

Potential in the treatment of neovascular Age-related Macular Degeneration and Diabetic Macular Edema in Poland. The population needs and access to therapy

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Abstract

Objectives

The aim of this study was to investigate the situation of patients with neovascular Age-related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME) in Poland, in terms of health needs and availability of treatment.

Methods

We collected data on the epidemiology of both diseases from the literature, as well as statistical data and data on medical services provided obtained from the National Health Fund.

Results

Based on available data, it is difficult to precisely estimate the actual number of patients with AMD and DME in Poland. In 2021, in Poland over 130 000 patients used any medical service settled according to the ICD-10 codes: H35.0, H35.8 or H36.0. About 26% with AMD and 19% with DME required hospitalization. Despite the fact that in recent years the number of patients in the Drug Program offering access to best therapeutic standards (aflibercept or ranibizumab, and then also with brolucizumab) has been increasing, it is still a small percentage of those who could be treated.

Conclusions

The analysis of data regarding the implementation of the AMD and DME treatment program in Poland indicates a large untapped potential. Despite the existence of a possibly large number of patients only a small number receives treatment.

1. Introduction

Neovascular Age-related Macular Degeneration (nAMD) and Diabetic Macular Edema (DME) have a significant impact on patient morbidity in Poland, substantially re-

ducing quality of life and placing a burden on the national budget. The treatment for both ophthalmic diseases aims to slow their progression and prevent vision loss. The gold standard in Poland, as in the rest of Europe, involves anti-vascular endothelial growth factor (anti-VEGF) drugs administered directly to the patient's eye: aflibercept, ranibizumab, and brolucizumab.^[1,2] The high costs of these modern therapies necessitated the creation of a dedicated health service, known as a “drug program” (DP), which guarantees cost-free treatment for eligible patients. Initially, there were separate programs for each condition, but in 2022 they were merged into a single, coherent program. Drug programs are contracted by hospitals and are a popular method in Poland for providing patients access to the most expensive medications.

A serious problem in the treatment of retinal diseases in Poland is the low level of public awareness regarding ophthalmic conditions. A significant proportion of Poles with vision problems do not seek medical help, with 32% of Poles having never visited an ophthalmologist.^[3] As a result, the true epidemiology is underestimated, making it difficult to assess whether the drug programs (DPs) are fulfilling their role.

The aim of this study was to determine the current prevalence of AMD and DME in Poland and to understand the characteristics of a well-treated patient. Summarizing the potential needs for treating both diseases based on population requirements provides useful insights that can help guide future steps toward improving patient care.

2. Materials and Methods

A structured desk review was conducted on the research and documents related to nAMD and DME in Poland from March 2023 to April 2024, including current practice guidelines, evaluation reports, and epidemiology. Additionally, some peer-reviewed studies dedicated to diseases coded H35.0, H35.3, H35.8, and H36.0 (in the International Classification of Diseases, Tenth Edition, ICD-10) were evaluated. In this classification, there is no specific code for macular edema, including diabetic macular edema, and patients may be diagnosed with diabetic retinopathy, other specified retinal disorders, or non-proliferative retinopathy and retinal vascular changes. The most recent data regarding ophthalmology in the country was collected from National Health Fund (NHF). National data was also balanced against external sources such as the United Nations and the American Academy of Ophthalmology.

3. Results

Epidemiology

Determining the size of the population with retinal diseases in Poland is challenging, primarily due to the large scale of underdiagnosis. The number of patients diagnosed with DME or nAMD is much lower than epidemiological data would suggest. However, there is a steady increase in the number of people with retinal problems in Poland (Figure 1).

