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Accessibility, Cost Effective Immunotherapy in Serbia for patients with metastatic colorectal cancer- Kovacevic Aleksandra– Military Medical Academy

Kovacevic Aleksandra

Military Medical Academy, Center for Clinical Pharmacology, Belgrade, Serbia

Colorectal cancer has been a health burden for many years. Although it's considered to be a disease of the developed world, the incidence rate of CRC has been on the increase in developing countries also (Favoriti et al., 2016; Douaiher et al., 2017). consistent with the planet Health Organization GLOBOCAN database (Bray et al., 2018), is that the third most ordinarily diagnosed cancer and therefore the fourth main explanation for cancer death within the world, accounting for 881,000 deaths in 2018. Colorectal cancer also causes substantial morbidity and mortality in Serbia. consistent with an equivalent database, the amount of latest cases of in 2018 was 6,049 (12.6% of any sort of cancer), while the amount of the deaths caused by was 3,187 (2.9% of all cancer-related deaths) (The Global Cancer Observatory, 2018). The Serbian health system is facing an additional challenge due to a steep rise in the number of people diagnosed with CRC. From 1997 to 2007, the incidence of CRC increased by 24.6% (Knezevic, 2009). Since this trend will, without doubt, stress the National Health Insurance Fund (NHIF) of Serbia, the objectives of this study were to identify different types of medical services provided to CRC patients and therefore the associated expenditures so as to estimate the entire medical cost at the national level between 2104 and 2017. This information is expected to assist healthcare decision planners and policymakers on how to allocate resources optimally. Patients with metastatic colorectal cancer (mCRC) have typically overall survival (OS) of approximately 30 months, if multi disciplinary team approach was applied. The first-line treatment comprises cytotoxic agents, a fluoropyrimidines in various protocols, combined with irinotecan or oxaliplatin. Additional benefit, in the terms of clinical outcome for such patients, is shown by adding the monoclonal antibodies (bevacizumab, as anti-VEGF and cetuximab and panitumumab as anti-EGFR). Second-line treatment comprehends adding the anti-angiogenic fusion protein aflibercept or anti-VEGFR2 antibody ramucirumab to the firstline protocols. The third line treatment is multi-targeted kinase inhibitor regorafenib. In Serbia, all cytotoxic drugs and monoclonal antibodies bevacizumab and cetuximab, are reimbursed for mCRC patients. Aflibercept, ramucirumab and regorafenib are not on the National Health Insurance Fund (NHIF) reimbursement list. Therefore, we conducted a retrospective randomized case series study, in the large tertiary health care hospital in Serbia. It was concluded that patients with added reimbursed monoclonal antibodies, had 6-month longer OS in five-year period, associated with significantly higher direct medical costs and ICER that was three-fold higher than informal willingness to pay threshold of Serbia. Costs could be significantly decreased only when bevacizumab biosimilars would be available on the Serbian market, but not prior than in 2022, when European Avastin patent expires. European patent on Erbitux expired in 2014; there aren't any biosimilar competitors in Europe approaching the horizon. Aflibercept is the only third-line treatment option that is registered but not reimbursed in Serbia, and ramucirumab and regorafenib are not registered. As a conclusion, it could be said that novel third-line biological treatment is neither available nor reimbursed for the Serbian patients with mCRC. New patent expiration of the monoclonal antibodies is expecting to allow biosimilar market entry and generate significant savings to the NHIF, which is expected to increase the affordability for mCRCtreatment.

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