Treatment Patterns and Reasons for Switching Among US Patients With Multiple Sclerosis Taking the Glatiramer Acetate Class of Products

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INTRODUCTION

- Multiple sclerosis (MS) is a debilitating neurological disorder affecting over 2.3 million people worldwide[1]
- FOGA® 20 mg/mL, the first US Food and Drug Administration (FDA)-approved generic followed by Mylan's generic glatiramer acetate in October, 2017.[2,3]
- Persistence data on FOGA are relevant to inform optimal clinical treatment decisions when different treatment choices exist, including branded GA (branded glatiramer acetate [GA] 20 mg/mL or 40 mg/mL [COP20 or COP40]), FOGA, and other disease-modifying therapies (DMTs)

OBJECTIVE

- To characterize treatment patterns and reasons for switching in patients with MS taking GA.

METHODS

Study Design

- Two data sources were used for these analyses.

Claims Data

- 1,957 adult MS patients with ≥1 pharmacy claim or written prescription for FOGA (FOGA 20 mg/mL) between June 1, 2015 and September 30, 2017, who were sourced from OM1, a large, geographically representative US health claims database linked with electronic medical records
- All patients were followed before and after the index date (first pharmacy claim for FOGA during the identification period)
  - The first switch from FOGA to other DMTs was evaluated post-index, and FOGA restarts and switches to a second DMT were also evaluated
  - Persistence was defined as remaining on FOGA
- Discontinuation of FOGA was defined as a gap in therapy (i.e. days without FOGA after the end of the last fill) of 60 days, or switch to another DMT
  - Restart was defined as a fill of FOGA after the discontinuation period
  - Reversal status in was available for some but not all records. All known reversed FOGA index claim records (see Patient Disposition) and any subsequent reversed records were excluded from the analysis. Discontinuations and switches, therefore, may appear in the data in the absence of patient exposure to treatment

Chart Audit

- A cross-sectional online chart audit from 209 neurologists in February 2019 of 1003 US patients who switched to a new DMT within the prior 3 months, of which 767 charts were analyzed as first switches from initial DMT

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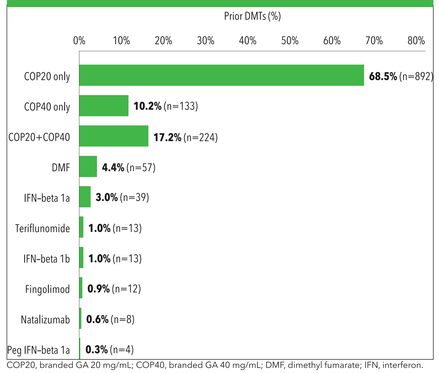
RESULTS

Patient Disposition

- 1957 patients had a FOGA index date during the identification period (75% female, mean age 51 years; insurance coverage: 55% commercial, 75% Medicaid, 24% Medicare, 5.2% >1 type, 8% unknown) with median 1.36 years follow-up
- A total of 655 patients (33.5%) had no record of another DMT (i.e., were treatment naïve) prior to their FOGA index date
- Of the 1302 patients (66.5%) who had at least 1 DMT prior to the index date, the most commonly recorded prior DMTs were as follows (patient can be counted in multiple DMTs) (Figure 1):

Figure 1. DMTs Prior to Index Date



COP20, branded GA 20 mg/mL; COP40, branded GA 40 mg/mL; DMF, dimethyl fumarate; IFN, interferon.

- An additional 166 patients (excluded from the analysis) had a reversed FOGA claim
  - 41% had no other DMT claim, and 29% and 23% had COP20 and COP40 claims, respectively

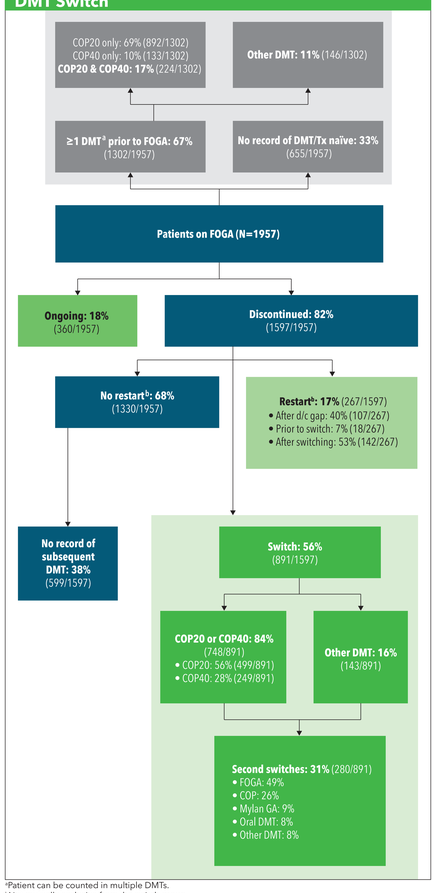
FOGA Discontinuations and Restarts

- Of the 1957 patients in the study cohort, 360 patients (18%) remained on FOGA. 1597 patients (82%) discontinued FOGA; of these, 267 (17%) restarted FOGA during follow-up, and 599 (38%) had no record of any subsequent DMT (Figure 2)

Initial Switch From FOGA

- 891 patients (56%) switched to another DMT from FOGA (Figure 2)
  - Of the patients who switched, 748 switched to COP20 or COP40

