Patient Utilization and Switching Patterns of Patient Assistance Programs (PAPs) for Monoclonal Antibodies (mAbs) Targeting the Calcitonin Gene-Related Peptide (CGRP) Pathway for Migraine Prevention: A Retrospective US Cohort Study

Karen M. Stockl,[1] Jasjit K. Multani,[1] Robert Urman,[2] Mark E. Bensink,[3] Rolin L. Wade,[1] Ani C. Khodavirdi,[2] Jingsong Lu,[1] Karminder Gill[2]

[1]IQVIA, Falls Church, VA, USA; [2]Amgen Inc., Thousand Oaks, CA, USA; [3]Benofit Consulting, Brisbane, QLD, Australia

INTRODUCTION

- Manufacturers offer patient assistance programs (PAPs) such as free trial, bridge, copay card, eVoucher, and denial conversion programs to reduce out-of-pocket costs for patients.
- Among US retail pharmacy transactions during 2017 through 2019, programs offered by US manufacturers were concentrated among a few unique brand products and provided a median per claim offset of $51, covering approximately 87% of patient out-of-pocket costs.[1]
- For migraine prevention, some form of PAP is provided by the manufacturers for the four monoclonal antibodies (mAbs) targeting the calcitonin gene-related peptide (CGRP) pathway. These include Amgen for Aimovig® (erenumab-aooe), Teva for Ajovy® (fremanezumab-vfrm), Lilly for Emgality® (galcanezumab-gnlm) and Lundbeck for Vyepti® (eptinezumab-jjmr).[2-5]
- Prescription claims processed using these discount programs may be billed and paid outside of the patient's regular prescription drug benefit without producing a visible record in adjudicated insurance claims databases.
- Studies that leverage administrative claims databases may have incomplete or missing data which could result in misclassification of exposure to anti-CGRP pathway mAbs.[6,7]

OBJECTIVE

- To describe the utilization and switching patterns of PAPs among patients treated with subcutaneously-administered anti-CGRP pathway mAbs for migraine prevention

METHODS

Study design

- Descriptive, retrospective cohort study using open source claims data from the IQVIA Longitudinal Access and Adjudication Database (LAAD) and medical claims database (Dx)

Study timeframes

- Study period: May 17, 2017 through April 30, 2021
- Index period: May 17, 2018 through October 31, 2020
- Index date: Date of first claim for erenumab, fremanezumab, or galcanezumab during the index period
- Pre-index period: 360 days prior to index date
- Post-index period: 180 days after and including the index date

Patient identification criteria

- ≥1 claim for erenumab, fremanezumab, or galcanezumab during the index period (eptinezumab was not included due to limited data available at the time of the analysis)
- ≥18 years of age on index date
- Use of a pharmacy that consistently contributed data during the 180-day post-index period
- ≥2 medical claims (any cause) ≥30 days apart within the 360-day pre-index period
- Without any of the following data quality issues: missing age, missing sex, or having claims for ≥2 distinct anti-CGRP pathway mAbs on index date

Payer stratification

- Anti-CGRP pathway mAb claims, including those from PAPs, were stratified by payer and further categorized as visible or non-visible based on whether the claim would be expected to produce a record in adjudicated insurance claims databases.
  - Visible payer types: commercial, copay card, eVoucher
  - Non-visible payer types: free trial program, bridge program, denial conversion, cash

Study measures and analysis

- Demographics and index payer type were measured on the index date.
- Clinical characteristics were evaluated during the 360-day pre-index period.
- Use and switching of PAPs and payers were measured during the 180-day post-index period.
- Sankey diagrams were generated for each index medication to visualize payer conversion patterns at 7 monthly time intervals (Day 0, 1-30, 31-60, 61-90, 91-120, 121-150, and 151-180).

RESULTS

Figure 1. Percent of patients with a non-visible payer at index

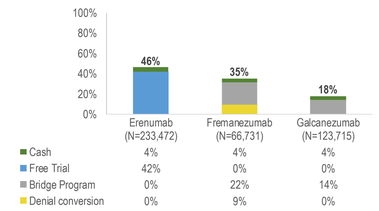


Figure 2. Post-index switch from a non-visible payer to a visible payer

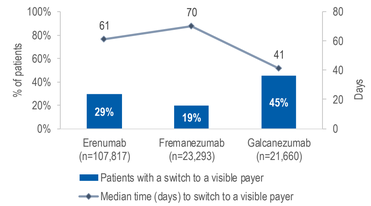


Figure 3. Post-index switch from a commercial payer to another payer

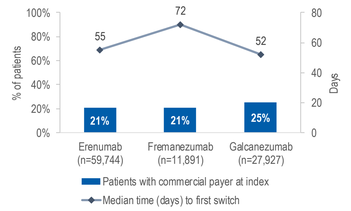
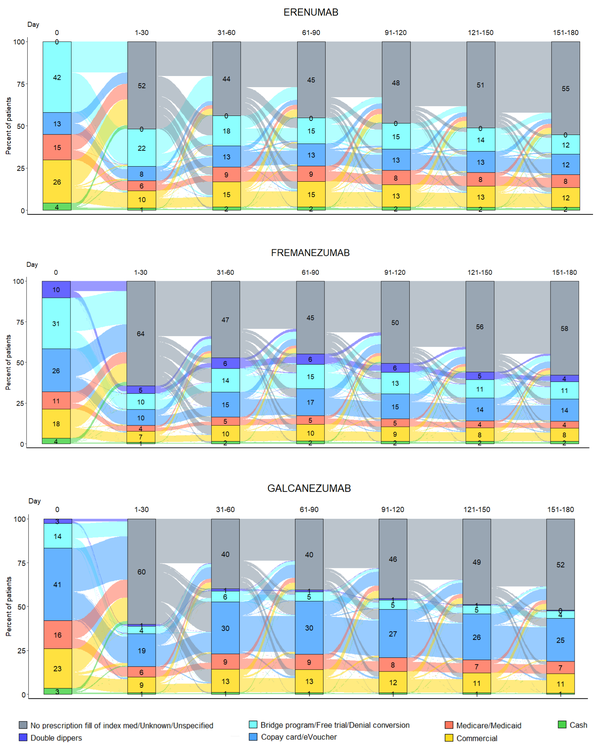


