

New oncology reimbursements in Belgium

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Overview of Belgian reimbursement news

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Pembrolizumab (Keytruda®)

As of April 20, 2016, pembrolizumab is reimbursed for the treatment of advanced melanoma.

In the pivotal Keynote-006 trial, patients with advanced melanoma were randomised in a 1:1:1 ratio to receive pembrolizumab, 10 mg/kg of body weight, every two weeks or every three weeks, or four doses of ipilimumab, 3 mg/kg, every three weeks.¹ Primary end points were progression-free (PFS) and overall survival (OS). The estimated 6-month PFS rates were 47.3% for pembrolizumab every two weeks, 46.4% for pembrolizumab every three weeks, and 26.5% for ipilimumab (hazard ratio [HR] for disease progression, 0.58; $p < 0.001$ for both pembrolizumab regimens versus ipilimumab; 95% confidence intervals [CIs], 0.46 to 0.72 and 0.47 to 0.72, respectively). Estimated 12-month OS rates were 74.1%, 68.4%, and 58.2%, respectively (HR for death for pembrolizumab every two weeks, 0.63; 95% CI, 0.47 to 0.83; $p = 0.0005$; hazard ratio for pembrolizumab every three weeks, 0.69; 95% CI, 0.52 to 0.90; $p = 0.0036$). The response rates were 33.7% and 32.9% with pembrolizumab administered every two or three weeks, respectively, as compared to 11.9% with

ipilimumab ($p < 0.001$ for both comparisons). Rates of treatment-related grade 3-5 adverse events were lower in the pembrolizumab groups (13.3% and 10.1%) than in the ipilimumab group (19.9%).

The PD-1 checkpoint inhibitor Keytruda® is now reimbursed as monotherapy for patients with advanced (metastatic or unresectable) melanoma. The reimbursement criteria are identical to those for Opdivo®. In order to be eligible for reimbursement, patients should be at least eighteen years old and have an ECOG performance status of zero or one. The reimbursement takes into account a posology of 2 mg/kg every three weeks and the treatment can be continued for as long as a clinical benefit is observed and for as long as the patient can tolerate the therapy. The simultaneous reimbursement of Keytruda® together with another PD-1 inhibitor is never allowed. Patients progressing under Opdivo® cannot switch to Keytruda® and vice versa. Reimbursement should be requested using the e-Health platform.

References

1. Robert C, Schachter J, Long GV, et al. Pembrolizumab versus ipilimumab in Advanced Melanoma. *N Engl J Med*. 2015;372(26):2521-32.

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