Real-World Switching Patterns Among US Generic Glatiramer Acetate Multiple Sclerosis Patients

P2-099

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INTRODUCTION

- Multiple sclerosis (MS) is a debilitating neurological disorder affecting over 2.3 million people worldwide[1]
- Glatopa® 20 mg/mL, the first US Food and Drug Administration (FDA)-approved generic follow-on glatiramer acetate (FOGA) for MS, became available in April, 2015[2,3]
- Persistence data on FOGA are relevant to inform optimal clinical treatment decisions when different treatment choices exist, including COPAXONE® (branded glatiramer acetate [GA] 20 mg/mL or 40 mg/mL [COP20 or COP40]), FOGA, and other disease-modifying therapies (DMTs)

OBJECTIVE

- To measure persistence to, discontinuation of, and patterns of switching from FOGA

METHODS

Study Design

- **Group 1:** The study included 95 adult MS patients with ≥1 pharmacy claim for FOGA between June 1, 2015 and June 31, 2016; these patients were sourced from the Optum claims database and were Medicare Advantage enrollees with Part D coverage. The Optum database contains medical and pharmacy claims across a geographically diverse, and fairly representative US patient population
- **Group 2:** Also included in a separate analysis were 1957 adult MS patients with ≥1 pharmacy claim or written prescription for FOGA (Glatopa 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
- For both aforementioned groups, 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 at least 30 days (Group 1), 60 days (Group 2), or switch to another DMT
  - Restart was defined as a fill of FOGA after the discontinuation period
- Reversal status in Group 2 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

RESULTS

Patient Disposition (Group 1)

- 95 patients were included in the analysis (76% female; mean age 61 years; mean [±SD] 428±116 days of follow-up)
- 88% had a fill for COP20 and 5% for COP40 in the 6 months prior to the index date

Persistence on FOGA (Group 1)

- 55 patients (58%) were non-persistent, either discontinuing with no evidence of another therapy or switching to another therapy
- Mean (±SD) persistence of the total cohort was 241±184 days
  - Among 40 patients remaining on FOGA: 412±122 days
  - Among 55 non-persistent patients: 112±101 days

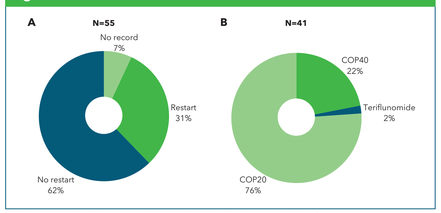
FOGA Discontinuations and Restarts (Group 1)

- Of the 55 patients who discontinued FOGA, 4 (7%) had no record of any subsequent DMT during follow-up, 17 (31%) restarted FOGA, and 34 (62%) did not restart FOGA (**Figure 1A**)

Initial Switch From FOGA (Group 1)

- 41 patients (43%) switched to another DMT from FOGA (**Figure 1B**)
  - Of the patients who switched, 31 (76%) and 9 (22%) switched to COP20 and COP40, respectively, and 1 (2%) switched to teriflunomide

Figure 1. (A) FOGA Restarts and (B) Initial Switch Medications

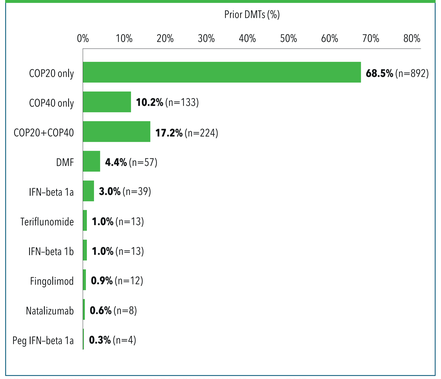


COP20, COPAXONE 20 mg/mL; COP40, COPAXONE 40 mg/mL; FOGA, follow-on glatiramer acetate.

