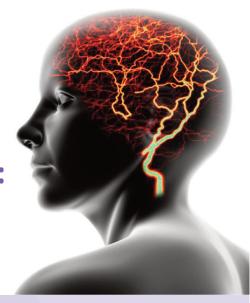


CGRP monoclonal antibody treatment: Request for reimbursement in the Middle East



Availability and reimbursement of anti-CGRP therapies vary across the Middle East, depending on national healthcare coverage, regulatory mechanisms and pricing and insurance policies.

Engaging with insurers and government

Experience has shown the importance of engaging with insurers and government regulators to demonstrate the potential benefits of anti-CGRP therapies not only for patients but also for employers and national economies.

There is published evidence that anti-CGRP therapies:

- Reduce monthly migraine days in patients with episodic and chronic migraine¹⁻⁹
- Marrove quality of life for patients 10-14
- Reduce migraine-related disability¹⁰⁻¹⁴
- Reduce indirect costs and sick leave 15,16

Personalised patient care

When interacting with payers over reimbursement for anti-CGRP therapies for individual patients, a detailed medical report documenting the need for treatment is likely to include:

- The patient's history of migraine including duration of disease and frequency and severity of attacks
 - A headache diary recording migraine attack frequency and severity may be useful
- The impact of the patient's migraine on their personal and working life and the lives of family members and carers

- Need for medical care, eg. consultations, Emergency Room or inpatient, in recent months or years
- Detailed description of previous migraine treatment failures including drug names, doses and duration of treatment
- Likely duration of anti-CGRP therapy (3-6 months then reassess), ie. treatment is not open ended

Following initial treatment, it is important to demonstrate the benefits and possible cost advantages to payers in order to agree further reimbursement. These are likely to include:

- Fifects of anti-CGRP therapy on number of migraine days (preventive treatment) and migraine symptoms (acute treatment)
 - Comparison with previous treatments
- Impact of treatment on patient's quality of life since starting anti-CGRP therapy
- Fifects on family and social life since starting anti-CGRP therapy
- Need for medical care, eg. consultations, Emergency Room or inpatient, since starting treatment
- Time off work, school or college since starting anti-CGRP therapy

References

- 1. Goadsby PJ, Reuter U, Hallström Y et al. A controlled trial of erenumab in episodic migraine. N Engl J Med. 2017 Nov 30;377(22):2123-2132.
- Tepper S, Ashina M, Reuter U et al. Safety and efficacy of erenumab for preventive treatment of chronic migraine: a randomised, double-blind, placebo-controlled phase 2 trial. Lancet Neurol. 2017 Jun;16(6):425-434.
- 3. Dodick DW, Silberstein SD, Bigal ME, et al. Effect of fremanezumab compared with placebo for prevention of episodic migraine: a randomized clinical trial. JAMA 2018; 319:1999–2008.
- 4. Silberstein SD, Dodick DW, Bigal ME, et al. Fremanezumab for the preventive treatment of chronic migraine. N Engl J Med 2017;377:2113–2122.
- Stauffer VL, Dodick DW, Zhang Q et al. Evaluation of Galcanezumab for the Prevention of Episodic Migraine: The EVOLVE-1 Randomized Clinical Trial. JAMA Neurol. 2018 Sep 1;75(9):1080-1088.
- 6. Detke HC, Goadsby PJ, Wang S, Friedman DI et al. Galcanezumab in chronic migraine: The randomized, double-blind, placebo-controlled REGAIN study. Neurology. 2018 Dec 11;91(24):e2211-e222.
- Ashina M, Saper J, Cady R et al. Eptinezumab in episodic migraine: A randomized, double-blind, placebo-controlled study (PROMISE-1). Cephalalgia. 2020 Mar;40(3):241-254.
- 8. Lipton RB, Goadsby PJ, Smith J et al. Efficacy and safety of eptinezumab in patients with chronic migraine: PROMISE-2. Neurology. 2020 Mar 31;94(13):e1365-e1377.
- 9. Croop R, Lipton RB, Kudrow K et al. Oral rimegepant for preventive treatment of migraine: a phase 2/3, randomised, double-blind, placebo-controlled trial. Lancet 2021; 397:51-60.
- 10. Buse DC, Lipton RB, Hallstrom et al. Migraine-related disability, impact, and

- health-related quality of life among patients with episodic migraine receiving preventive treatment with erenumab. Cephalgia 2018; 38: 1622-1631.
- 11. Spierings ELH, Ning X, Ramirez Campos V et al. Improvements in quality of life and work productivity with up to 6 months of fremanezumab treatment in patients with episodic and chronic migraine and documented inadequate response to 2 to 4 classes of migraine-preventive medications in the phase 3b FOCUS. Headache 2021; 61: 1376-1386.
- Tepper SJ, Ailani J, Ford JH et al. Effects of Galcanezumab on Health-Related Quality of Life and Disability in Patients with Previous Failure of 2-4 Migraine Preventive Medication Categories: Results from a Phase IIIb Randomized, Placebo-Controlled, Multicenter Clinical Trial (CONQUER). Clin Drug Investig. 2022 Mar;42(3):263-275.
- 13. Lipton RB, Charleston L, Tassorelli C et al. Patient-reported outcomes, health-related quality of life, and acute medication use in patients with a ≥ 75% response to eptinezumab: subgroup pooled analysis of the PROMISE trials. J Headache Pain 2022 Feb 7;23(1):23.
- 14. Johnston KM, L'Italien G, Popoff E et al. Mapping Migraine-Specific Quality of Life to Health State Utilities in Patients Receiving Rimegepant. Adv Ther. 2021 Oct;38(10):5209-5220.
- 15. Autio H, Purmonen T, Kurki S et al. Erenumab Decreases Headache-Related Sick Leave Days and Health Care Visits: A Retrospective Real-World Study in Working Patients with Migraine. Neurol Ther 2022; 11: 223-235.
- Tobin J, Ford JH, Tockhorn-Heidenreich A et al. Annual indirect cost savings in patients with episodic or chronic migraine: post-hoc analyses from multiple galcanezumab clinical trials. J Med Econ 2022; 25: 630-639.