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).