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Pharmacoeconomic Aspects of Using New Generation Drugs Of PCSK-9 Inhibitor and Acting on The Effect of Ribonucleic Acid Interference Classes in The Treatment of Patients With Hypercholesterolemia

Aim	Clinical and economic analysis of the feasibility of using new-generation drugs of the PCSK-9 inhibitor class (alirocumab and evolocumab) and the drugs that utilize in their action the effect of ribonucleic acid interference (inclisiran) in the treatment of patients with a high risk of cardiovascular events in medical organizations of the Moscow Region (MR).
Material and methods	Based on statistical and literature data on morbidity, as well as data from real-life practice about using alirocumab, evolocumab, and inclisiran in medical organizations of the MR, populations of patients with hypercholesterolemia and cardiovascular pathology were identified in that region. Two analytical models were developed that include the structure and number of patients receiving a combination therapy (high-dose statins + ezetimibe + alirocumab/evolocumab/inclisiran). To estimate the economic feasibility of the treatment with innovative drugs, direct medical costs were calculated for various therapeutic regimens. The cost of pharmacotherapy was calculated per patient per one-year course. A budget impact analysis (BIA) and a sensitivity analysis of the results were performed. The modeling period of the study was 3 years.
Results	The number of patients in different populations receiving the combination therapy will be 12,228 and 895 people in the first year, and 12,973 and 950 people in the third year, taking into account the determined increase in the patient number. The total costs of treating one patient with hypercholesterolemia and cardiovascular diseases during the first year of therapy with inclisiran are 23.31 and 27.66% lower than with evolocumab and alirocumab, respectively. The BIA revealed a slight increase in the total cost of treating patients in each population (by 1.39 and 1.69% compared to 2024). The increase in the regional budget will be related only with the annual increase in the number of patients with hypercholesterolemia. The sensitivity analysis showed the robustness of the results to changes in the initial parameter values.
Conclusion	The treatment of patients with dyslipidemia and high risk of cardiovascular events with alirocumab/evolocumab/inclisiran as part of the combination therapy is an economically justified strategy in the settings of the regional healthcare system.

Keywords	Alirocumab; evolocumab; inclisiran; PCSK-9 inhibitors; hypercholesterolemia; cardiovascular complications; budget impact analysis; clinical and economic analysis
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Introduction

Hypercholesterolemia (HCH) is a common disease characterized by high blood levels of low-density lipoproteins (LDL) and early development of atherosclerotic cardiovascular diseases (CVD) [1]. Elevated LDL cholesterol (C) concentrations are considered a key factor in the development and progression of atherosclerosis and the most important and common modifiable cardiovascular (CV) risk factor [2, 3]. CV pathology of atherosclerotic origin ranks first in morbidity and mortality in most countries [4].

Circulatory system diseases (CSDs) rank high among the diseases, which prevalence is growing particularly rapidly and steadily [5]. In the coming decades, growth of the CSD risk is predicted due to the increasing prevalence of risk factors, lifestyle features, and age-related transformation of the population with the increasing proportion of old people [6]. Currently, the Russian Federation is one of the countries with a high risk of CVD that prevail in the structure of overall mortality and determine high social losses in the working-age population.

Modern pharmacotherapy used in the treatment of patients with elevated LDL-C (dyslipidemia) has proven its efficacy and safety and is extensively used worldwide for primary and secondary prevention of CV events. However, most patients who receive lipid-lowering drugs often do not achieve target LDL-C values due to insufficient intensity of the prescribed therapy [7]. Thus, a relevant task for practitioners providing care to patients at risk of developing CVD is to optimize cholesterol-lowering therapy aimed at achieving the recommended lipid profile values and minimizing the risk of CV catastrophes at all stages of treatment [8].

Aim

Clinical and economic analysis of the feasibility of using new-generation drugs of the PCSK-9 inhibitor classes (alirocumab and evolocumab) and the drugs that utilize in their action the effect of ribonucleic acid interference (inclisiran) in the treatment of patients with a high risk of CV events in medical organizations of the Moscow Region (MR).