Patient Disposition (Group 2)

- 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 2**):

Figure 2. DMTs Prior to Index Date



COP20, COPAXONE 20 mg/mL; COP40, COPAXONE 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

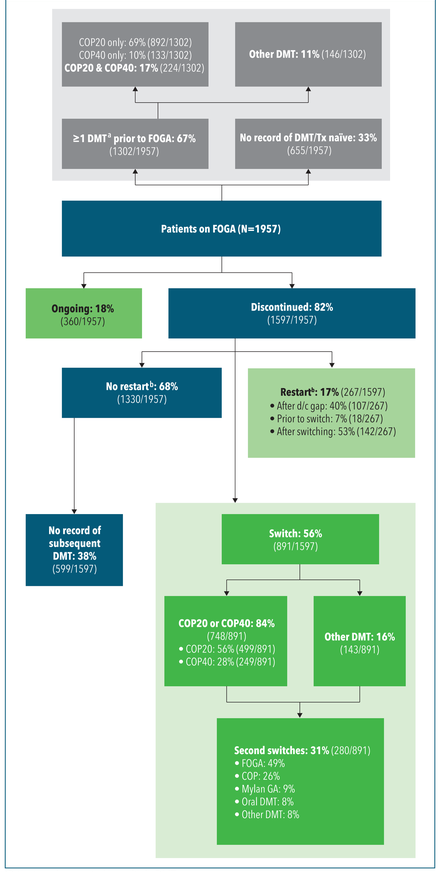
FOGA Discontinuations and Restarts (Group 2)

- 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 3**)

Initial Switch From FOGA (Group 2)

- 891 patients (56%) switched to another DMT from FOGA (**Figure 3**)
  - Of the patients who switched, 748 switched to COP20 or COP40

Figure 3. FOGA: Prior DMT, Discontinuation, and DMT Switch



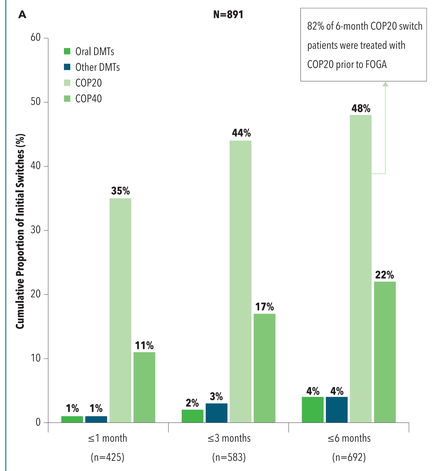
[a]Patient can be counted in multiple DMTs.
[b]Not mutually exclusive from the switch group.
COP20, COPAXONE 20 mg/mL; COP40, COPAXONE 40 mg/mL; d/c, discontinuation; DMT, disease-modifying therapy; FOGA, follow-on glatiramer acetate; Tx, treatment.

DMT Switches Within 6 Months of FOGA Index Date (Group 2)

- 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 4A**)
- Stratification of discontinuation and switch rates by prior COP use (**Figure 4B**) 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 4C**)

Figure 4. (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, COPAXONE 20 mg/mL; COP40, COPAXONE 40 mg/mL; d/c, discontinuation; DMT, disease-modifying therapy; FOGA, follow-on glatiramer acetate.

FOGA Restarts and Second Switches (Group 2)

- 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 3**)
  - 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 3**

SUMMARY AND CONCLUSIONS

- The majority of patients in both groups with a FOGA index date were previously treated with COP20
- In Group 1, among the 58% of patients who were non-persistent, the initial DMT switch typically occurred within ~3–4 months and most (76%) switched to branded GA, primarily COP20
- In Group 2, 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
- These results are consistent across multiple data sources, including Medicare and commercial patient populations
- Further studies are needed to confirm these observations for other FOGA products and doses
- The reasons for initial and subsequent switches need to be investigated
- Reversals were identified to be relevant to analyses of FOGA utilization and require further investigation

Acknowledgments

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Disclosures

Jyotsna Kasturi, Jessica Alexander, Rinat Ariely and **Michaela Vardi:** Employees of Teva Pharmaceuticals.
Sigal Melamed-Gal: Employee of Teva Pharmaceuticals at the time of the study.
Zhaohui Su, Thomas Brecht, and **Allison Bryant:** Employees of OM1.
Erin Hulbert: Employee of OptumInsight.

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