

ABSTRACT

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TITLE: COST-EFFECTIVENESS AND BUDGET IMPACT OF NEW THERAPIES FOR METASTATIC MELANOMA IN ITALY

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OBJECTIVES: About 232,000 new cases of melanoma are diagnosed worldwide each year, according to the WHO. More recent research led to the development of new therapies for metastatic melanoma such as targeted therapy (inhibition of BRAF and/or MEK genes) and checkpoint inhibitor immunotherapy. Both therapies prolong progression-free and overall survival compared with chemotherapy. The aim of this research was to compare combined targeted therapy and checkpoint inhibitor immunotherapy cost-effectiveness, through cost-effectiveness analysis (CEA) and budget impact analysis (BIA) for the Italian context over a period of three years.

METHODS: The cost-effectiveness analysis was conducted by adjustment of clinical efficacy results of Norwegian HTA Report on Metastatic Melanoma to Italian setting. We used the therapeutic strategy of one Italian region, Emilia-Romagna, to estimate BRAF + mutation in Italian population, while lifetime treatment costs were estimated from progression free survival of randomized clinical trial. The Italian budget impact regards both drug as treating adverse events costs over a three years period.

RESULTS: Incremental cost-effectiveness ratio (ICER) resulted respectively 62707, 175879, 31137 and 20161 €/QALY for dabrafenib+ trametinib, vemurafenib + cobimetinib, nivolumab and pembrolizumab. The cost-effectiveness analysis showed that targeted therapy was not cost-effective, despite clinical efficacy was superior than checkpoint inhibitor immunotherapy.

BIA showed that combined targeted therapy compared to checkpoint inhibitor immunotherapy requires nearly 200% additional resources for metastatic melanomas BRAF+ in all three years considered. The cost of treating adverse drug events (ADEs) does not significantly affect overall expenditure, but it resulted also significantly lower for patients receiving checkpoint inhibitor immunotherapy.

CONCLUSIONS: Recent therapies for metastatic melanoma improve clinical outcomes but have a significant impact on health systems' budgets.

Economic evaluations may help decision-maker to understand the value of new therapies of metastatic melanoma and to allocate health systems' budgets maximizing the clinical value.