollee with ≥1 pharmacy claim for cladribine tablets during the identification period April 1, 2019 through September 30, 2020 (date of the first claim for cladribine tablets is the index date)	201 (100.0)	
≥18 years old during year of index date	201 (100.0)	0 (0.0)
≥12 months of continuous enrollment in the health plan with medical and pharmacy benefits before the index date. The 12-month period before the index date is the baseline period	150 (74.6)	51 (25.4)
≥12 months of CE with medical and pharmacy benefits beginning on the index date. The 12-month period starting on the index date is the follow-up period	120 (80.0)	30 (20.0)
≥1 non-diagnostic ^a medical claim with an MS ICD-10-CM diagnosis code ^b in any position during the baseline or follow-up periods	120 (100.0)	0 (0.0)
Exclusion		
Missing or invalid demographic data (gender or geographic region)	120 (100.0)	0 (0.0)
≥1 claim with an ICD-10-CM or CPT code indicating pregnancy in the baseline or follow-up periods	113 (94.2)	7 (5.8)

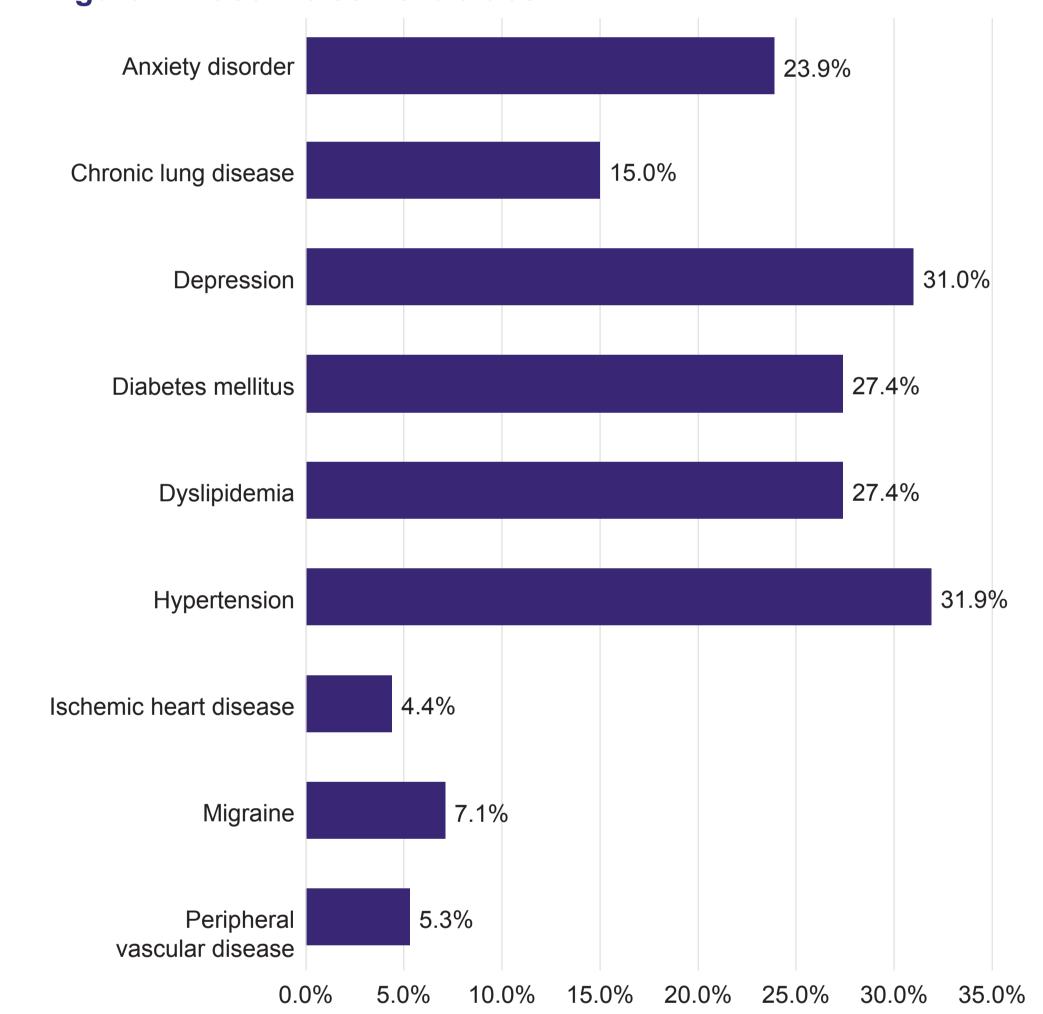
are examples of diagnostic claims. MS diagnosis: ICD-10-CM G35.xxx.