Material and methods

The study was based on the hypothesis of clinical and economic feasibility of using a combination therapy with inclisiran in patients with lipid metabolism disorders and a risk of CV events compared to a multicomponent therapy in combination with alirocumab and evolocumab, which is currently used in medical organizations of the Moscow Region. The economic outcomes of introducing new treatments to clinical practice was evaluated from the perspective of the regional healthcare system. Only direct medical costs paid from budgetary and/or the compulsory health insurance (CHI) funds were taken into account.

This study was performed in consistency with the methodological guidelines for conducting a budget impact analysis (BIA) [9]. To perform the BIA, an original mathematical model was constructed using a Microsoft Excel package. The model provides a long-term economic assessment of the efficacy of a combination therapy with alirocumab, evolocumab, and inclisiran in patients with abnormal lipid profile in combination with CV events.

General characteristic of the study

The study used several assumptions:

- the study included only adult patients with lipid metabolism disorders and CV events who received a drug therapy with statins at maximum tolerated doses in combination with ezetimibe and alirocumab/evolocumab/inclisiran;
- with a controlled course of the disease, patients are managed by respective specialists in an outpatient clinic;
- in case of complications, a patient with this disease, in addition to emergency medical care (EMC), can be treated in a 24-hour hospital;
- a patient can receive various types of revascularization, including coronary and aortic stenting/bypass grafting;
- after acute CV events, the patient can receive medical rehabilitation.

Cost analysis

The cost analysis included only direct medical costs related with the treatment of adult patients with HCH and risk of CV events, who required multicomponent therapy in combination with alirocumab/evolocumab/inclisiran. The study assessed the costs of:

- combination lipid-lowering therapy;
- outpatient visits to specialists for disease control and drug administration;
- emergency medical care;
- treatment in a 24-hour hospital if CV events occur;
- treatment in a day hospital (drug administration);
- rehabilitation after acute CV events.

For all drugs included in the list of vital and essential drugs (VED), the cost of one package was calculated based on the price registered in the State Register of Maximum Selling Prices (SRMSP), taking into account the value added tax (VAT). The VAT for drugs in the Russian Federation is 10% (preferential taxation). The cost of ezetimibe and inclisiran, which are not included in the VED list, was determined based on the average retail price per package according to the Pharmindex.RF website [10].

The dosing regimen of the drugs was determined based on the clinical guidelines, "Lipid metabolism disorders," "Acute coronary syndrome without ST-segment elevation on the electrocardiogram," "Acute coronary syndrome with ST-segment elevation on the electrocardiogram," "Stable ischemic heart disease", and official instructions for medical use of the SRMSP [11-19]. The cost of drug therapy was calculated per patient for one year. The study assumed that all patients were prescribed high-intensity lipid-lowering therapy, namely statins at high doses. Currently, the use of the following statins is justified to achieve the target level of LDL-C and reduce the risk of CV complications: rosuvastatin, atorvastatin, pitavastatin, and simvastatin. In calculating the cost of high-dose statin therapy, we took into account only atorvastatin for the entire cohort of patients, since, according

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to the most recent statistics, this drug is prescribed in 91% of cases.

According to the official instructions for use of the State Register of Medicines, inclisiran is administered as a subcutaneous injection under the direct supervision of a physician or another health care professional. Thus, the patient, taking into account the frequency of administration of the drug, visits a medical organization to perform a subcutaneous injection. The cost of injection was included in the costs of one outpatient visit for a disease. Alirocumab and evolocumab can be used by the patient independently after training in the technique of their administration.

Since lipid metabolism disorders, such as elevated blood LDL-C, are direct predictors of CV events, the study assessed the health care system resources related with the introduction of risks of these complications, the mean annual frequency of which was determined based on the results of randomized clinical trials and meta-analyses [20–24]. When CV complications occurred, the patient called the ambulance and then received treatment in a 24-hour hospital. The mean frequency of hospitalizations in a 24-hour hospital per patient was equal to the incidence of severe complications per year.

