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Research Paper

Formulary and Insurance Lists of Medicines as a Means of Control of Quality of Medical Care to Patients with Primary Open-Angle Glaucoma

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ABSTRACT: *National pharmacological policy should be aimed at substantiated selection and rational use of medicinal drugs in order to ensure affordable, high-quality, efficient and safe pharmacotherapy. Primary open-angle glaucoma (POAG) is still among the most common ophthalmic pathologies, characterized by steady increase in incidence. Therefore, the society is facing a challenge of optimizing costs for POAG pharmacotherapy, which should be addressed at the nation level. We have identified antiglaucoma medicines, recommended for inclusion in formulary and insurance lists, namely, Timolol, Latanoprost and Travoprost ophthalmic solutions for monotherapy, and combinations of antiglaucoma mono-drugs such as Arutimol 0.5% and Taflotan, Arutimol 0.5% and Lanotan, Azopt and Taflotan based on the results of complex marketing and pharmacoeconomic studies. The introduction of partial reimbursement of the cost of these medicines for patients with POAG will bring them more opportunities for using highly efficient and safe medicines from S01E Group "Antiglaucoma medicines and miotics" under conditions of limited funding of medical and pharmaceutical industries. Particular attention is drawn to the availability of domestic medicine Lanotan eye drops, 0.05 mg/ml, 2.5 ml number 1 produced by OJSC Farmak (Ukraine) among those recommended for inclusion in FL and IL as both a monotherapy for POAG and a part of treatment regimens that combine several AGMs.*

Keywords: *antiglaucoma medicines, primary open-angle glaucoma, formulary list, insurance list, optimization of pharmaceutical care.*

I. INTRODUCTION

One of the most pressing and difficult outstanding issues pertaining to health care reform is provision of medicines to population [1]. Today, medicines of high price segment remain unaffordable for the vast majority of Ukraine's population, especially for pensioners. National pharmacological policy should be aimed at substantiated selection and rational use of medicinal drugs (MD) in order to ensure affordable, high-quality, efficient and safe pharmacotherapy [2]. Most pressing issue in this regard is formation of formulary and insurance lists of MD, the cost of which should be compensated from the health budget and health insurance [3, 4].

Over the past decades, WHO has been active with introducing the concept of affordable and high-quality medical care to the population in conditions of scarce funding of health care by developing a list of basic medicinal drugs, formed on the basis of research of efficacy and security analysis, cost-effectiveness study, assessment of affordability and effect on quality of life [5, 6].

Primary open-angle glaucoma (POAG) is among the most common ophthalmic pathologies, the incidence of which is still under a steady growth [7]. According to the data provided by WHO, over 100 million people worldwide suffer from glaucoma, with approximately 10% of them blind in both eyes. Irreversible consequences of the disease, manifested by progression of visual function loss until complete blindness, lead to disability and incapacitation of patients. POAG treatment is long-lasting procedure (lifetime in most cases), accompanied by significant financial costs for both patients and health industry in a whole [8, 9].

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In view of the above-mentioned, we are facing a problem of optimizing POAG pharmacotherapy costs, which should be addressed at the national level.

II. THE PURPOSE OF THE WORK

The development of science-based formulary (FL) and insurance (IL) lists of antiglaucoma medicines (AGM) based on the results of complex marketing and pharmacoeconomic studies, which implementation at the level of ophthalmologists and generally in the health-care system may improve the quality and efficacy of care to studied patient population and facilitate optimization of financing system under conditions of introduction of health insurance in Ukraine.

Especially important is introduction of the above MD lists for treatment of pathologies with a predominance of outpatients to health industries of countries, which have adopted the practice of partial reimbursement of medical costs. Patients with POAG correspond to the above concept in Ukraine. Therefore, scientific study for substantiation of AGM inclusion to FL and IL is highly important for pharmaceutical and healthcare industries in the modern conditions of reforming the health care system.

We have developed and recommended the lists of main MDs for treatment of POAG, which should be introduced at all levels of care in state, municipal and private ophthalmologic health care institutions in order to optimize selection of POAG treatment regimens and costs for purchase of AGMs.

III. MATERIALS AND STUDY METHODS

While forming up recommendations for inclusion of AGMs to FL and IL, it is very important to take into account all MD selection criteria, namely, to be guided by the requirements of current medical care protocols, to consider the MD administration evidence database, to carry out comparative analysis of the efficacy and safety parameter - the cost-efficacy ratio of MDs with similar action mechanisms; to assess the possibility of AGM costs reimbursement; to consider the information regarding side effects resulting from MD administration. The data on compliance and effect of selected AGMs on quality of life of patients with POAG is also important indicator.

The advantage in selection of AGMs, recommended for inclusion in FL and IL, is given to single-component domestic MDs, pharmaceutical substances referred to under international nonproprietary names (NPN). However, unlike trade names (TM), NPNs do not characterize the pharmaceutical forms and dosages of MDs, and do not reflect (do not take into account) peculiar indications for use, side effects, pharmacological and pharmacoeconomic characteristics, and differences between branded and generic drugs.

IV. RESULTS AND DISCUSSIONS

As was found in previous studies, combined AGMs of fixed composition have an advantage over combination of several one-component AGMs as part of a treatment regimen in terms of occurrence of side effects, patient compliance and cost-efficacy index. Therefore, they have proven scientific assumptions for inclusion in FN and IL.