Table 2. Baseline demographics and clinical characteristics

Demographic Characteristic	Total (n=113)
Age, years Mean (SD) Median	52 (11.6) 53
Age groups, n (%) 18-44 years 45-64 years ≥65 years	28 (24.8) 71 (62.8) 14 (12.4)
Sex, n (%) Female Male	85 (75.2) 28 (24.8)
Geographic region, n (%) Northeast Midwest South West	7 (6.2) 20 (17.7) 71 (62.8) 15 (13.3)
Insurance type, n (%) Commercial MAPD	54 (47.8) 59 (52.2)
MS severity level ^a , n (%) Low (0-4) Moderate (5-10) High (11+)	40 (35.4) 53 (46.9) 20 (17.7)
Quan-Charlson comorbidity score Mean (SD) Median	0.82 (1.32) 0.00

^aDeveloped by Nicholas J, et al. *Neurology* 2017;88(16 suppl):P2.052, this algorithm assigns weights to relapse, symptoms (10 groups), DMT utilization (intravenous, oral, and platform [interferon beta-1a, interferon beta-1b, glatiramer acetate]), durable medical equipment, and MS-related hospitalizations. These weights are summed to create a

Figure 1. Baseline comorbidities



^aLaboratory and diagnostic radiology services provided in free-standing (ie, outside of a hospital system or provider office) score and 3 derived severity categories: low (0-4), moderate (5-10, and high (≥11).

Figure 2. Baseline healthcare resource use and relapse

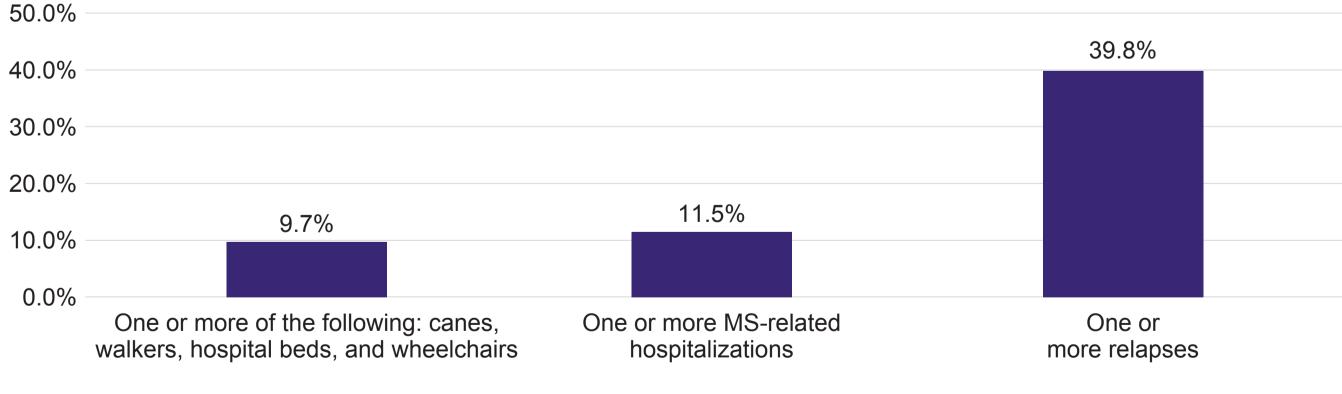


Figure 4. Proportion of DMTs by patients with DMT use in the baseline period (n=74)