The frequency of outpatient visits of uncomplicated patients to appropriate specialists (cardiologist) was determined based on the average indicators of the frequency of care provision and ratio of visits to specialists, extracted from the standard of medical care: Order of the Ministry of Health of the Russian Federation dated 06/10/2021 #612n "On approval of the standard medical care for adults with electrocardiogram ST-segment elevation acute myocardial infarction (diagnosis, treatment and dispensary observation)" and amounted to once per month [25]. The cost of a visit to a cardiologist was calculated based on the standard financial costs per visit for the disease in accordance with the Tariff Agreement for the implementation of the Moscow Regional Compulsory Medical Insurance Program for 2024 [26].

The cost of inpatient treatment was determined based on the standard financial costs per hospitalization in a 24-hour (24hH) and day (DH) hospitals at the expense of the CHI funds. The costs of providing medical care were calculated according to the Methodological Recommendations on Methods of Payment for Medical Care at the expense of the CHI of the Federal CHI Fund (FCHIF) [27], taking into account the data of the Tariff Agreement for the Implementation of the Moscow Regional Compulsory Health Insurance Program for 2024.

Population of patients with lipid metabolism disorders and cardiovascular diseases in the Moscow region

In the study, the target population size was calculated using two analytical models. The initial number of patients for the first model was established based on the data from the territorial compulsory health insurance fund (TCHIF) of the Moscow region on the number of admitted patients, morbidity statistics on the number of registered cases of ischemic heart disease (IHD) in the territory of the Moscow region [28], and data from a published reports on the number of patients with dyslipidemia receiving combination therapy [29]. The patient population size for the second model was calculated based on information about the preferential drug provision (PDP) for patients with HCH and CVD and data provided by the TCHIF of the Moscow region on the number of patients who received medical care in a DH (administration of necessary drugs).

Based on the obtained data and considering the characteristics of patients with indications for therapy with PCSK-9 inhibitors (alirocumab and evolocumab) and the drugs with the action based on the effect of ribonucleic acid interference (inclisiran), patients diagnosed with IHD were included in the estimated population. According to the clinical guidelines "Stable ischemic heart disease", IHD is a myocardial lesion caused by impaired blood flow in the coronary arteries (CA). The main cause of the organic damage is CA atherosclerosis. IHD is a disease, the development of which is determined by the presence and further growth of an obstructive or non-obstructive atherosclerotic plaque.

According to the annual data of the Russian Ministry of Health on the morbidity by main classes, groups and individual diseases, the number of patients with IHD is expected to increase. Based on these data, the number of IHD patients has increased annually by 3.00% as shown by two mathematical models.

Budget impact analysis

The analysis was performed in accordance with the methodological recommendations of the Center for Healthcare Quality Assessment and Control of the Ministry of Health of the Russian Federation [9] to assess the economic consequences for the healthcare system of the Moscow region when changing the dosing frequency of alirocumab and evolocumab and introducing a new treatment method with inclisiran in adult patients with CSDs and lipid metabolism disorders.

For the BIA, two scenarios of using various drug therapy schedules in patients with CSC and lipid metabolism disorders were considered:

- current medical practice: a basic scenario; describes the costs of using combination therapy with alirocumab/evolocumab in the analyzed population at medical organizations in the territory of the Moscow region;
- modeled medical practice: an alternative scenario; describes the predicted change in the costs of healthcare in the Moscow region if pharmacotherapy with inclisiran is used in medical practice.

The BIA provides for a stepwise transition of patients from the alirocumab/evolocumab treatment to the inclisiran treatment. The proportion of each drug therapy in the total population structure is determined based on the PDP for patients with CSD in the Moscow region. An increase in using the inclisiran treatment strategy is predicted due to the possible patient switching from the alirocumab/evolocumab treatment.

Since inclisiran is not included in the VED list, it can be prescribed only by decision of the medical commission. The analysis of the PDP determined the number of patients receiving inclisiran. Thus, in 2024, 0.03% of all patients with CVD in the Moscow region took inclisiran. The annual patient switching (%), i.e. the decline in the use of alirocumab and evolocumab, was also predicted taking into account the proportion of patients who can achieve the LDL-C goal <1.4 mmol/l on PCSK-9 inhibitors, as which we determined based on a published report. Thus, the modeled annual proportion of patients on combination therapy with inclisiran in 2025 and 2026 is 5.09 and 10.18%, respectively.

