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

Izabela Domitrz, Wojciech Kozubski, Jacek J. Rożniecki, Adam Stępień, Magdalena Boczarska-Jedynak

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The latest paper concerning the management of migraine in Poland was published in 2021 [1] and the previous one (in Polish) in 2019. The Polish recommendations were based on the guidelines of migraine treatment developed by the European Headache Federation (EHF, 2019) [2] and the American Headache Society (AHS) published in 2021 [3]. The Polish guidelines took into consideration special Polish conditions and therapeutic options available in Poland, in regard to the Summary of Product Characteristics of the drugs with indication for use in migraine, the evidence-based medicine approach, good clinical practice rules, and the knowledge and experience of the experts of the Polish Headache Society (PHS/PTBG), the Headache Section of the Polish Neurological Society (HSPNS/SBGPTN), and the Polish Pain Society (PPS) [1]. It should be underlined that both the EHF and the AHF have also updated the migraine treatment guidelines/statements recently [4, 5].

Both the above-mentioned societies have approved the use of monoclonal antibodies (mAbs) against calcitonin gene related peptide and its receptor (CGRP/CGRP-R) for the prevention of migraine in patients aged 18 years or older who are diagnosed with chronic migraine according to the criteria of the International Classification of Headache Disorders, third edition (ICHD-3) [6], or who have episodic migraine with at least 4 headache days per month [6]. Initially, in the publications from 2021 (AHS) [3] and 2019 (EHF) [2] mAbs against CGRP/CGRP-R were recommended in those who had contraindications, did not tolerate or had no response to at least 6-week treatment courses with at least two of the following medications (combining/including recommendations in episodic and chronic migraine): topiramate, valproic acid, β-blockers (metoprolol, propranolol, timolol, atenolol, nadolol), tricyclic antidepressants (amitriptyline, nortriptyline), serotonin reuptake inhibitors (venlafaxine,
duloxetine) or other level A or B treatments, and, in the case of chronic migraine specifically, onabotulinum toxin type A (ONA-BoNTA), as well. In the light of the reimbursement program in Poland mentioned below [7, 8] it needs to be stressed that ONA-BoNTA is obligatory therapy used first before a patient changes the treatment to mAbs in the prophylaxis of chronic migraine. What is interesting, the latest AHS/EHF statements from this year [4, 5] clearly emphasize that the mAbs anti-CGRP/CGRP-R may be the first choice medications and there is no need for any prior treatment with the above-mentioned substances. It is important to state that many experts, including Polish national experts (PHS/PTBG, HSPNS, PPS), maintain and stated that a very good safety profile and high clinical efficacy make mAbs against CGRP/CGRP-R the first-line treatment for chronic migraine, and even for episodic pain with frequent attacks [1]. The Polish reimbursement program for the treatment of chronic migraine announced by the Ministry of Health on July 22, 2022, however, has some specific regulations. For economic reasons, this new program is based on “two lines” of treatment; however, in fact, there is a three-step therapeutic approach (Figure 1). The initial line of chronic migraine treatment includes unsuccessful treatment with at least two “classical” oral medications (out of three: 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 ONA-BoNTA in the dose of up to 195 IU, according to the PREEMP (PREEMPT – Phase III Research Evaluating Migraine Prophylaxis Therapy) protocol. If this therapy fails (which is evaluated after 3 cycles of therapy every 12 weeks), patients can be treated with the “second line medications” – mAbs: erenumab 140 mg s.c. monthly or fremanezumab 225/675 mg s.c. monthly/quarterly. The other two mAbs are currently not reimbursed, but galcanezumab will probably be included in this program soon, followed by eptinezumab, the only one administered intravenously every 3 months. Table I shows the drugs recommended by the PHS/HSPNS.

Treatment efficacy should be assessed and the decision about the continuation of the treatment should be made after 3 administrations (9 months) of ONA-BoNTA or 3 months from the first administration of mAb anti-CGRP/CGRP-R. Treatment is considered to be effective if reduction in monthly headache/migraine days reaches at least 50%, relative to the pre-treatment baseline month, based on the obligatory patient’s headache diary. Functional deterioration of the patient assessed as a Migraine Disability Assessment (MiDAS) score of at least 30% is a reason to restart the therapy, after the end of treatment in accordance with the program’s regulations.

All details of the chronic migraine reimbursement program are available on websites of the Ministry of Health and the National Health Fund [7, 8], and a detailed description and interpretation with possible misinterpretation considering any doubts will be published by PHS/HSPNS in Polish, just before the program enters into force.

It is worth adding that more new medications will probably be included in the migraine recommendations soon. The small-molecule CGRP

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**Table I.** Drugs used for prophylactic treatment in chronic migraine, doses, and class according to PHS/HSPNS recommendation

| Drug                          | Dose                  | Recommendation |
|-------------------------------|-----------------------|----------------|
| Valproic acid/sodium valproate| 500–1500 mg daily     | A              |
| Topiramate                    | 50–200 mg daily       | A              |
| Amitriptyline                 | 50–150 mg daily       | B              |
| ONA-BoNTA                     | 155–195 IU every 12 weeks | A/B         |
| mAbs-CGRP/CGRP-R              | 1x/4 weeks or 12 weeks | A              |

PHS – Polish Headache Society, HSPNS – Headache Section of Polish Neurological Society, ONA-BoNTA – onabotulinum toxin type A, mAbs – monoclonal antibodies.
Conflict of interest

ID has served as an expert on advisory boards and as a lecturer for the following companies: Allergan AbbVie, Novartis, Teva, Eli Lily; WK has served as an expert on advisory boards and as a lecturer for the following companies: Allergan AbbVie, Novartis, Teva, Eli Lily; AS has served as an expert on advisory boards and as a lecturer for the following companies: Allergan AbbVie, Novartis, Teva, Eli Lily. MBJ has contracted advisory boards, consultations and lectures for Allergan AbbVie, Novartis and Teva.

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