SUMMARY

nivolumab/ipilimumab

**OPDIVO 10 mg/ml and
YERVOY 5 mg/ml,****solutions for dilution for infusion****Inclusion in B-RAF mutation subgroup****Original French opinion adopted by the Transparency Committee on
22 November 2023****The legally binding text is the original French opinion version****Transparency Committee's Conclusions****Clinical Benefit**

Like OPDIVO/YERVOY (nivolumab/ipilimumab) in the indication as a first-line treatment for patients with an ECOG score of 0 or 1, whose tumour exhibits no B-RAF mutation, without active brain metastasis:

- ➔ Melanoma is a skin cancer with a high metastatic potential, which may, in advanced cases, involve metastatic complications and is potentially life-threatening in the short or medium term.
- ➔ This is a specific curative melanoma treatment.
- ➔ The efficacy/adverse effects ratio of the nivolumab + ipilimumab association is high.
- ➔ There are alternative medications in this indication.
- ➔ The nivolumab + ipilimumab association is a first-line treatment for the patient population with an ECOG score of 0 or 1, with advanced-stage melanoma with a B-RAF mutation and without active brain metastasis.

➔ Public health benefit:

The OPDIVO/YERVOY (nivolumab/ipilimumab) association is unlikely to have an impact on public health.

Considering these elements, the Committee deems that, as for patients without B-RAF mutations, the clinical benefit of the OPDIVO/YERVOY (nivolumab/ipilimumab) association is substantial as a first-line treatment for patients with an ECOG score of 0 or 1, whose tumour exhibits B-RAF mutation, without active brain metastasis.

Clinical Added Value

In view of:

- the evidence of a gain in efficacy in relation to ipilimumab monotherapy, which is not the conventional treatment in this context;
- the increased toxicity (discontinuation of treatment due to adverse event in approximately one in two patients) among selected patients (99.8% in good general health or preserved general health);
- the update in the treatment of patients with BRAF mutation highlighted by the guidelines in force in particular;

the Committee deems that the OPDIVO/YERVOY (nivolumab/ipilimumab) association provides no clinical added value (CAV V) in the therapeutic strategy for adult advanced melanoma patients (see RMP population).