Alirocumab, evolocumab, and inclisiran are available as a solution for subcutaneous injections and can be used both in inpatient and outpatient settings. The study assumed that the identified patient populations will receive the required drug therapy through the PDP and CHI. The frequency of use of the analyzed drugs at two levels of medical care that we determined is static and does not change throughout the entire modeling period. The study assumed that at the hospital stage of medical care for patients with HCH and CV complications, the alirocumab, evolocumab, and inclisiran are administered in a DH. Hospitalization costs were calculated based on the standard expenses for the respective clinical statistical group (CSG).

Sensitivity analysis

To evaluate the impact of changes in baseline parameters on the study results, a sensitivity analysis was performed. The sensitivity analysis was performed on input parameters, including the cost of inclisiran and the annual proportion of patients on combination therapy with this innovative drug. The selected criterion of cost was changed by 10% from the baseline value, and the annual proportion of patients was increased from the baseline value of 5.09% to 10.18% and 20.36.

Results

Results of the assessment of the cost of different drug regimens

In order to determine the economic feasibility of different drug treatments in medical organizations of the Moscow region, we calculated the costs of each treatment per patient with HCH and concomitant CVD for a one-year course. The results of the cost analysis are presented in Table 1.

According to the official instructions for use of the SRMSP, inclisiran is administered to the patient by a physician or another health care professional, therefore, the inpatient use of this drug is possible. However, due to the current absence of a CSG for the inpatient administration of this drug, and since according to the PDP in the Moscow region for 2024 inclisiran is prescribed by decision of the medical board, the study assumed that after receiving the required drug, the patient was administered it in the outpatient setting. Taking into account the regimen of the inclisiran treatment and the fact that the patient with HCH and concomitant CVD visits a cardiologist every month, no additional costs were provided for the administration of inclisiran.

The annual costs of the inclisiran treatment per patient in the first year of treatment are 23.31% and 27.66% lower than the costs of the evolocumab and alirocumab treatment, respectively. The alirocumab treatment is associated with the highest costs (12,354.69 rubles) and inclisiran combination therapy is associated with the lowest costs (2,982.89 rubles) for treatment of complications.

Based on the official instructions for use of inclisiran, patients need three packages of the drug in the first year of therapy. Subsequent injections are administered every 6 months, i.e. already two packages of the drug are needed for a one-year course of treatment. Thus, the total cost of treating one patient in the second and subsequent years will be 261,158.25 rubles. Changing the dosing regimen will help reduce the cost of inclisiran combination therapy for such patients and will make this strategy even more cost-effective compared to pharmacotherapy with alirocumab and evolocumab.

Since the incidence of CV events varies depending on the drug therapy used, the costs of managing emergency conditions and rehabilitation vary for each treatment strategy.

Results of determining the target patient population

Step-by-step determination of the population of patients with HCH and CV complications receiving com-

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Table 1. Treatment costs per patient with hypercholesterolemia and cardiovascular diseases

Parameter	Therapy with alirocumab	Therapy with evolocumab	Therapy with inclisiran (1st year)	Therapy with inclisiran (2nd and subsequent years
Direct medical costs, rubles				
Costs of drug therapy	501 741.07	475 715.21	367 287.48	249 922.10
Costs of drug therapy (by PDP)	120 466.35	105 535.75	60 344.15	40 229.43
Costs of drug therapy (by CMI)	366 083.40	354 988.13	291 752.01	194 501.34
Costs of inpatient visits	6 360.00	6 360.00	6 360.00	6 360.00
Costs of treatment of complications, rubles				
Unstable angina	232.48	1 478.99	346.49	346.49
Ischemic stroke	870.40	933.70	1 038.39	1 038.39
Myocardial infarction	3 490.19	1 694.33	1 598.00	1 598.00
Revascularization	7 761.61	5 543.99	–	–
TOTAL	**12 354.69**	**9 651.01**	**2 982.89**	**2 982.89**
Costs of rehabilitation, rubles				
Medical rehabilitation of a patient after acute myocardial infarction	1 886.59	915.85	863.78	863.78
Medical rehabilitation of a patient after acute cerebrovascular disease	862.93	925.69	1 029.48	1 029.48
TOTAL	**2 749.52**	**1 841.54**	**1 893.26**	**1 893.26**
Costs of UMC	215.95	208.92	138.39	138.39
TOTAL	**523 421.23**	**493 776.68**	**378 662.02**	**261 158.25**

MP, medicinal product; PDP, preferential drug provision; CMI, compulsory medical insurance; UMC, urgent medical care.

plex therapy is presented in Figures 1 and 2 for two analytical models.