Figure 2. FOGA: Prior DMT, Discontinuation, and DMT Switch



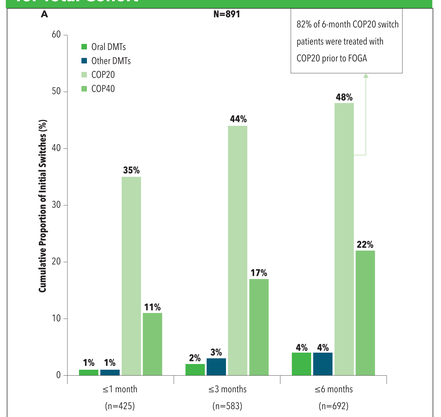
[a]Patient can be counted in multiple DMTs.
[b]Not mutually exclusive from the switch group.
COP20, branded GA 20 mg/mL; COP40, branded GA 40 mg/mL; d/c, discontinuation; DMT, disease-modifying therapy; FOGA, follow-on glatiramer acetate; Tx, treatment.

DMT Switches Within 6 Months of FOGA Index Date

- Initial DMT switches from FOGA were calculated over 6 months, cumulatively, starting from switches that occurred within the first month. By 6 months, 78% (n=692) of all initial switches (n=891) had occurred, with 90% (n=621) switching to COP20 or COP40 (Figure 3A)
- Stratification of discontinuation and switch rates by prior COP use (Figure 3B) demonstrated that:
- Initial FOGA discontinuation was higher for patients who had prior COP use (COP20: 83.7%; COP40: 88.7%; both: 89.3%) than for patients with no prior COP use (75.1%)
  - Switches occurred more frequently in patients with prior COP use (53.2%) than in those with no prior use (31.9%)
  - Patients who had prior use of both COP20 and COP40 had a higher proportion of post-index switches (66.1%) than did patients with COP20 only (50.6%) or COP40 only (49.6%)
- Patients with prior COP experience showed reduced time to initial switch (Figure 3C)

Figure 3. (A) DMT Switches Within 6 Months of FOGA Index Date. (B) Discontinuation and Switch Rates by Prior COP Use. (C) Median Time to Discontinuation, Restart of Initial Switch by Prior DMT and for Total Cohort

A



B

Rates (%)	Prior COP20	Prior COP40	Prior Both COP	No Prior COP
FOGA d/c	83.7	88.7	89.3	75.1
Switch	50.6	49.6	66.1	31.9

C

Median Days (range)	Prior COP20	Prior COP40	Prior Both COP	No Prior COP	Total
To FOGA d/c	30 (11–131)	30 (5–55)	30 (5–98)	30 (30.0–107.5)	30 (13–113)
To restart	109 (41–213)	67 (23.5–114.5)	79 (42–144)	94 (37–187)	96 (39–196)
To initial switch	28 (6–152)	28 (6–132)	22 (5–117)	79 (14–220)	35 (7–157)

COP20, branded GA 20 mg/mL; COP40, branded GA 40 mg/mL; d/c, discontinuation; DMT, disease-modifying therapy; FOGA, follow-on glatiramer acetate.

FOGA Restarts and Second Switches

- Of the 1957 patients in the cohort, 360 (18%) remained on FOGA, 1330 (68%) discontinued and did not restart FOGA, and 267 (14%) discontinued and restarted FOGA (Figure 2)
  - Of the 267 patients who restarted FOGA, 107 (40%) restarted after a gap (no other DMT), 18 (7%) restarted after a gap and prior to another DMT switch, and 142 (53%) restarted after another DMT
- 280 patients (31% of switchers) had >1 switch; second switch DMTs are shown in Figure 2

Chart Audit

- From the chart audit, 102, 34, and 73 patients were on branded GA, FOGA, and generic GA, respectively, as the first switch from initial DMT
- Of these patients, 26% on branded GA, 59% on FOGA, and 38% on generic GA took another GA product as their initial DMT
- Reasons for switching from branded GA to generic GA (see Figure 4A) were primarily related to insurance/copay (71%)
- Reasons for switching from FOGA or generic GA to branded GA (see Figure 4B) were varied, including patient request, tolerability, dosing profile, insurance/copay, and efficacy (7–32%)

Figure 4a. Reasons for Switching from branded GA to FOGA/Generic GA (n=34). 4b. Reasons for Switching from FOGA/Generic GA to branded GA (n=19)

SUMMARY AND CONCLUSIONS

- The majority of patients with a FOGA index date were previously treated with COP20
- 82% discontinued FOGA within a median of 30 days and 68% did not restart FOGA
  - In the discontinuation cohort, 56% switched to another DMT, 17% restarted FOGA, and 38% discontinued with no record of any DMT in the follow-up period
  - At the initial switch, 84% switched to COP20 or COP40
  - At the second (or subsequent) switch, 49% of switches were to FOGA
- The majority of patients switched from branded GA to FOGA/generic GA specifically due to issues surrounding the lower cost of generics.
- However, patients switched onto branded GA from FOGA/generic GA due to more clinically related issues such as efficacy and tolerability in addition to cost.
- The reasons for initial and subsequent switches need to be further investigated

References

1. Browne P et al. *Neurology* 2014;83:1022–1024.
2. Grossman I et al. *Ann NY Acad Sci* 2017;1407:75–89.
3. Sandoz receives FDA approval for FOGA™ as the first generic competitor to MS therapy branded GA® 20 mg [press release]. https://www.us.sandoz.com/news/media- releases/Sandoz-therapy-2. Accessed August 13, 2018.

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