Cost-Consequence Analysis of Fremanezumab Treatment in Patients With Migraine and Comorbid Major Depressive Disorder in the UK Using Results From the UNITE Study

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To estimate the cost consequences of introducing fremanezumab for the treatment of migraine in patients with comorbid major depressive disorder (MDD) who are eligible for treatment with monoclonal antibodies targeting the calcitonin gene-related peptide pathway (CGRP pathway mAbs)

Background

- Migraine has been linked with several psychiatric conditions and shown to be highly comorbid with depression[1–4]
- Compared with those without depression, patients with comorbid depression have increased headache-related disability, decreased quality of life, and higher migraine-associated medical costs[4–6]
- Fremanezumab, a CGRP pathway mAb, is approved for episodic and chronic migraine prevention[7,8]
- In the Phase 4, randomized, double-blind, placebo-controlled UNITE study (NCT04041284), conducted in patients with migraine and comorbid MDD, treatment with fremanezumab resulted in significant improvements in migraine and depressive symptoms versus placebo[9,10]
- To date, the potential economic impact of improvements in migraine and depressive symptoms with fremanezumab among this patient population is unknown

Total annual cost savings of £11,552.30 per patient were estimated based on the existing market share of fremanezumab

Table 1. Total Costs and Cost Consequence Over a 1-year Time Horizon (N=1)

	Base case scenario	Alternate scenario	Cost consequence
Drug acquisition and administration costs (£)	4,787.1	4,787.1	–
Direct costs (£)	9,042.3	6,331.8	–2,710.4
Indirect costs (£)	18,994.3	10,152.5	–8,841.8
Total costs (£)	32,823.7	21,271.4	–11,552.3

Direct costs included costs associated with HCU. Indirect costs were based on the average number of hours missed in the last week due to health, health impairment while at work and average wage rates from publicly available data.
ER, emergency room; GP, general practitioner; HCU, healthcare utilization.

- The majority (76.5%) of total cost savings was due to a predicted decrease in indirect costs associated with work productivity and activity impairment (WPAI)

Table 2. Direct Costs and Cost Consequence Over a 1-year Time Horizon (N=1)

	Base case scenario	Alternate scenario	Cost consequence
GP visits (£)	438.2	369.0	–69.2
ER visits (£)	673.7	529.2	–144.6
Hospitalizations (£)	802.9	654.6	–148.2
Nurse practitioner (£)	17.1	16.0	–1.1
Neurologist (£)	810.5	599.9	–210.6
Mental health visits (£)	6,299.9	4,163.1	–2,136.8

Mental health visits included visits to a psychiatrist, psychologist, or therapist.
ER, emergency room; GP, general practitioner.

- Among disease management resources, the largest cost savings were due to the reduction in mental health visits costs

Conclusion

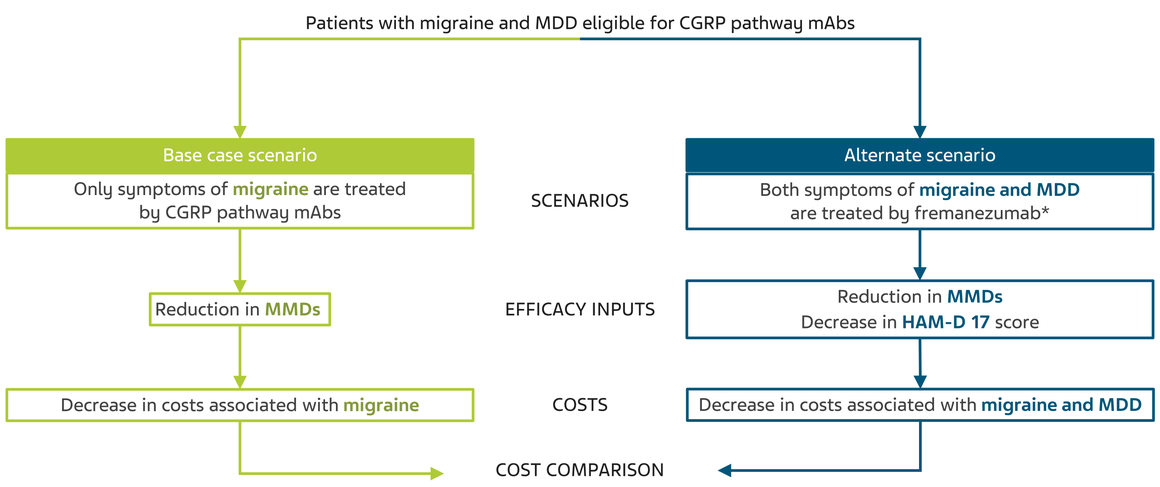
In patients with both migraine and MDD, treatment with fremanezumab can result in substantial direct and indirect cost savings from a UK societal perspective

These results may be of interest to clinicians and healthcare decision makers

Methods

- An Excel-based, cost-consequence model, with a 1-year time-horizon, was developed to estimate cost differences for patients with migraine and MDD in two scenarios, **Figure 1**
  - In the base case scenario, only symptoms of migraine are treated by CGRP pathway mAbs
  - In an alternate scenario, symptoms of both migraine and MDD are treated by fremanezumab

Figure 1. Model Structure



*Data on improvements in symptoms of MDD with other CGRP pathway mAbs were not available.
CGRP, calcitonin gene-related peptide; HAM-D 17, Hamilton Depression Rating Scale-17; mAb, monoclonal antibody; MDD, major depressive disorder; MMDs, monthly migraine days.