According to the data extrapolation to the total population of IHD patients in the Moscow region, based on statistics of morbidity in the region, in the third year of analysis, 12,973 people will receive combination therapy with alirocumab/evolocumab/inclisiran.

Results of the budget impact analysis

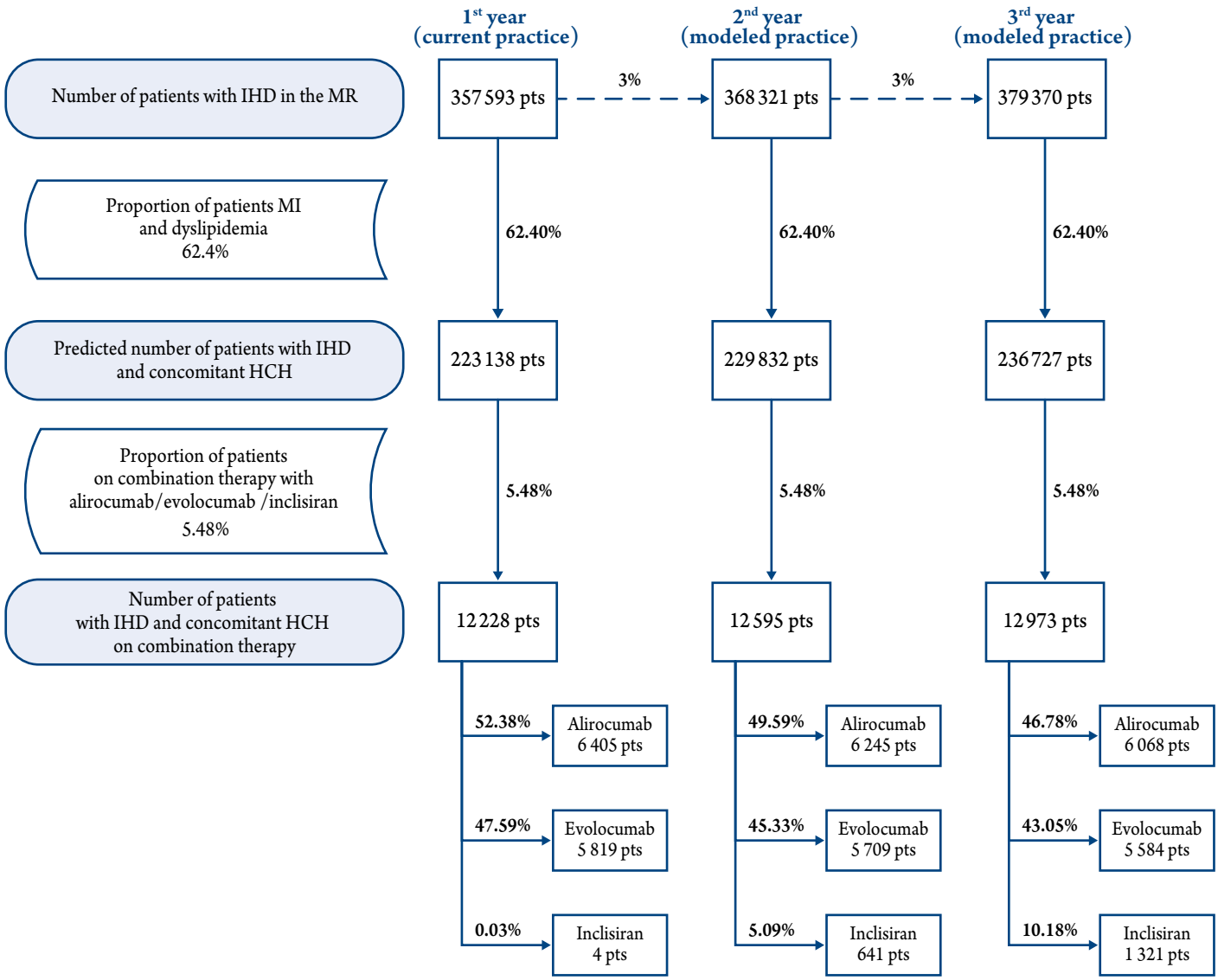
Total direct medical costs for two analytical models taking into account the characteristics and size of target patient populations are presented in Table 2. It should be noted that at the time of the study, inclisiran was not included in the VED list. Therefore, the cost calculation used the price that we determined based on data from the PharmIndex.RF analytical portal [10].

