SUMMARY

binimetinib

MEKTOVI 45 mg

film-coated tablets

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 6 November 2024

Summary of opinion

Favourable opinion for reimbursement in the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation in combination with encorafenib.

No clinical added value of the MEKTOVI 45 mg film-coated tablet form compared to the proprietary medicinal product containing binimetinib already available.

Transparency Committee's conclusions

Clinical Benefit

- 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 curative treatment.
- The efficacy/adverse effects ratio is moderate given the lack of evidence of an increase in overall survival.
- There are therapeutic alternatives.
- The encorafenib-binimetinib combination is a first-line therapeutic option for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation.

Public health benefit

Considering:

- the seriousness of advanced melanoma (unresectable or metastatic),

- its prevalence, estimated to be 3,208 patients in France,
- the partially met medical need,
- data demonstrating an increase in PFS for the encorafenib and binimetinib combination compared to vemurafenib monotherapy, but the lack of evidence of an increase in overall survival,
- the absence of direct or robust comparative data versus the other BRAF and MEK inhibitor combinations, which are currently considered to be the reference treatment,
- the absence of quality of life data,
- and, therefore, the lack of additional response to the partially met medical need,
- the absence of an impact on the organisation of care,

the BRAFTOVI/MEKTOVI 45 mg film-coated tablet combination is unlikely to have an additional impact on public health.

The Committee considers that the clinical benefit of the BRAFTOVI/MEKTOVI 45 mg film-coated tablet (encorafenib/binimetinib) combination is moderate in the MA indication.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

This medicinal product is a range supplement that does not provide any clinical added value (CAV V) compared to the form already listed.