Real-world treatment chronic migraine in Poland

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The Global Burden of Disease (GBD) database indicates that primary headaches, the most prevalent type of headache, are a significant economic burden specifically regarding migraines in young adults, to mitigate long-term complications linked with these conditions [1]. In 2019, headache disorders were the 14th leading cause of disability adjusted life years (DALYs) globally. Globally, the prevalence trend of migraine among individuals aged 15 to 39 years is increasing [2]. It is estimated that 14% of the world population suffer from migraine [2, 3], and migraine is considered a lifelong disease [4]. The high prevalence across age groups underscores the need for targeted intervention strategies, mainly in the group of patients with chronic migraine (CM). This form of migraine [5] entails the highest costs, both direct and indirect, burdening not only the patients but also the state budget [6]. In recent years several novel and efficient medications to treat CM have been introduced into therapy. They are characterised by a greater reduction in the frequency of migraine attacks and the number of headache days per month, with fewer side effects than other previously used drugs. We realise that the high cost of such therapies means that only a minority of migraine patients who could benefit from these medications can afford them. Furthermore, information on cost-effectiveness is still lacking. Due to the above, the treatment of CM is covered by reimbursement in many countries, including Poland. The question arises whether the reimbursement program for CM treatment in Poland is efficient and sufficient. Two years have passed since the start of reimbursed treatment under the Preventive Treatment of Patients with Chronic Migraine, but in reality the first centres to include this treatment for patients have been using it for about 1.5 years. In fact, the first centre (currently not active) started treating CM patients 2 months after the program was launched, and another one (currently one of the 3 most active out of 61 centres) after another 4 months.

According to the periodic, publicly available report of the National Health Fund, which is published on their website, 1420 (the first line) and 809 (the second line) patients were treated in the program up to the end of June 2024. This means that 2229 patients with CM actively sought and received help with treatment [7]. Probably these were patients who had previously been under neurological care, so this does not include everyone in need.

In Poland, only a few epidemiological studies of migraine have been conducted so far [8]. The latest studies indicate that 10% of the popula-

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tion suffers from migraine, which means that from 37.5 mln (Central Statistical Office; April 2024) about 3.7 mln Poles suffer from migraine [8]. However, most of them do not use regular medical care, which negatively affects the quality and effectiveness of their treatment. The studies also show that migraine occurs almost 3 times more often in women than in men. Additionally, it is known that CM occurs in about 2% of the general population and 20% of the migraine population, which means that in Poland it affects about 700,000 people. Assuming that less than half of CM patients use effective medical care (less than 350,000 Poles) and half of them are actively treated with oral medications (175,000) and another half are satisfied with such treatment, there are less than 90,000 of the most troublesome and resistant type of CM patients. So, do the just over 2000 patients treated in the refund program per year (we assume that a patient remains in the program for 2 years 3 months to 2 years 9 months) satisfy the problems of our patients. Interestingly, we do not see any major discrepancies in the number of patients included in the program in individual provinces, e.g. Masovian (5.5 mln - 255 patients - 0.004%), Silesian (4.3 mln - 225 patients - 0.005%), Greater (3.5 mln – 182 patients – 0.005%), Lesser (3.4 mln - 261 patients - 0.007%), Lower Silesian (2.8 mln – 170 patients – 0.006%), Lodzkie (2.3 mln - 140 patients - 0.006%) vs. Opole (940,000 - 21 patients - 0.002%), and Lubusz (970,000 - 39 patients - 0.004%) [7]. This number of patients treated for CM is independent of the number of centres in the province (from 1 to 7).

It is important to mention that the Polish reimbursement program for the treatment of CM announced by the Ministry of Health in July 2022 has some specific regulations. For economic reasons, this program is based on 2 lines of treatment; however, in fact, there is a three-step therapeutic approach. The initial line of chronic migraine treatment includes unsuccessful treatment with at least 2 classical oral medications (out of 3: valproic acid and its derivatives, topiramate, amitriptyline) and documented failure of treatment with these oral medications recommended in Polish conditions. The first line of treatment in the reimbursement program is botulinum toxin type A (ONA-BoNTA) and the second line medications the anti-calcitonin gene-related peptide (CGRP) or the anti-receptor CGRP monoclonal antibodies (anti-CGRP/CGRP-R mAbs) - fremanezumab or erenumab [9]. The other 2 anti-CGRP mAbs are currently not reimbursed, but eptinezumab and galcanezumab will probably be included in this program soon.