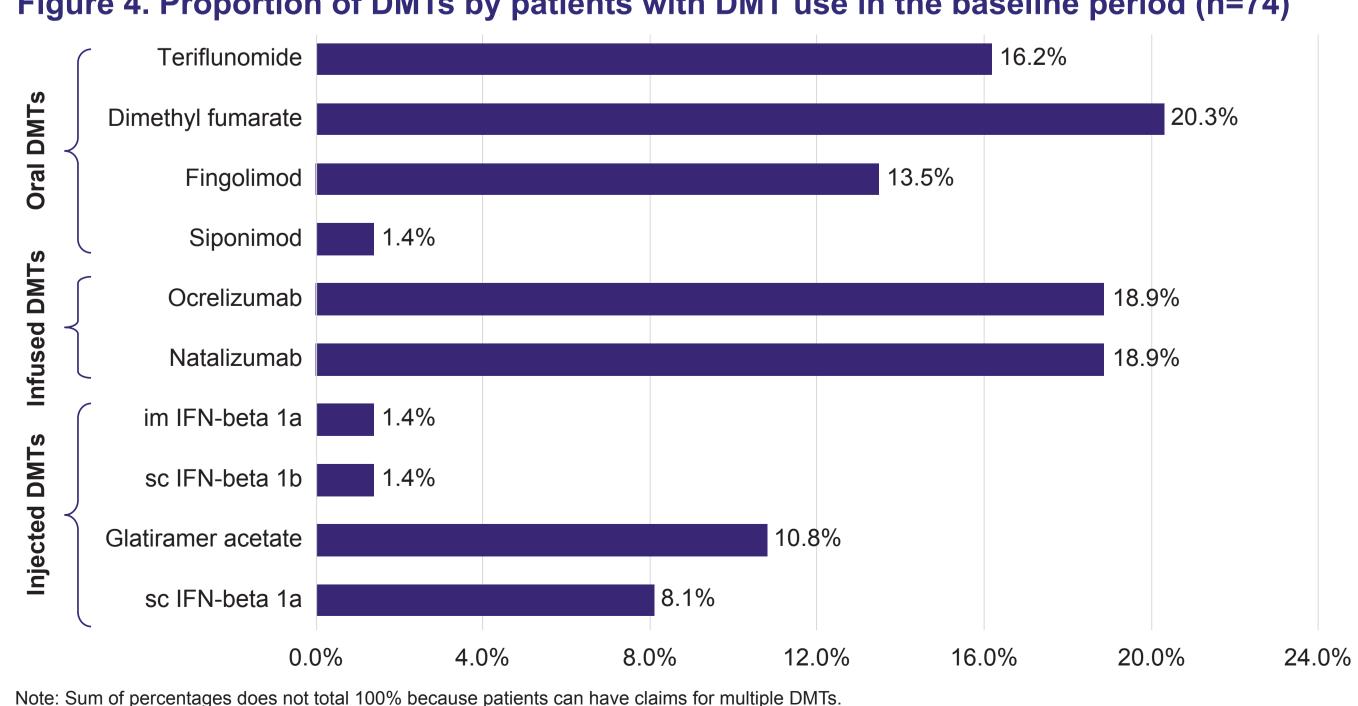


Figure 3. Baseline MS symptoms experienced by patients

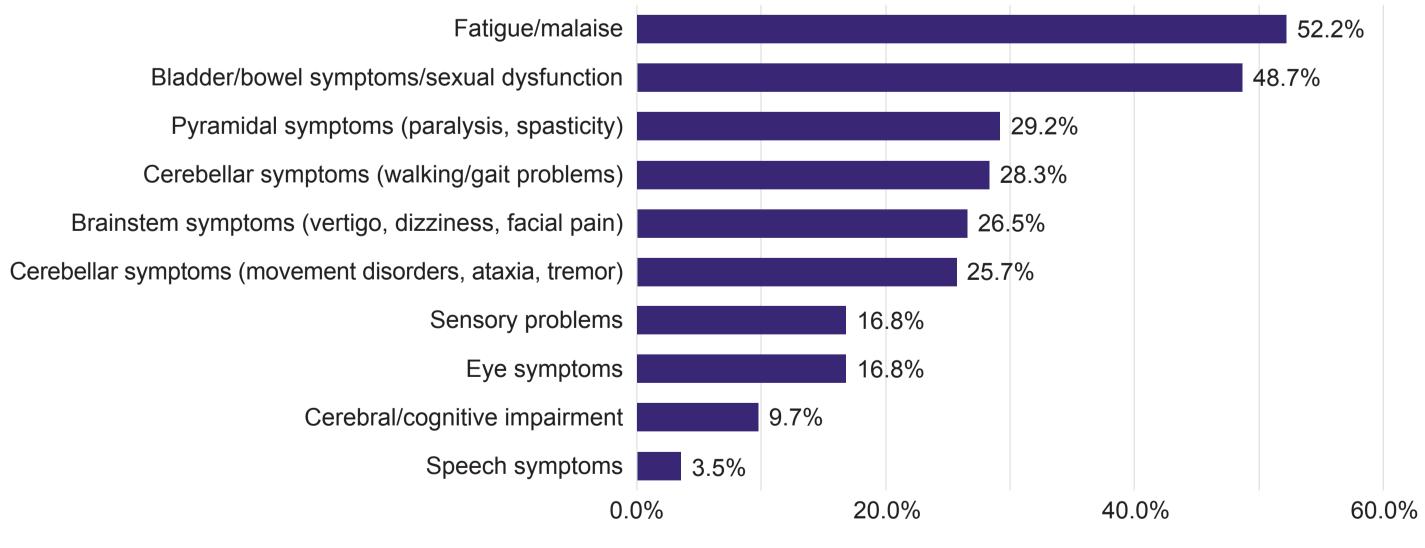


Table 3. DMT use during baseline

Baseline DMTs	Total (n=113)	MS Severity Level			
		Low (n=40)	Moderate (n=53)	High (n=20)	<i>P</i> value
Patients with no DMT use during baseline, n (%)	39 (34.5)	18 (45.0)	14 (26.4)	7 (35.0)	
Patients treated with ≥1 non-cladribine tablets DMT during baseline, n (%)	74 (65.5)	22 (55.0)	39 (73.6)	13 (65.0)	0.176
Number of unique non-cladribine tablets DMTs during baseline					
Mean (SD)	0.73 (0.60)	0.55 (0.50)	0.89 (0.67)	0.65 (0.49)	0.022
Median	1.0	1.0	1.0	1.0	

References: 1. Nicholas J, et al. Neurology 2017;88(16 suppl):P2.052

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