In the first model, the total costs of treating patients with HCH and a high risk of CV complications of the combination therapy with innovative drugs for current practice will amount to 6,126,275.60 rubles. The inclisiran treatment is related with the lowest costs over the entire modeling period: in the first year of the modeled practice, 237,044.60 rubles and in the second year, 412,949.58 rubles. A gradual increase in the population of patients treated with this drug leads to an expectable growth of costs. The BIA showed that the use of multicomponent therapy with alirocumab, evolocumab and inclisiran allowing for the annual increase in the number of IHD patients (3.00%), a gradual increase (inclisiran) and decrease in the proportions (alirocumab and evolocumab) of the use of the analyzed drugs, will lead to an increase in final costs by 2026 by 1.34%, i.e., additional costs for the health care budget of the Moscow region will be 83,386,859.60 rubles. Noteworthy, during the second year of modeling, there will be a decrease in costs by 0.03% (1,605,305.90 rubles) compared to the first year.

With the second analytical model, the scheme with inclisiran also shows the lowest costs over the time preestablished in the study. Results of the BIA based on the real-life practice of using innovative drugs in the Moscow region showed that the use of these drugs will lead to an increase in total costs by 2026 by 1.67%, i.e. additional costs of the regional healthcare budget will be 7,763,304.50 rubles. The total costs of treatment in the first year of the modeled practice will be higher by 1.20% (5,585,755.55 rubles) compared to the current practice, and in the second year of modeling, by 0.47% (2,177,548.95 rubles) compared to the first year of the modeled practice.

It should be emphasized that the inclusion of inclisiran in the VED list will make this treatment strategy even more cost-effective. Thus, in the first analytical model, the costs will decrease by 0.08% (5,087,014.32 ru-

Figure 1. Population of patients with IHD and lipid metabolism disorder in the Moscow region (first model)



IHD, ischemic heart disease, MI, myocardial infarction, MR, the Moscow Region.

bles) during the second year of modeling compared to the first year, and by 2026, the final costs will increase by 1.23% vs. 1.34%. In the second model, the costs will increase by 1.60% vs. 1.67% by 2026, and in the second year of modeling, by 0.40%.

Thus, the gradual expansion of using inclisiran in both populations will lead to a uniform reduction in the final costs of drug therapy for patients with lipid metabolism disorders and CSD in the Moscow region. The growth of costs will be due only to the annual increase in the population of patients with these diseases.

Results of the sensitivity analysis

The deterministic sensitivity analysis demonstrated the robustness of the study results. With an increase in the annual proportion of patients taking inclisiran as part of complex therapy and a 10% price increase (prices for alirocumab and evolocumab remain unchanged), prescribing inclisiran to patients with HCH and risk of CV events remains an economically justified choice.

Discussion

The most clinically significant forms of dyslipidemia are known to be those characterized by increased LDL-C. This abnormality is one of the main risk factors for CVD, which significantly contributes to mortality due to their high prevalence. Elevated cholesterol is among the main risk factors for myocardial infarction and stroke [30-33].

