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DMT49

Real-World Utilization of Ofatumumab for Treatment of Multiple Sclerosis (MS): Trends Nine Months after FDA Approval

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SUMMARY

1 **This retrospective study provides the first comprehensive look at ofatumumab (OMB) initiation over the first 9-months after Food and Drug Administration (FDA) approval, using a nationally representative claims database in the United States (US).**

2 **Over the 9 months after FDA approval, OMB use appeared to increase in patients who were naive to disease-modifying therapies (DMTs) at baseline.**

INTRODUCTION

- Ofatumumab (OMB) received United States (US) Food and Drug Administration (FDA) approval in August 2020 as the first B-cell therapy to be self-administered by a once-monthly subcutaneous autoinjector pen for relapsing forms of multiple sclerosis (MS).
- The FDA approval was based on the efficacy and safety of OMB demonstrated in the two phase III ASCLEPIOS trials.[1]
- This study provides the first comprehensive look at real-world OMB initiation, over the first 9-months after FDA approval, using a nationally representative claims database.

OBJECTIVE

- To describe patient demographic and clinical characteristics, and prior disease-modifying therapy (DMT) use among patients with MS initiating OMB at 3-, 6-, and 9- months after FDA approval in the US.

METHODS

STUDY DESIGN

- This was a retrospective cohort study of patients with MS initiating OMB in the US using IQVIA's open-source pharmacy and medical claims databases (IQVIA LRx-Dx).

INCLUSION AND EXCLUSION CRITERIA

- Adult patients (≥18 years) with a diagnosis of MS, and a prescription of OMB from August 2020 to May 2021, were included.
- The index date was defined as the first OMB prescription claim. DMT-naïve patients were defined as no DMT prescribed 12 months prior to index date (baseline period).

ANALYSES

- Separate descriptive analyses were conducted at 3-months (Oct 2020), 6-months (Feb 2021) and 9-months (May 2021) after FDA approval.
- Data for categorical variables were summarized as counts and percentages while those for continuous variables were presented as means and standard deviations (SD).

POPULATION MEASURES

- Patient demographics
- Baseline MS relapse (based on a validated algorithm[2])
- Previous year's treatment status (DMT naive or experienced)
- Prior DMTs received
- Median time of washout period
- Baseline disability levels (mild, moderate, or severe, based on claim-based disability score[3])
- Baseline MS-related symptoms
- Comorbidities

ETHICS

- This study is compliant with HIPPA, and no identifiable or protected health information was extracted for the study

RESULTS

- The number of patients initiating OMB increased from 243 at 3-months to 2,101 at 9-months.

BASELINE DEMOGRAPHIC CHARACTERISTICS

- The mean (SD) age of patients on OMB was 47.6 (12.2) years at 3-months, 48.2 (12.3) years at 6-months, and 48.3 (12.2) years at 9-months. The mean age of patients recruited in ASCLEPIOS I & II trials was 38-39 years.
- Most patients were female (3-month: 74.5%, 6-months: 72.5%, and 9-months: 74.0%).
- The proportions of patients ≥55 years were 30.0% at 3-months, 32.7% at 6-months, and 33.4% at 9-months follow-up.

BASELINE CLINICAL CHARACTERISTICS

- The five most common comorbidities were osteoarthritis, hypertension, depression, dyslipidemia, and chronic pain (Table 1).
- Relapse in the prior year was experienced by 27.6% of 3-month patients, 19.2% of 6-month patients, and 18.3% of 9-month patients. (Table 1).
- Common MS-related symptoms included fatigue, sensory problems, anxiety, urinary track infection, eye symptoms, and muscle weakness.

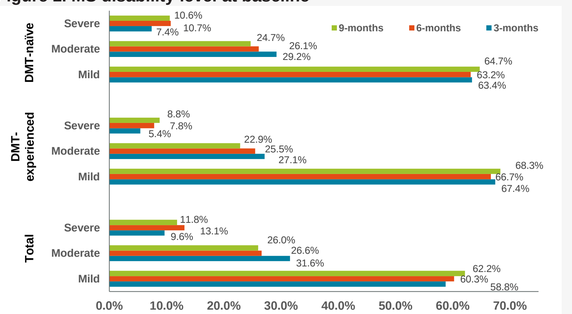
Table 1. Baseline clinical and treatment characteristics

