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Characteristics and Treatment Patterns of Patients With Multiple Sclerosis Initiating Cladribine Tablets in the United States

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CONCLUSIONS

In this database of 395 patients with MS, most were female (72.4%) and in urban care settings (80.3%), and approximately half were aged 45-64 years (52.7%)

Approximately 9.6% of patients switched to another DMT in the 2-year follow-up period

Approximately 85% of patients had a history of DMT use among which the most common DMTs were dimethyl fumarate (15.4%), ocrelizumab (13.7%), fingolimod (12.7%), teriflunomide (11.6%), and natalizumab (11.4%)

The insights gained from this study of 395 patients provide a better understanding of the real-world characteristics and care journeys of a diverse population of patients initiating cladribine tablets

BACKGROUND

- There are limited data available examining real-world use of cladribine tablets in patients with MS to inform the decisions of US payers

OBJECTIVE

To better understand the characteristics and treatment journey of US patients with MS initiating cladribine tablets

METHODS

- This study used data from the Komodo Healthcare Map™ database
- Eligibility criteria were: ≥1 MS diagnosis claim between 1/1/2016–5/31/2022; ≥1 claim for cladribine tablets between 3/31/2019–5/31/2022 (initiation date = index); no claim for cladribine infusion between 3/31/2019–5/31/2022; age ≥18 years; and continuous eligibility with healthcare insurance one year before (baseline) and 2 years after (follow-up) cladribine tablets initiation
- Information collected included demographics, clinical characteristics, prior DMTs, and switching during the 2-year follow-up period
- Findings were analyzed descriptively

RESULTS

Baseline demographics

- Among 395 patients meeting eligibility criteria with 2 years of follow-up (**Table 1**):
  - Mean (SD; range) age was 46.4 years (11.5; 20.0-70.0)
  - 72.4% were female
  - 38.0% were White, 10.4% were Black or African American, 0.8% were Asian or Pacific Islander, 3.3% other race, and 47.6% were unknown race
  - 4.8% were Hispanic or Latino, and 58.7% had unknown ethnicity
  - Geographical distribution was 43.0% South, 24.1% Midwest, 22.3% Northeast, and 10.6% West
  - Most patients were in urban (80.3%) versus suburban (8.9%) or rural (5.8%) care settings

Table 1. Baseline demographic characteristics

Demographic characteristic	N=395
Age, years	
Mean (SD)	46.4 (11.5)
Median (IQR)	47.0 (17.0)
Min	20.0
Max	70.0
Age (years), categories, n (%)	
18–30	42 (10.6%)
31–44	128 (32.4%)
45–64	208 (52.7%)
65–74	17 (4.3%)
Patient gender, n (%)	
Female	286 (72.4%)
Male	109 (27.6%)
Patient region, n (%)	
Midwest	95 (24.1%)
Northeast	88 (22.3%)
South	170 (43.0%)
West	42 (10.6%)

RESULTS, CONT.

Table 1. Baseline demographic characteristics, cont.

Demographic characteristic	N=395
Population density, n (%)	
Urban	317 (80.3%)
Suburban	35 (8.9%)
Rural	23 (5.8%)
Unknown	20 (5.1%)
Race, n (%)	
White	150 (38.0%)
Black or African American	41 (10.4%)
Asian or Pacific Islander	3 (0.8%)
Other	13 (3.3%)
Unknown	188 (47.6%)
Ethnicity, n (%)	
Hispanic or Latino	19 (4.8%)
Non-Hispanic or Latino	144 (36.5%)
Unknown	232 (58.7%)

Other baseline characteristics

- Among 395 patients meeting eligibility criteria with 2 years of follow-up (**Table 2**):
  - Healthcare payers were: 75.4% commercial, 12.6% Managed Medicaid, 7.3% Medicare Advantage, and 3.5% Medicare. Year of cladribine tablets initiation was 2019 for 32.2% and 2020 for 67.9%
  - Of the 43 patients on Medicare or Medicare Advantage, 33 (76.6%) were below the age of 65
  - Mean (SD) CCI score was 1.0 (1.5)