The Polish Headache Society, the Headache Section of the Polish Neurological Society, and

the Polish Association for the Study of Pain and Pain Research recommendations and statements suggest that mAbs targeting the CGRP pathway be included as a first-line treatment option, which might guarantee much better compliance and adherence to these therapies, as well as long-term satisfaction of patients from the beginning of the treatment [10, 11]. In our opinion, patients with chronic migraine and medication overuse are likely to benefit most from mAbs, and not only patients in whom classical oral migraine prophylactics or ONA-BoNTA for chronic migraine are ineffective, not tolerated, or contraindicated should be treated with a mAbs. The treatment costs for these medications are currently still very high. This remains a major obstacle to widespread access to treatment with new drugs. There is therefore an urgent need to develop the most cost-effective access program to new therapies.

It seems that modifying the criteria for including patients in the reimbursed treatment by shortening the time of treatment with traditional oral medicines or eliminating such a need and leaving all medicines in the same line of treatment, while leaving the decision to the treating physician with an individual approach to the patient, could increase access to modern and effective treatment of the most disabling type of CM.

The evolution of the current medication program in Poland is desirable for several reasons. Firstly, shortening and simplifying the criteria for inclusion in the program, and secondly, the possibility of faster switching of drugs available in the program and improving the treatment monitoring system.

The possibility of early treatment with new drugs, although more expensive individually, is beneficial in the long term for the patient, the healthcare system, and society. Direct costs related to doctor visits are reduced, as well as indirect costs through reduced sick leave from work and patients' productivity at work.

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Ethical approval

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Conflict of interest

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- 1. GBD 2019 Diseases and Injuries Collaborators (2020) Global burden of 369 diseases and injuries in 204 countries and territories, 1990-2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet 396: 1204-22. Erratum in: Lancet 2020; 396: 1562.
- Stovner LJ, Hagen K, Linde M, et al. The global prevalence of headache: an update, with analysis of the influences of methodological factors on prevalence estimates. J Headache Pain 2022; 23: 34.
- 3. Woldeamanuel YW, Cowan RP. Migraine affects 1 in 10 people worldwide featuring recent rise: a systematic review and meta-analysis of community-based studies involving 6 million participants. J Neurol Sci 2017; 372: 307-15.
- 4. Buse DC, Fanning KM, Reed ML, et al. Life with migraine: effects on relationships, career, and finances from the chronic migraine epidemiology and outcomes (CaMEO) study. Headache 2019; 59: 1286-99.
- 5. Headache Classification Committee of the International Headache Society (IHS). The International Classification of Headache Disorders, 3rd edition. Cephalalgia 2018; 38: 1-211.
- 6. Ashina M, Katsarava Z, Do TP, et al. Migraine: epidemiology and systems of care. Lancet 2021; 397: 1485-95.
- 7. www.nfz.gov.pl/zarzadzenia-prezesa/uchwaly-rady-nfz/ uchwala-nr-292024iv,6679.html
- 8. www.pzh.gov.pl/wp-content/uploads/2019/06/ RAPORT-MIGRENA-ca%C5%82y.pdf
- 9. Domitrz I, Kozubski W, Rożniecki J, Stępień A, Boczarska-Jedynak M. The Polish Headache Society and the Headache Section of the Polish Neurological Society Consensus Statement: update on new pharmacological therapies for migraine in clinical practice and public medication reimbursement program for chronic migraine. Arch Med Sci 2022; 18: 1705-7.
- Domitrz I, Kozubski W, Stępień A, et al. The Polish Experts' Consensus Statement: 2023 Update on new therapies for migraine. Arch Med Sci 2024; 20: 339-43.
- Stępień A, Kozubski W, Rożniecki J, Domitrz I. Rozpoznawanie i leczenie migreny 2024 – aktualizacja rekomendacji – opracowanie Grupy Ekspertów Sekcji Bólu Głowy Polskiego Towarzystwa Neurologicznego i Polskiego Towarzystwa Badania Bólu. Ból 2024; 25: 9-33.