

# Furthering benefit/risk ratio and cost effectiveness of anticancer drugs

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**BACKGROUND:** In Russia, the incidence of melanoma is increasing steadily. The approved standard of specialized medical care for melanoma of the skin defined the range of drugs, recommended for the provision of quality health care. However, it appears that the most effective innovative and safe medicines are at the same time the most expensive drugs. The most important is the assessment of drug use, taking into account their relative efficacy, safety (risk/benefit) and cost (economic efficiency), which may help to create the conditions for controlling their use. Based on this analysis, it is necessary to introduce drugs on the lists of drugs within the framework of the provision of state guarantees of free medical care to citizens (patients).

**OBJECTIVE:** To analyze the drug use according to the standard of specialized medical care for melanoma of the skin, to perform information retrieval in specialized libraries and databases Cochrane, Pubmed, Medline, as well as in the database of the state register of medicines (GRLS) of Russian Ministry of Health.

**METHODS:** The nomenclature of drugs was determined according to the standards of specialized medical care for 2006 and 2012, to the data of GRLS; information searches were performed in specialized libraries and databases Cochrane, Pubmed, Medline.

**RESULTS:** Analysis of anticancer drugs for melanoma of the skin consisted of determining of nomenclature of drugs, included in the standard of specialized medicine care. The standard of specialized medicine care for patients with malignant melanoma of the skin (with specialized assistance) (Order dated December 6, 2006 № 828) includes the following anticancer drugs: dacarbazine (alkylating agents), vinblastine (antineoplastic agent - an alkaloid), cisplatin (platinum), lomustine (nitrosoureas), bleomycin (antitumor agent, an antibiotic) [1]. The standard of specialized medical care in melanoma skin generalization or recurrent disease (chemotherapy) (Order of November 7, 2012 № 604n) includes the following anticancer drugs: lomustine and fotemustine (nitrosoureas), dacarbazine and temozolomide (alkylating agents), cisplatin (platinum) [2]. So, the standard of specialized medical care for melanoma of the skin by 2012 compared with the standard of care by 2006 includes temozolomide and fotomustin and excludes vinblastine and bleomycin. Based on the database GRLS of Russian Ministry of Health Care [3], as well as information retrieval in databases of Cochrane, Pubmed, Medline the efficacy and safety of melanoma of the skin have proven innovative products, in particular, such as vemurafenib (Zelboraf) dabrafenib (Tafinlar) and trametinib (Mekinist) that are already registered in Russia. At the stage of the clinical study are targeted drugs, such as GSK1120212, AMG 678, pembrolizumab, ipilimumab, tremilimumab, nivolumab and etc. The inclusion or exclusion of data from the restrictive

drug lists, such as lists of “Vital and essential medicines”, “Drugs for certain categories of citizens”, the “Minimum range”, according to the Russian Government Decree №871 of 28.08.2014 [4] is carried out after the risk/benefit ratio and cost effectiveness assessment to increase their availability. The availability of high-quality, effective and safe drugs for medical use within the reduced budget, taking into account the formation of a rational and balanced system of health care is the main task of the strategy of the drug provision of the population of Russia for the period till 2025 [5].

**CONCLUSIONS:** The most rational use of limited resources and cost containment within the framework of state regulation refers to modern trends in the health care of the Russian Federation. There is a need to develop targets aimed at all subjects of the pharmaceutical market, to increase the availability of innovative drugs for melanoma of the skin treatment. This strategy should be based on evidence and assessments of the efficacy, safety and economic viability of anticancer drugs.

Keywords: Anticancer drugs, standard, medical care, melanoma, benefit/risk ratio, cost effectiveness

**Conflict of interest statement:** None.

## References

- [1] “On approval of the standard of care to patients with malignant melanoma of the skin (with specialized assistance)”. Ministry of Health and Social Development of the Russian Federation, 2006 Dec 6, Order № 828
- [2] “On approval of the standard of specialized medical care for melanoma of the skin, and the generalization of relapse (chemotherapy)”. Ministry of Health of the Russian Federation, 2012 Nov 7, Order № 604n
- [3] State Register of Medicinal Products [Internet] – Available from: <http://grls.rosminzdrav.ru>
- [4] “On approval of the formation of lists of drugs for medical use and minimal assortment of drugs needed for medical care”. The Government of the Russian Federation, 2014 Aug 28. Government Decree №871
- [5] “Strategy of the drug provision of the population of the Russian Federation until 2025, The Ministry of Health, 2013 February 13, Order of № 66.