The actual extent of the epidemic of retinal diseases is difficult to estimate based on available data. However, depending on the source, in 2021 there were approximately 180,000 to 232,000 patients with DME and about 109,000 to 130,000 patients with nAMD in Poland.^[3-6] The actual magnitude of patients is difficult to estimate even for experts. The number of alleged cases of DME in Poland varies between 50,000 and 200,000, depending on the expert, and the number of patients with nAMD is estimated to be around 150,000.^[7,8]

Based on the average occurrence of AMD in Europe and the United Nations’ population forecasts for Poland, it is estimated that the number of patients with AMD in the country will increase significantly, reaching approximately 360,000 cases by 2055.^[3] Approximately 36,000 neovascular cases are expected within this group, based on the rule that around 10% of all AMD cases are associated with retinal swelling due to the accumulation of serous fluid.^[9]

The incidence of DME increases with the duration of diabetes. The number of diabetics in Poland is growing by approximately 2.5% annually. In 2018, there were 2.9 million adults diagnosed with diabetes (one in eleven Poles). One-third of these individuals had macular degeneration, and 300,000 required treatment.^[8-13] The rising number of patients with diabetes indicates a parallel increase in the

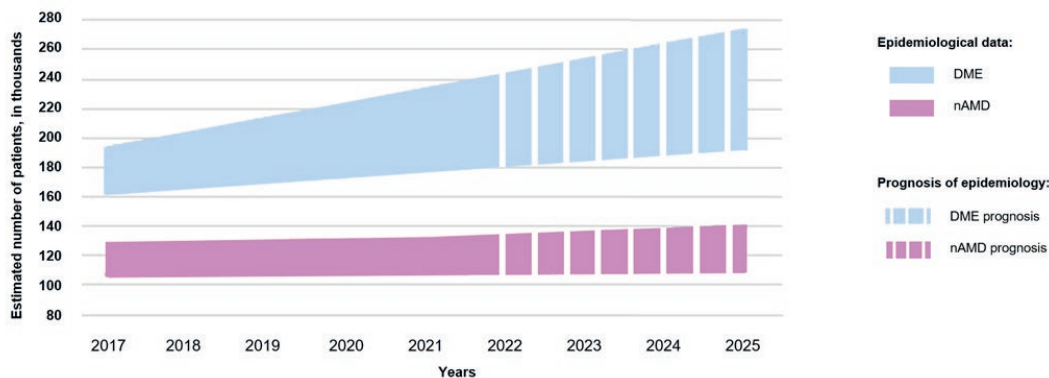
number of DME cases. According to the national consultant in ophthalmology, DME affects 14% of diabetic patients in Poland. Experts estimate this results in approximately 10,000 new cases per year.^[8,14] These estimates align with a large meta-analysis dedicated to the projected number of DME cases by region, published in 2021 by the American Academy of Ophthalmology. The study highlighted increasing trends in this disease in Europe: in 2020, there were 3.16 million DME cases on the continent, which is expected to rise to 3.51 million by 2030 and reach 3.63 million by 2045.^[15]

Diagnosed cases

In 2021, in Poland, slightly over 130,000 patients used medical services for conditions coded according to ICD-10 as H35.0, H35.8, or H36.0. This means that only about 55% to 70% of people suffering from DME are diagnosed. The situation was even worse for patients with AMD; out of approximately 1.3 million patients (both dry and neovascular), fewer than 200,000 used medical services—representing just 15% to 18% of the entire estimated population affected by this condition (Table S1, supplementary data). Considering that about 30% of AMD cases in Poland are at an advanced stage, it is evident that a significant portion of the Polish population with this disease does not benefit from treatment at all.^[3]

Hospitalizations

Of the diagnosed patients (main or associated diagnosis), approximately 26% with AMD and 19% with DME resulted in hospitalization (Figure 2a). Every eighth hospitalization of a patient with AMD, and every third with DME, falls under the diagnosis-related group (DRG) B84, which covers small vitreoretinal procedures where most hospitalized patients undergo recombinant protein injections (Figure 2b). Additionally, in 2020, over 13,000 hospitalized DME patients underwent photocoagulation.



DME indicates diabetic macular edema; nAMD, neovascular age-related macular degeneration.

