

PP069 Health Technology Assessment Of Radium-223 Dichloride In Resistant Metastatic Prostate Cancer

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INTRODUCTION:

Metastatic castration-resistant prostate cancer (mCRPC) is an incurable disease and represents a significant clinical, economic, and social burden. The therapeutic scenario of mCRPC has completely changed over the last years with the approval of several treatments (1). Radium-223 is a new target-alpha therapy showing a significant survival benefit in mCRPC patients (2,3). The study aimed to evaluate the introduction of radium-223 in Italy using Health Technology Assessment methodology.

METHODS:

To assess epidemiological, clinical, economic, organizational, social, and ethical aspects, a literature review was carried out. A cost-effectiveness and a budget impact analysis were performed from the National Health Service (NHS) perspective to compare radium-223 with other treatments and determine the budgetary impact of the utilization of radium-223 for the treatment of mCRPC.

RESULTS:

In Italy, prostate cancer represents the most diagnosed cancer in men and the third in the whole population. When the disease becomes metastatic, approximately 80 percent of patients develop bone metastases, commonly associated to skeletal-related events (SREs) with a significant impact on survival, quality of life, and costs (1). Radium-223 is a novel alpha particle emitting therapeutic agent which targets new bone growth surrounding bone metastases. Different from other

radiopharmaceuticals, radium-223 prolongs overall survival with a favorable safety profile (2,3). In order to optimize patient outcome, the management of radium-223 should be viewed in a multidisciplinary context. The administration is quite simple and requires only basal shielding. Currently it can be administered in hospital inpatient settings and in some regions the outpatient usage is allowed. Finally, radium-223 showed a favorable budget impact profile and cost-effectiveness when compared with best supportive care and new therapeutic agents (abiraterone, enzalutamide, cabazitaxel) (1).

CONCLUSIONS:

The introduction of radium-223 allows provision of a new therapy, offering a valid alternative to patient with mCRPC without any increase of costs for the NHS.

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PP071 Health Technology Assessment In Bulgaria: A Review Of The First Fifteen Reports Assessed

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INTRODUCTION:

In Bulgaria, the regulatory body sets for the first time legal requirements for Health Technology Assessment (HTA) in Law on Medicinal Products in Human Medicine (LMPHM) on 27 June 2015. The next essential step for HTA capacity building was the promulgation of Ordinance 9 / December 1, 2015 on the conditions and procedures for conducting health technology assessment by the Ministry of Health (1). In the beginning of 2016, the Main Price and Reimbursement Committee was set and launched a process for establishing the small working groups with the task of reviewing the first applicants reports of pharmaceuticals for inclusion in the Positive Drug List (PDL).

METHODS:

The objective of this study is to summarize the recommendations of the newly established HTA Committee in Bulgaria and to examine the characteristics of the technologies and the key considerations that led to those decisions. We systematically read all published by the Committee recommendations for 2016 and analyzed them under: type of recommendations (positive or negative for inclusion in PDL), population, specialization, type of service, type of justification and the impact on final conclusions.

RESULTS:

For the first year of its work the HTA Committee was able to assess fifteen technologies (pharmaceuticals) and only one received a negative recommendation (6 percent) from the working group. All the rest (n = 14; 94 percent) were recommended for funding. The final recommendation from the Main Price and Reimbursement Committee is available for four (27 percent) technologies – all positive for inclusion in PDL. All recommendations were connected with adults and in oncology (n = 4; 27 percent); heart diseases (n = 4; 27 percent); Chronic Obstructive Pulmonary Disease, COPD (n = 2; 13 percent); diabetes (n = 2; 13 percent); psoriasis (n = 2; 13 percent); Hepatitis C (n = 1; 7 percent). The only negative recommendation was justified due to lack of robust evidence, safety issues and credibility of HTA analysis (2).

CONCLUSIONS:

The information about the number of applications received from the Committee is not available and correct conclusions about the capability is not possible, but indirect circumstances, as the lack of well-trained HTA experts, certainly impede establishment of the small working groups and slow the assessment process (3). At this point it is clear that additional efforts are need to overcome the barriers and smooth adoption and implementation of HTA methods in Bulgaria.

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PP072 Applying Sensitivity Analysis For Robust Choice Of Health Technologies

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INTRODUCTION:

The aim of this work is to evaluate the stability and robustness of the solution obtained at the end of the