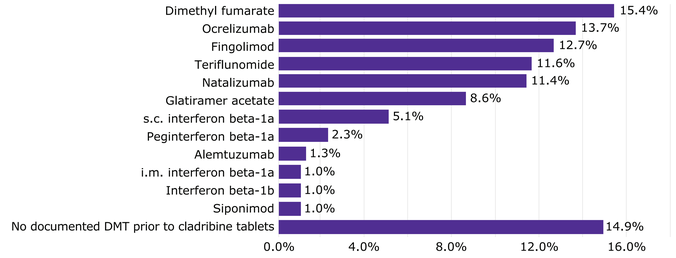
Table 2. Other baseline characteristics

Other characteristics	Value
Cladribine tablets index year, n (%)	
2019	127 (32.2%)
2020	268 (67.9%)
2021	0 (0%)
Healthcare payer channel at index date, n (%)	
Commercial	298 (75.4%)
Managed Medicaid	50 (12.6%)
Medicare	14 (3.5%)
Medicare Advantage	29 (7.3%)
Other (TriCare, Veterans Affairs, etc.)	2 (0.5%)
Unknown	2 (0.5%)
Charlson Comorbidity Index (CCI)	
Mean (SD)	1.0 (1.5)
Median	0
Range	[0–8]

DMT treatment history prior to initiating cladribine tablets

- These data focus on the DMTs prior to cladribine tablets until the longest available look-back period (i.e., 1/1/2016) and are not restricted to the 12-month baseline (**Figure 1**)
- The results showed that 336 patients (85.1%) had a prior DMT before initiating cladribine tablets
- Dimethyl fumarate, ocrelizumab, fingolimod, teriflunomide, and natalizumab were the most common DMTs prior to initiating cladribine tablets

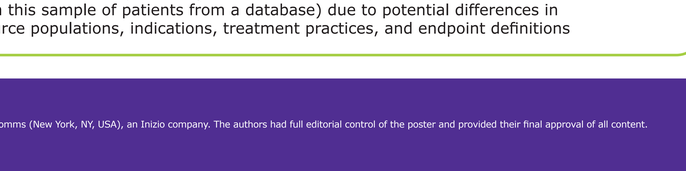
Figure 1. DMT treatment history prior to initiating cladribine tablets (N=395)



DMT treatment history during the 12-month baseline prior to initiating cladribine tablets

- These data focus on DMTs taken during the 12-month baseline period prior to cladribine tablets (**Figure 2**)
- The results demonstrate that 242 patients (61.3%) had a prior DMT before initiating cladribine tablets
- Dimethyl fumarate, ocrelizumab, fingolimod, teriflunomide, glatiramer acetate, and natalizumab were the most common DMTs prior to initiating cladribine tablets

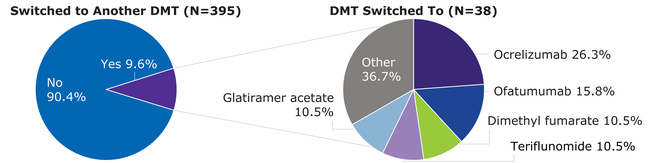
Figure 2. DMT treatment history during the 12-month baseline period prior to initiating cladribine tablets (N=395)



Switching after cladribine tablets

- Among the 395 patients who received cladribine tablets, 38 (9.6%) had evidence of another DMT and no additional claim for cladribine tablets in the follow-up period (**Figure 3**)
  - Of these 38 patients, the majority switched to ocrelizumab (26.3%), ofatumumab (15.8%), dimethyl fumarate (10.5%), teriflunomide (10.5%), and glatiramer acetate (10.5%)
- The mean (SD; median) time from cladribine initiation to switch to a subsequent DMT was 13.3 (7.2; 14.7) months

Figure 3. Switches after cladribine tablets



LIMITATIONS

Limitations of this study include the small sample size, the lack of a control group, and inaccurate or missing data

The observed results may not be generalizable to other patient populations (ie, from this sample of patients from a database) due to potential differences in data source populations, indications, treatment practices, and endpoint definitions

Abbreviations: CCI, Charlson Comorbidity Index; **DMT**, disease-modifying therapy; **i.m.**, intramuscular; **IQR**, interquartile range; **max**, maximum; **min**, minimum; **MS**, multiple sclerosis; **s.c.**, subcutaneous; **SD**, standard deviation; US, United States.

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