Figure 1. Estimated number of patients with DME and nAMD in Poland

The number of hospitalizations in 2020 slightly decreased, likely due to the COVID-19 pandemic, but the trend for small vitreoretinal procedures, including recombinant protein injections, continued to rise. This increase was particularly notable in the number of AMD hospitalizations, which reached nearly 14,000 in 2022, 1.6 times the number from 2020. The trend for DME was harder to determine due to changes in the disease-assigned codes reporting by the NHF. However, the overall trends in Poland are not optimistic, especially given the increasing aging of the population (the rate of Poles aged 65+ in 2060 is expected to be 18.5% higher than it was in 2013).^[3]

Drug Programs

In 2015, the B.70 drug program for patients with nAMD was implemented in Poland, allowing affected individuals to be treated according to the best therapeutic standards with aflibercept or ranibizumab, and later with brolocizumab. For DME, no active substances were nationally reimbursed until 2021. Treatment was conducted only within the DRG B84 group (small vitreoretinal procedures) in hospital settings. However, this approach was burdensome for ophthalmology centers because recurrent injections (approximately 32,000 in 2019) required patient hospitalization each time.^[7] Finally, in 2021, the B.120 drug program was created, based on bevacizumab, aflibercept, and dexamethasone, and soon expanded to include ranibizumab. In mid-2022, both drug programs (B.70 and B.120) were merged, and since then, patients with both diseases have been treated under a single program (retaining the B.70 number), with two separate subgroups: nAMD and DME.^[16]

Participation in the program requires meeting strict criteria (Figure S1, supplementary data). Inclusion to the DP

provides the patient with regular injections of the drug and control of the effectiveness of the therapy, which has a significant impact on the achieved results. However, access to the DP B.70 is not easy and varies from region to region.^[13] In 2022, nationwide, only 5% of facilities signed a contract with the NHF for the implementation of the program (nAMD and DME). Qualification and therapy take place in selected ophthalmology facilities, but they are not evenly distributed across the country: in four (out of sixteen) voivodeships is aggregated 40% of contractors and 46% of contracted amount of money.^[17,18]

In March 2023, a total of 192 centers serviced contracts under DP B.70, with a total value exceeding PLN 260 million. The voivodeships (territorial entities in Poland) with the highest activity in the treatment of patients in the program were Silesian (15 facilities with contracts totaling PLN 42 million), Lower Silesian (19 facilities with contracts totaling PLN 27 million), and Mazovian (the largest number of centers, 20, with contracts totaling over PLN 23 million). The Opole and Warmian-Masurian voivodeships were the least active, with five facilities contracted for just over PLN 4 million and six facilities contracted for PLN 6 million, respectively.^[18] Even considering that the number of patients in those voivodeships is lower due to a smaller overall population, access to treatment is more restricted, partly because of the long distances to the nearest ophthalmologist. Uneven access to treatment in the DP forces patients to seek care in other, often distant, provinces: more than 70% of patients treated in the Mazovia Province do not actually live there, resulting in financial and time burdens due to the need for travel. Ultimately, only about 70% of patients in Poland receive free treatment for nAMD as part of NHF-financed care, while the remaining 30% opt for more accessible but paid treatment within the private healthcare sector.^[13]