	3-months			6-months			9-months		
	Total (N=243)	DMT-naïve (n=114)	DMT-experienced (n=129)	Total (N=1,015)	DMT-naïve (n=556)	DMT-experienced (n=459)	Total (N=2,101)	DMT-naïve (n=1,226)	DMT-experienced (n=875)
Charlson Comorbidity Index									
Mean (SD)	0.4 (0.8)	0.4 (1.0)	0.3 (0.7)	0.3 (0.8)	0.4 (0.9)	0.3 (0.7)	0.3 (0.8)	0.4 (0.9)	0.3 (0.7)
Comorbidities, %									
Osteoarthritis	32.5	35.1	30.2	31.3	30.6	32.2	32.2	33.8	29.8
Hypertension	15.2	14.9	15.5	16.7	17.1	16.3	18.2	19.1	17.0
Depression	10.7	14.0	7.8	12.2	12.6	11.8	13.5	13.5	13.5
Dyslipidemia	9.9	6.1	13.2	11.3	10.3	12.6	11.4	11.5	11.3
Chronic pain	9.9	13.2	7.0	7.9	9.4	6.1	8.8	9.6	7.5
Sleep disorder	8.6	7.0	10.1	9.3	9.4	9.2	9.9	9.9	9.9
MS Relapse in the previous year									
Patients with a relapse, n (%)	67 (27.6)	28 (24.6)	39 (30.2)	195 (19.2)	112 (20.1)	83 (18.1)	384 (18.3)	233 (19.0)	151 (17.3)
MS-related symptoms, %									
Fatigue	12.3	11.4	13.2	11.1	11.2	11.1	11.0	11.2	10.9
Sensory problem	11.9	14.0	10.1	14.0	15.8	11.8	14.1	16.4	11.0
Anxiety	11.5	9.6	13.2	9.8	9.4	10.2	12.1	13.1	10.7
Eye symptom	9.1	7.9	10.1	8.2	9.4	6.8	7.7	8.2	6.9
Muscle weakness	5.3	6.1	4.7	6.3	7.6	4.8	5.7	5.9	5.5
UTI	9.1	9.6	8.5	7.0	5.6	8.7	7.3	6.6	8.3

DMT, Disease-modifying therapies; MS, Multiple Sclerosis; SD, Standard deviation; UTI: Urinary tract infection

- Most patients initiating OMB in the real world had a mild level of disability[3] at all time points (Figure 1).

Figure 1. MS disability level at baseline

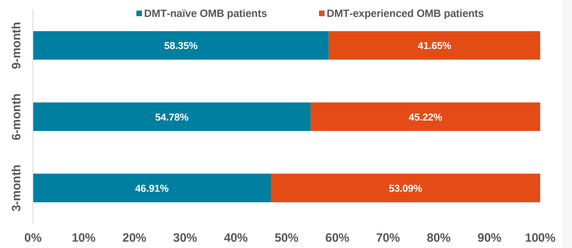


DMT, Disease-modifying therapies; MS, Multiple Sclerosis; SD, Standard deviation

BASELINE TREATMENT CHARACTERISTICS

- At 3-months, 6-months and 9-months, 46.9%, 54.8% and 58.4% patients, respectively were DMT-naive in prior year and 53.1%, 45.2% and 41.7% patients, respectively had DMT exposure in prior year (Figure 2).

Figure 2. Prior 1-year DMT exposure



DMT, Disease-modifying therapies; MS, Multiple Sclerosis; SD, Standard deviation

- For all three time points, oral DMT therapies were most common, followed by intravenous (IV) infusions, then self-injectables during the 12-month pre-index period among DMT-experienced patients (Table 2).
- Ocrelizumab was the most common DMT used prior to initiation of OMB, followed by DMF and teriflunomide (Table 2).

Table 2. DMT received in 12-months pre-index period

	3-months (N=129)		6-months (N=459)		9-months (N=875)	
	%	Median WP, days	%	Median WP, days	%	Median WP, days
Oral	52.7	-	51.6	-	50.6	-
DMF	18.6	34	23.3	62	19.8	63
Fingolimod	7.0	39	8.3	38	8.3	52
Teriflunomide	19.4	48	14.8	51	16.3	64
Cladribine	0.0	-	0.4	98	0.6	217
Siponimod	7.0	98	5.2	93	5.0	75
Ozanimod	0.0	-	0.4	56	0.2	56
DRF	0.8	71	2.0	26	2.7	48
IV Infusion	32.6	-	33.3	-	32.2	-
Natalizumab	11.6	35	8.3	53	8.2	46
Alemtuzumab	0.0	-	0.0	-	0.1	301
Ocrelizumab	20.2	168	24.2	174	23.4	179
Rituximab	0.8	278	0.9	191	0.6	207
Injectable	19.4	-	19.0	-	21.1	-
GA	11.6	31	11.5	37	13.1	37
INF-β	7.8	44	7.8	49	8.6	48

DMF, Dimethyl fumarate; DMT, Disease-modifying therapies; DRF, Diroximel fumarate; GA, Glatiramer acetate; INF- β, Interferon-beta; IV, intravenous; WP, washout period

DISCUSSION & LIMITATIONS

- This study suggests that OMB may be increasingly used as an early therapy. Additional research is needed to support this hypothesis.
- Due to the way of data cut, there are patient overlaps in the cohorts (3mo is part of 6mo and 9mo), however, removing the overlap patients likely results in more obvious differences between the cohorts.
- Coding errors or omission is possible. The study results are from a short observational period, so should not be generalized.

CONCLUSIONS

- Further understanding the patient profile for those who initiated ofatumumab in real-world settings may help inform treatment decisions. Future studies on the long-term effectiveness of OMB are needed.

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