Table 1. Patient demographics and clinical characteristics

	Erenumab N=233,472	Fremanezumab N=66,731	Galcanezumab N=123,715
Age			
Mean (SD)	47.4 (14.0)	46.1 (13.4)	45.9 (13.7)
Median	47	46	46
Sex, n (%)			
Female	200,754 (86.0)	57,918 (86.8)	105,843 (85.6)
Geographic region (n, %)			
Northeast	38,151 (16.3)	11,437 (17.1)	17,779 (14.4)
Midwest	49,003 (21.0)	11,501 (17.2)	26,404 (21.3)
South	98,535 (42.2)	30,370 (45.5)	57,341 (46.3)
West	40,653 (17.4)	11,947 (17.9)	19,923 (16.1)
Payer type (n, %)			
Cash	9,981 (4.3)	2,390 (3.6)	4,325 (3.5)
Commercial	59,744 (25.6)	11,891 (17.8)	27,927 (22.6)
Medicare	30,936 (13.3)	6,120 (9.2)	16,129 (13.0)
Medicaid	4,334 (1.9)	911 (1.4)	3,702 (3.0)
Patient assistance program	128,411 (55.0)	45,406 (68.0)	71,614 (57.9)
Co-pay card[1]	30,556 (13.1)	5,213 (7.8)	5,956 (4.8)
eVoucher	0 (0)	12,376 (18.6)	44,924 (36.3)
Denial conversion	0 (0)	6,052 (9.1)	0 (0)
Bridge program	0 (0)	14,851 (22.3)	17,335 (14.0)
Free trial program	97,836 (41.9)	0 (0)	0 (0)
Double dippers[2]	19 (0.01)	6,914 (10.4)	3,399 (2.8)
Unspecified/unknown	66 (0.03)	13 (0.02)	18 (0.01)
Most frequent (≥20% of patients) comorbid conditions, (n, %)			
Hypertension	50,359 (21.6)	13,042 (19.5)	25,668 (20.8)
Generalized anxiety	49,792 (21.3)	13,875 (20.8)	26,644 (21.5)
Depression	47,190 (20.2)	12,675 (19.0)	23,916 (19.3)
Chronic pain/fibromyalgia	49,288 (21.1)	12,305 (18.4)	21,158 (17.1)
Pre-index use of anti-migraine treatments (n, %)			
Acute treatments	205,096 (87.9)	58,502 (87.7)	108,525 (87.7)
Non-migraine specific preventive treatments	200,111 (85.7)	56,500 (84.7)	104,886 (84.8)

[1]Patients who had a claim with a copay card and another payer type (e.g., commercial) were classified as copay card.
[2]Double dippers included patients with more than one patient assistance program.

Figure 4. Payer switch patterns during the post-index period



SUMMARY OF KEY RESULTS

- The majority of patients (55% erenumab, 68% fremanezumab, and 58% of galcanezumab) received their first anti-CGRP pathway mAb prescription through a PAP (Table 1).
- Non-visible payers were billed for 46% erenumab, 35% fremanezumab, and 18% galcanezumab index claims (Figure 1).
- Among patients with non-visible index payers, switch to a visible payer occurred in 29% erenumab, 19% fremanezumab, and 45% galcanezumab patients in the post-index period (Figure 2).
  - Median time to switch from non-visible to visible payer was 61, 70, and 41 days, respectively.
  - Mean (SD) number of claims prior to switch was 2.0 (1.2), 2.0 (1.3), and 1.6 (1.1), respectively.
- Among patients with a commercial index payer, a switch to another payer occurred in 21% of erenumab patients, 21% of fremanezumab patients, and 25% of patients on galcanezumab in the 180-day post-index period (Figure 3).
  - Median time from index commercial payer to first payer switch was 55, 72, and 52 days, respectively.
  - Mean (SD) number of refills prior to switch was 3.4 (1.8), 3.2 (1.8), and 3.4 (1.8), respectively.
- Switching between payers was frequent over the 180-day post-index period as illustrated in the Sankey diagrams (Figure 4).
- Switching from index anti-CGRP pathway mAb to a different anti-CGRP pathway mAb was low (6% for erenumab, 7% for fremanezumab, and 4% for galcanezumab).

CONCLUSIONS

- Use of PAPs and payers not visible in insurance claims was common yet variable across anti-CGRP pathway mAbs.
- Results suggest that adjudicated health insurance claims data may be missing claims for anti-CGRP pathway mAbs which may lead to exposure misclassification of these therapies.
- Cautious interpretation is warranted when assessing incident exposure to anti-CGRP pathway mAbs in studies using adjudicated insurance claims data.

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DISCLOSURES

KMS, JKM, RLW, and JL are employees of IQVIA. IQVIA was hired by Amgen to conduct this study. RU, ACK, and KG are employees and stockholders of Amgen. MEB is an employee of Benofit Consulting. Benofit Consulting was hired by Amgen to support the study design and conduct.

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