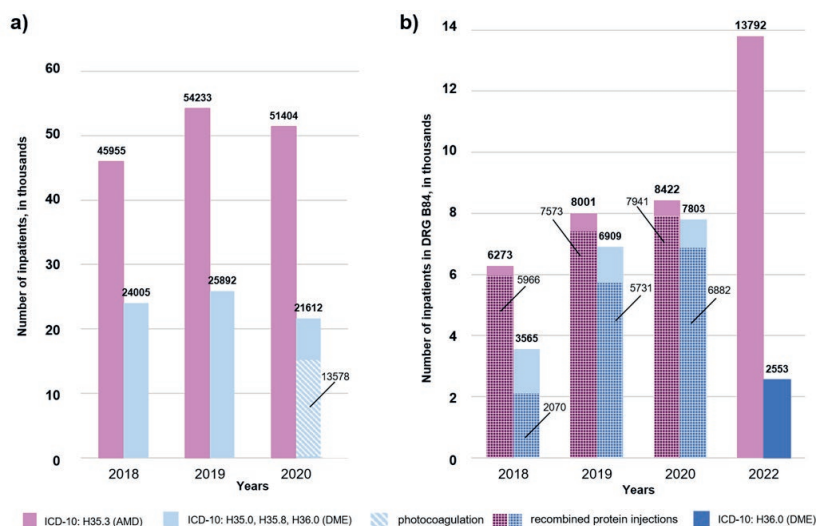


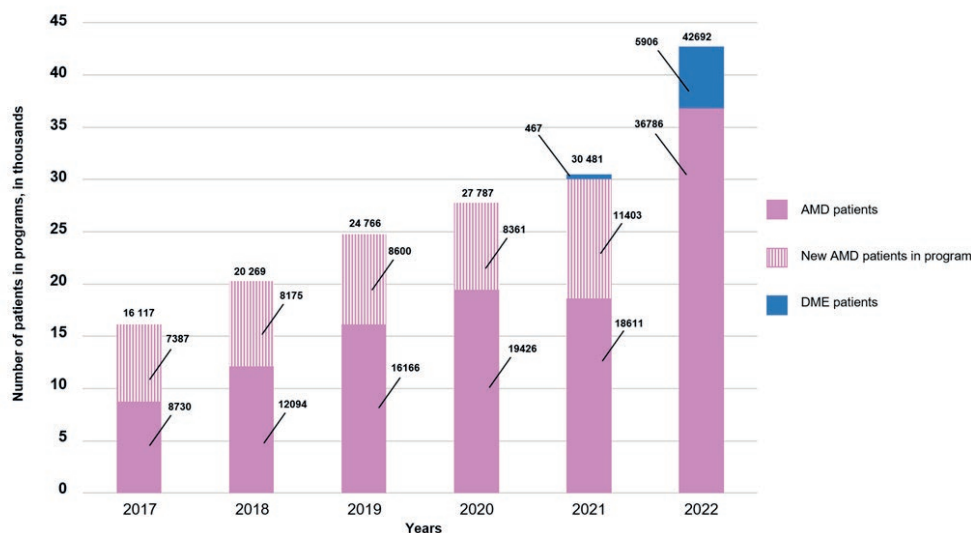
Figure 2. Number of inpatients with AMD and DME in Poland and number of hospitalized in DRG B84

The number of patients included in the DP is a small percentage of those who, according to epidemiological data, meet the eligibility criteria for it. In the case of DME, 467 and 5,906 patients were included in DP in 2021 and 2022, respectively, out of an estimated 16,600 to 22,700 potentially eligible patients.^[3,7,19,20] For nAMD, there were 30,014 and 36,786 patients included in DP in 2021 and 2022, respectively (Figure 3).

Patients are qualified for treatment under PL B.70 with the participation of the Coordinating Team for the Treatment of Retinal Diseases, composed of ophthalmology specialists and operating at each center that provides qualification for the program.^[21] The average time interval to start treatment under PL B.70 for both AMD and DME is approximately 8 days. The longest waiting times are in the Warmian-Masurian and Silesian voivodeships (20 and 17 days, respectively), while the shortest waiting times are in the Podlaskie, Lesser Poland, and Holy Cross Provinces (1 to 3 days). Waiting time does not depend on the average number of patients per treatment provider: in the Pomeranian Province, only 5 patients wait to start treatment, while in Kujawsko-Pomorskie, as many as 225 patients wait. In both regions, the average number of patients per facility involved in B.70 is around 160.^[22]

The percentage of rejected applications to the DP in 2022 was 14%. The highest rejection rate was in the Lubuskie Voivodeship at 24%, while the lowest was in the Mazovian Voivodeship at 5%.^[23] The main reasons for not qualifying for the program are advanced eye lesions (76% of rejection cases in nAMD and 48% in DME) and low visual acuity (68% and 36%, respectively). In the case of DME, unregulated diabetes is also a common reason for disqualification (32%). Patients with both diseases who do not meet the conditions for inclusion are treated outside the DP: half are treated under small vitreoretinal procedures (DRG B84), while the other half are treated in the private sector.^[13,24] (Table 1).

Patients treated outside the program include those who do not meet the eligibility criteria as well as those who have been excluded from it. Between 2017 and 2019, an average of around 3,000 patients per year left the program, while this number almost tripled between 2020 and 2021. This increase is likely due to the COVID-19 pandemic and the difficulties in maintaining the continuity of injections and frequent check-ups (every third doctor cites this as a reason for patient exclusion). Additionally, the main reasons for discontinuation are a decrease in visual acuity (68%) and permanent structural changes in the eye (48%).^[13] There are also cases of patient exclusion due to the ab-



Note: In 2022 no data of new involved patients. AMD indicates age-related macular degeneration; DME, diabetic macular edema.