Currently, the leading strategy for CV prevention in HCH is control of blood lipids in patients with a high risk of CV events, i.e., reducing LDL-C to its target values with lipid-lowering therapy to minimize the risk of

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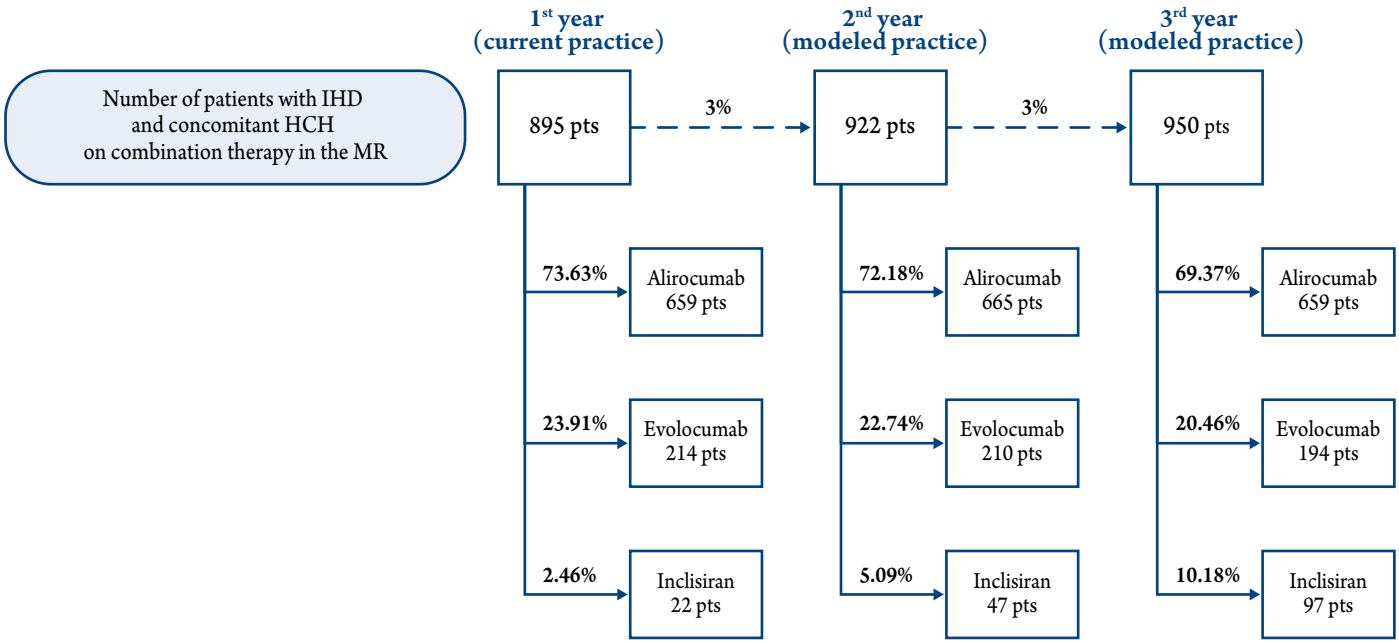
Figure 2. Population of patients with IHD and lipid metabolism disorder in the Moscow Region (second model)



IHD, ischemic heart disease, MI, myocardial infarction, MR, the Moscow Region.

Based on data from real-life practice of using the analyzed drugs in medical organizations of the Moscow Region, it was found that 950 patients will receive the combination treatment during the third year of modeling.

CV events. Until recently, the main treatment for this category of patients was high-intensity statin therapy in combination with fibrates, ezetimibe, and omega-3 polyunsaturated fatty acid drugs.

Not all patients requiring lipid-lowering therapy can take the above drugs due to contraindications or adverse reactions. Also, some patients fail to achieve the lipid profile goal. This warrants developing and studying basically new drugs for correction of hyperlipidemia. According to the latest guidelines on dyslipidemia, if the LDL-C goal cannot be achieved with a combination treatment containing statins in maximum doses and ezetimibe, PCSK-9 inhibitors and drugs with the action based on the ribonucleic acid interference is indicated. Drugs of these classes are important in the treatment of patients with a high risk of CV events, specifically in patients with severe/widespread forms of atherosclerosis (multivessel CA disease, multifocal atherosclerosis), or signs of atherosclerosis progression (repeated CV events within 5 years after the primary CV event) despite achieving target LDL-C with combination therapy.

Study limitations

This study was performed in 2024, when inclisiran was not included in the VED list. Currently, this drug is included in the relevant list [34]. Thus, if a clinical and economic analysis is conducted at present, this circumstance may affect the cost parameters obtained in this study analysis.