- The assumed efficacy of fremanezumab in treating migraine and MDD was based on data from the UNITE study, which included a 12-week double-blind period and 12-week open-label extension[9,10]
- Model parameter inputs and clinical assumptions are summarized in **Table 3** and **Table 4**, respectively

Table 3. Model Parameter Inputs for the Base Case Analysis (N=1)

Parameter	Model inputs
Population	
Patients with migraine and MDD eligible for CGRP pathway mAbs, N	1
Market shares, %*	
Fremanezumab	48
Erenumab	33
Galcanezumab	17
Eptinezumab	2
Efficacy[9,10]	
Migraine treatment	
Change from baseline in MMDs at Week 12, days	−5.4
MDD treatment	
Change from baseline in HAM-D 17 score at Week 12	−6.7
Change from baseline in PHQ-9 score at Week 12	−7.8

*UK CGRP pathway mAb market shares as of March 2024.
CGRP, calcitonin gene-related peptide; HAM-D 17, Hamilton Depression Rating Scale-17; mAb, monoclonal antibody; MDD, major depressive disorder; MMDs, monthly migraine days; PHQ-9, Patient Health Questionnaire-9.

Table 4. Clinical Assumptions Associated with the Model

	Clinical assumptions		
1	Improvements in symptoms of migraine and MDD observed at 12 weeks in the UNITE DBP and at 12 weeks in the OLE are the same at 52 weeks	5	Reduction in MMDs is the same for all CGRP pathway mAbs
2	No treatment waning	6	Reduction in HAM-D 17 scores is ONLY applied to fremanezumab†
3	A similar efficacy between monthly and quarterly doses for fremanezumab and between participants with CM and EM	7	A clinically meaningful reduction from baseline in HAM-D 17/ PHQ-9 score is indicative of depression treatment‡
4	Adherence to fremanezumab or another CGRP pathway mAb is 100%*	8	Adverse event costs are the same between all CGRP pathway mAbs§

*This assumption was made to show maximal budget impact; †Based on data availability; ‡A HAM-D 17 score of ≤8 is considered as full remission. A >5 points change from the baseline in PHQ-9 score is considered clinically meaningful; §Based on this assumption, adverse event costs were not considered.
CGRP, calcitonin gene-related peptide; CM, chronic migraine; DBP, double-blind period; EM, episodic migraine; HAM-D 17, Hamilton Depression Rating Scale-17; mAb, monoclonal antibody; MDD, major depressive disorder; MMDs, monthly migraine days; OLE, open-label extension; PHQ-9, Patient Health Questionnaire-9.

- Drug and administration costs were obtained from UK public sources (MIMS UK, 2024 and the National Schedule of National Health Service costs, 2024)[11,12]
- Healthcare resource utilization and WPAI among individuals with migraine with and without comorbid depression were obtained from the 2022 EU and UK National Health and Wellness Survey, and their respective costs were estimated[13]
  - Scan the QR code for detailed methodology on cost estimations and modeling assumptions

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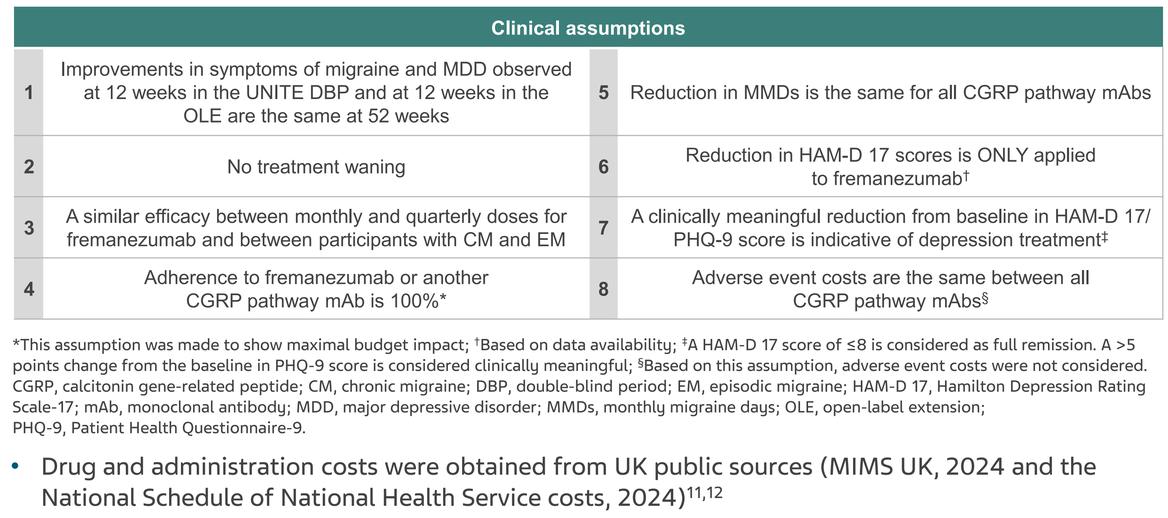
Additional results

- An analysis was performed to assess the impact on the cost consequence of the alternate versus the base case scenario, when there is an increase of 10%, 20%, 50%, and 100% in market share of fremanezumab, compared with the base case analysis
- When fremanezumab market shares were increased, this resulted in higher direct cost savings and therefore total cost savings, **Figure 2**

Figure 2. Cost Consequence of the Base Case versus Alternate Scenario with Variable Fremanezumab Market Share Values Over a 1-year Time Horizon (N=1)



Direct costs included drug acquisition and administration costs and costs associated with HCU, including the cost of ER visits, hospitalizations, GP visits, nurse practitioner visits, neurologist visits, and mental health visits (psychiatrist, psychologist/therapist). Indirect costs were based on the average number of hours missed in the last week because of one's health, and/or health impairment while at work, and average wage rates from publicly available data.
ER, emergency room; GP, general practitioner; HCU, healthcare utilization.

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