Figure 3. Number of patients treated in drug programs B.70 and B.120

Table 1. Number of hospitalizations related to recombinant protein injections among patients non-qualified to the program

	Years				
	2016	2017	2018	2019	2020
Number of hospitalizations related to recombinant protein injection	2 757	8 433	18 243	33 351	35 465
Percentage of these hospitalizations among all hospitalizations in the DRG B84 group	32%	55%	80%	88%	92%

sence of visible signs of active disease for at least 4 months, eliminating the need for further injections. When these patients' conditions deteriorate, they must undergo the entire qualification procedure for the program again. Unfortunately, some do not reapply due to the burdensome nature of the process.^[13]

In 2022, the intravitreal injection service was positively recommended by the President of the Polish Agency for Health Technology Assessment and Tariff System to become a guaranteed outpatient specialist care service. This greatly simplifies treatment, as numerous ambulatory care units improve the accessibility of injections for patients while maintaining a comparable safety level for the procedure. Moreover, some of the public payer's expenses incurred in hospital treatment can be transferred to ambulatory care units.^[25] This allows for a reduction in spending that is already heavily burdening the national

budget. The total costs of drugs used in the B.70 and B.120 programs have been gradually increasing over the years, along with the rise in the number of patients involved and medications used. Additionally, there is an increase in non-drug services, including outpatient visits, diagnostics, and qualifications (Figure 4).

The total cost of the programs (all components) increased from nearly PLN 200 million in 2019 to almost PLN 290 million in 2022. However, it should be noted that the number of beneficiaries increased from 25,000 to 43,000 during this period. The average annual cost of treatment for an individual participant in the B.70 program from 2019 to 2021 ranged between PLN 7,000 and PLN 8,000, while the combination of programs in 2022 reduced the average cost to PLN 6,600. Drug costs account for approximately 53% of the total program cost each year (Figure 5).

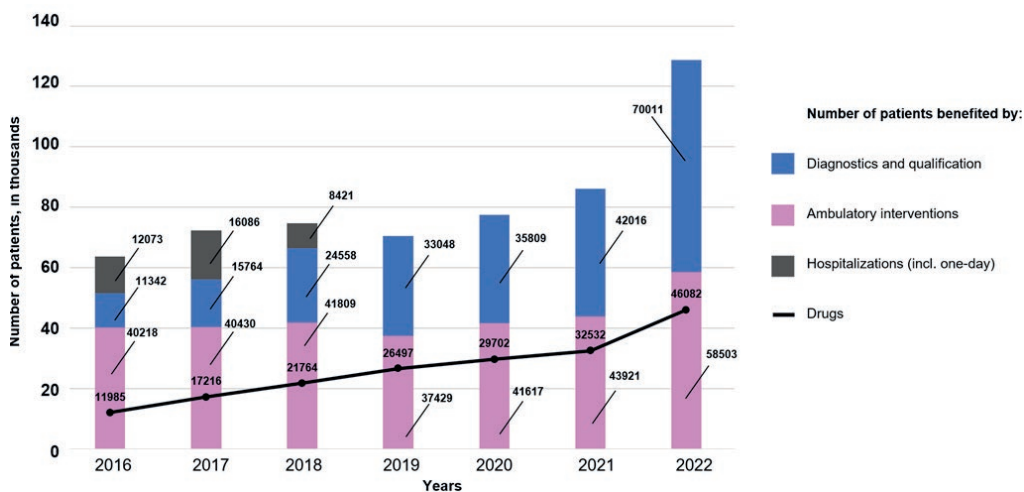


Figure 4. Number of patients using drugs, services and procedures in drug programs B.70 and B.120