Conclusions

The study analysis allows the following conclusions:

1. For the BIA, two analytical models were constructed that allowed for the characteristics and size of the target patient populations. Based on the results of the modeling, morbidity statistics for the Moscow region, and data of real-life practice that have used the analyzed drugs for three years, it was found that 12,973 and 950 patients will receive a combination therapy with alirocumab/evolocumab/inclisiran;
2. The annual cost of the inclisiran therapy is 378,662.02 rubles for patients in the first year and 261,158.25 rubles for patients in the second and subsequent years, which is 23.31% and 27.66% (1st year), 47.1%1 and 50.11% (2nd and subsequent years) lower than for evolocumab and alirocumab, respectively;
3. The BIA showed that in the first model, the use of the analyzed drugs will lead to an increase in total costs by 2026 by 1.34%, in the second model, by 1.67%. The analysis shows a clear trend towards a reduction in the cost of treating patients with HCH and risk of CV complications if the use of inclisiran is expanded;
4. Deterministic sensitivity analysis confirmed the robustness of the obtained results.

Table 2. Results of BIA of different drug treatments in the study patient population

Parameter	Current practice	Proportion, %	Modeled practice, 1st year	Proportion, %	Modeled practice, 2nd year	Proportion, %
First model						
Combination therapy with alirocumab						
Number of patients (total), including	6 405	52.38	6 245	49.59	6 068	46.78
• Statin therapy, number of patients	6 365		6 206		6 030	
• Statin + ezetimibe therapy, number of patients	40		39		38	
Cost, rubles	3 290 063 346,10		3 207 344 473,20		3 100 976 413,70	
Combination therapy with evolocumab						
Number of patients (total), including	5 820	47.59	5 709	45.33	5 584	43.05
• Statin therapy, number of patients	5 783		5 673		5 549	
• Statin + ezetimibe therapy, number of patients	37		36		35	
Cost, rubles	2 834 847 702,49		2 766 878 744,47		2 695 736 511,64	
Combination therapy with inclisiran						
Number of patients (total), including	4	0.03	641	5.09	1 321	10.18
• Statin therapy (year 1), number of patients	4		633		672	
• Statin therapy (year 2 and further), number of patients	–		4		641	
• Statin + ezetimibe therapy, number of patients	–		4		8	
Cost, rubles	1 364 604,94	–	237 044 604,63	–	412 949 590,62	–
TOTAL	**6 126 275 653,53**	–	**6 211 267 822,30**	–	**6 209 662 515,97**	–
Cost difference, rubles	–	–	84 992 168,77	1,37	–1 605 306,33	–0.03
Second model						
Combination therapy with alirocumab						
Number of patients (total), including	659	73.63	665	72.18	659	69.37
• Statin therapy, number of patients	655		661		655	
• Statin + ezetimibe therapy, number of patients	4		4		4	
Cost, rubles	345 798 096,05		347 011 720,93		341 838 613,75	
Combination therapy with evolocumab						
Number of patients (total), including	214	23.91	210	22.74	194	20.46
• Statin therapy, number of patients	213		209		193	
• Statin + ezetimibe therapy, number of patients	1		1		1	
Cost, rubles	104 075 459,26		101 801 733,48		93 666 770,31	
Combination therapy with inclisiran						
Number of patients (total), including	22	2.46	47	5.09	97	10.18
• Statin therapy (year 1), number of patients	22		25		50	
• Statin therapy (year 2 and further), number of patients	–		22		47	
Cost, rubles	8 183 791,24	–	14 829 647,79	–	30 315 267,32	–
TOTAL	**458 057 346,55**	–	**463 643 102,20**	–	**465 820 651,38**	–
Cost difference, rubles	–	–	5 585 755,65	1.20	2 177 549,18	0.47

The study showed that a gradual expansion of using the combination therapy with inclisiran will help reduce the annual total costs for the treatment of patients with HCH and a risk of CV complications and decrease the burden on the budget of the regional healthcare system. Therapy with inclisiran is clinically effective and economically feasible for the treatment of adult patients with CV diseases and lipid metabolism disorders in the Moscow Region.

Conflict of interest

No conflict of interest.

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