Selection of reasonable POAG treatment regimens with due account to individual patient is extremely demanding task, which requires significant time and effort from ophthalmologists, strict compliance with doctor`s appointments, and significant financial costs incurred by patients. Integral components of successful pharmacotherapy in patients with POAG are not only timely diagnostics of the disease with modern techniques, but also selection of best case-driven AGMs, based on the results of clinical trials and the data obtained during the study of pharmacoeconomic aspects of POAG treatment and effect of selected AGMs on quality of life of each patient.

Therefore, the AGMs were included in FL and IL with due account to their efficiency and safety (affordability) based on the results of marketing and pharmacoeconomic studies, on normative-legal documents regulating the pharmacotherapy of patients with POAG, as well as counting on received data regarding effect of AGMs on patients` quality of life.

First-line medicines for POAG treatment are β-blockers. The feasibility of including Timolol to FL and IL has been proven on the grounds of its presence in POAG treatment protocols, as well as considering the frequency of Timolol-containing regimens prescribed by ophthalmologists (Timolol`s share in prescriptions to patients with POAG was 41.29%). In terms of effect on patients` QL, cost-efficacy index, and according to expert evaluation of ophthalmologists, only Arutimol eye drops 0.5%, 5ml, Chauvin Ankerpharm (Germany) were found superior to Timolol. AGMs not recommended for inclusion in FL and IL are β-blockers based on NPN betaxolol (Betalmic 0.5% eye drops, solution 0.5%, 5 ml or 10 ml in a bottle-dropper number 1 produced by LLC Unimed Pharma (Slovak Republic) and Betoptic®S eye drops, 0.25%, 5ml in Drop-Tainer® dispensers, 1 dispenser per a cardboard box, produced by Alcon-Courveur, Belgium.

Only Betoptic®S eye drops, 0.25%, 5ml in Drop-Tainer® dispensers, 1 dispenser per a cardboard box, produced by Alcon-Courveur, Belgium encountered among the above-mentioned preparations. This medicine

had a low rate of prescriptions (2.51%) and did not presented any positive effect on QL of patients (patients with POAG administered Betoptic®S eye drops, 0.25%, 5ml in Drop-Tainer® dispensers, 1 dispenser per a cardboard box, produced by Alcon-Courveur, Belgium); QL ranged from 66 to 133 points). AGM Betaxolol also received the poorest feedback from experts - Betalmic 0.5% eye drops, 0.5% solution, 5 ml or 10 ml in a bottle-dropper No. 1 produced by Unimed Pharma (Slovak Republic) received 11.11 points and Betoptic®S eye drops, 0.25%, 5ml in Drop-Tainer® dispensers, 1 dispenser per a cardboard box, produced by Alcon-Courveur (Belgium) received 11.74 points.

The AGMs of the first choice also include prostaglandin analogues. This group of AGMs is characterized by effective IOP improvement (in average, latanoprost and travoprost preparations cause IOP lowering by 21.03 ± 7.18% and 22.82 ± 5.6%, accordingly) and slightly pronounced side effects, occurring in 47.29% of patients using them. The compliance of patients was also high (4.67 ± 0.4 points of maximum possible 5.0) in the group administered this AGM, preconditioned mostly by their continuing effect. Despite prostaglandin analogue preparations attributed to the high price category, they were recommended for inclusion in FL and IL based on their efficiency and safety parameters and significant positive impact on QL of patients with POAG.

Compared to mono-drugs, combined AGMs of fixed composition encountered in very few single treatment sheets, therefore, their analysis is irrational due to unreliability of the results, and, therefore, consideration of the appropriateness of their inclusion in FL and IL is unreasonable.

At the same time, a retrospective analysis of antiglaucoma therapy regimens indicate the advisability of inclusion of antiglaucoma mono-drug combinations in FL and IL, such as Arutimol eye drops 0,5%, 5ml, Chauvin Ankerpharm (Germany) + Taflotan eye drops,15 mg/ml, 2.5 ml No. 1, Santen (Finland), Arutimol eye drops 0,5%, 5ml, Chauvin Ankerpharm (Germany) + Lanotan eye drops 0.05 mg/ml, 2.5 ml No. 1 produced by OJSC Farmak (Ukraine), Azopt eye drops, 10 mg/ml, 5 ml in Drop-Tainer® dispensers No. 1, produced by Alcon-Courveur (Belgium) + Taflotan eye drops, 15 mg/ml, 2.5 ml No. 1, Santen (Finland). These AGM combinations allow to quickly achieve target stable IOP values (39.09 ± 7.73; 37.55 ± 6.8; 40.04 ± 7.59, respectively), have optimal cost-effectiveness index (3.4, 3.82, and 5.65, respectively), and ensure pretty good QL score (99.77 ± 12.67; 102.80 ± 21.44; and 107.25 ± 22.67, respectively).

V. CONCLUSION

Forming up and introduction of AGM FL and IL may facilitate solving important medical and social problem related to economic optimization and improvement of medical and pharmaceutical care for patients with POAG.

Introduction of partial reimbursement of costs of AGMs, recommended for inclusion in FL and IL, would allow patients with POAG have more opportunities for using highly efficient and safe AGMs in case of optimization of the range of medicines from S01E Group "Antiglaucoma medicines and miotics" driven by scarce funding of medical and pharmaceutical industry.

The results of complex studies of pharmacotherapy characteristics and medicinal support to patients with POAG is the basis for determining the focus in optimization of medical and pharmaceutical care provided to subject patients.

Particular attention is paid to available domestic medicine Lanotan eye drops, 0.05 mg/ml, 2.5 ml No. 1 manufactured by OJSC Farmak (Ukraine) among those recommended for inclusion in FL and IL for both POAG monotherapy and as part of treatment regimens combining several AGMs.

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