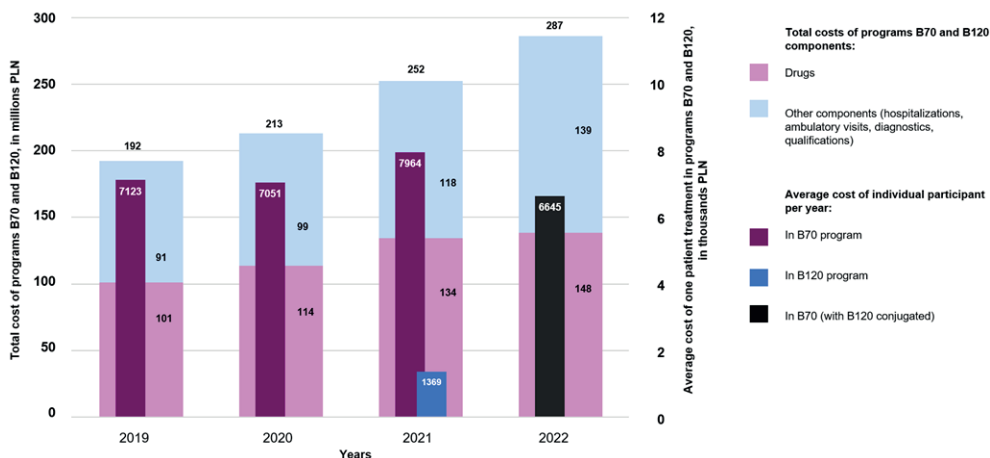


Figure 5. Total costs of drug programs B70 and B120 components and average cost of individual participant per year

4. Discussion

Awareness of eye diseases in Poland remains low. Achieving a satisfactory level of treatment for retinal diseases will be challenging in a society where only one in five Poles has heard of AMD and only one in nine is aware of DME.^[3] According to the Health Care Institute, 32% of Poles have never visited an ophthalmologist, and an equal proportion feel ashamed and uncomfortable about their condition in front of others.^[3] Education aimed at raising awareness and supporting patients with retinal diseases, as well as preventing them from feeling socially excluded, seems necessary.

In 2022, nationwide, only 5% of facilities signed a contract with the National Health Fund for the implementation of the DP B.70.^[13] Difficulties related to accessing facilities performing intravitreal injections within the DP were particularly noticeable during the COVID-19 pandemic when the number of patients excluded from the program increased significantly. From 2017 to 2019, an average of 3,200 patients left the program annually. However, during the pandemic years of 2020-2021, the number of excluded patients rose to nearly 8,900 per year. The primary reason for exclusion was failing to appear before the attending physician at two consecutive checkpoints specified by the program, resulting in the refusal of further cost-free treatment.^[16,26]

Despite a relatively large number of ophthalmologists (1.07 per 10,000 inhabitants), there is a severe lack of optometrists in Poland, causing significant organizational problems in the prevention and diagnosis of eye diseases.^[27] Patients are referred to specialists too late, often in the advanced stage of macular edema.^[13] In a survey commissioned by Retina AMD Poland association, as many as 24% of doctors pointed to organizational difficulties resulting from a large number of patients.^[13] A significant difficulty in treating patients under the program was the high degree of complexity of the qualification procedures - gradually simplified after the program was introduced.^[26] Ophthalmology facilities, inexperienced in servicing patients under drug programs (DP B.70 was the first and so far the only drug program for patients with ophthalmological issues), implemented and developed the program more slowly than multi-specialty facilities that had been using DPs for a long time in other medical fields. This contributed to inequalities in access to treatment across the country and partially explains the low percentage of diagnoses compared to epidemiological data.

In 2019, the recombinant protein injection procedure as part of the DRG was priced at PLN 616-724, depending on whether it was performed as a one-day treatment or as part of hospitalization. The cost of an anti-VEGF intra-

vitreal injection in the ambulatory mode within the DP is approximately PLN 380.^[7] The administration of drugs within the DP significantly reduces the costs of treating retinal diseases in Poland, so it should be aimed at the widest possible coverage of patients with DME and nAMD with this form of treatment.

Unfortunately, patients with AMD and DME face significant challenges due to inefficiencies in the Polish healthcare system. Factors such as long waits for ophthalmologists, flaws in prevention programs, excessive bureaucracy in drug programs, and other systemic issues often pose serious barriers to effective treatment. While the Polish third-party payer (NHF) and the Ministry of Health may theoretically save on treatment costs, the long-term consequences result in high social costs.

5. Conclusion

The analysis of data regarding the implementation of the AMD and DME treatment program in Poland indicates significant untapped potential. Despite the large number of potential patients, only a small fraction receives treatment. This can be attributed to factors such as low public awareness of the disease and underdiagnosis. Access to the best available medical technologies and treatment opportunities is currently fragmentary and unevenly distributed. There is an urgent need to improve access to AMD and DME treatment in Poland.

Close cooperation among health market analysts, the public payer, and ophthalmologists is essential for the optimal allocation of financial and medical resources, ensuring effective treatment for patients suffering from retinal edema in Poland.

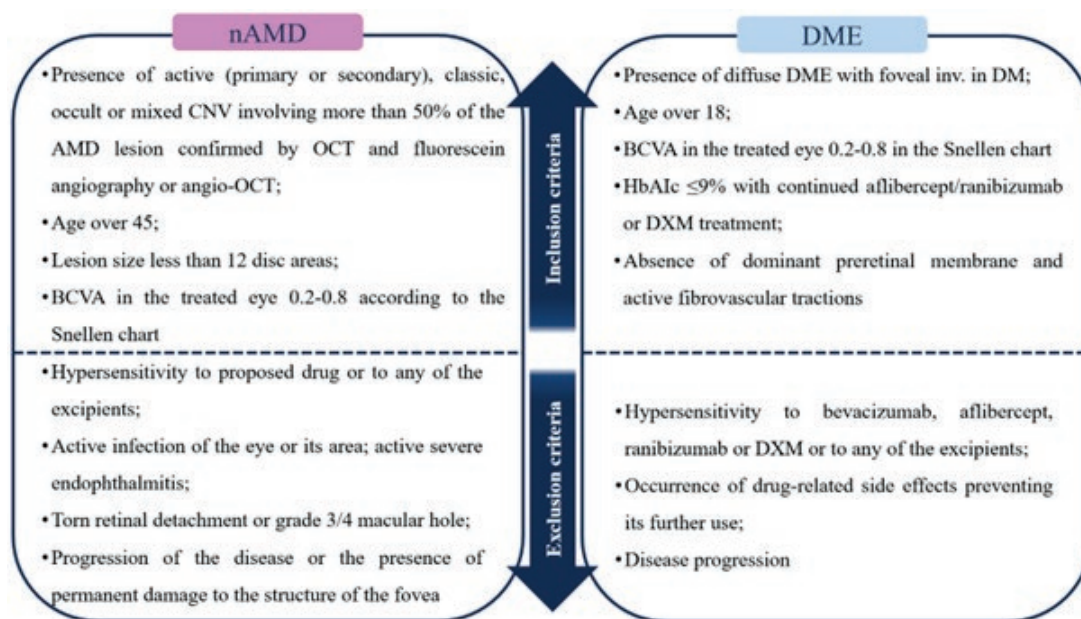
Notes:

All authors declare that there are no conflicts of interests. All authors declare that this research did not receive any funding for the research.

6. Supplementary Data

	Years				
	2017	2018	2019	2020	2021
Number of diagnosed cases of H35.0 ,H35.8 ,H36.0) DME as a main diagnosis(130 788	132 648	138 787	113 890	131 787
Number of diagnosed cases of H35.3) AMD as a main diagnosis(161 546	174 186	188 033	170 892	199 861

Note: Numbers of AMD cases constitute both, dry and neovascular form
 AMD indicates age-related macular degeneration; DME, diabetic macular edema; ICD-10, International Classification of Diseases, tenth edition.
 Source: "Open Data" Portal. National Health Fund [cited: 10.03.2023] Available from: <https://dane.gov.pl/pl/dataset/2557> <https://dane.gov.pl/pl/dataset/2557>



AMD indicates age-related macular degeneration; BCVA best corrected visual acuity; CNV, choroidal neovascularization; DME diabetic macular edema; DXM, dexamethasone; HbA1c, glycated hemoglobin; nAMD, neovascular age-related macular degeneration; OCT, optical coherence tomography.
 Source: Ministry of Health. Drug Program B.70 [cited: 22.07.2023] Available from: <https://www.gov.pl/web/zdrowie/obwieszczenia-ministra-zdrowia-lis-ta-lekow-refundowanych>

Figure S1. The main criteria for patients for drug program participation

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