



TRANSPARENCY COMMITTEE

OPINION

22 JANUARY 2020

brentuximab vedotin
ADCETRIS 50 mg powder for concentrate for solution for infusion

New indication

► Key points

Unfavourable opinion for reimbursement in the first-line treatment of adult patients with CD30+ Stage IV Hodgkin lymphoma (HL).

► Role in the care pathway?

The first-line treatment of adults with Hodgkin lymphoma is based on chemotherapy, following by radiotherapy in the event of persistent disease. The chemotherapy protocols used are ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine) and BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone) protocols.

The choice of protocol depends primarily on the clinical stage of the disease, the presence of certain risk factors and the patient's characteristics (age, medical history, general health, etc.).

Role of the medicinal product in the care pathway

ADCETRIS in combination with AVD chemotherapy has no role in the treatment of previously untreated adult patients with CD30+ Stage IV Hodgkin lymphoma (HL).

COMMITTEE'S CONCLUSIONS

Clinical Benefit

- ▶ CD30+ Hodgkin lymphoma is an uncommon malignant blood disease that is life-threatening.
- ▶ This proprietary medicinal product is part of a specific curative cancer treatment.
- ▶ The efficacy/adverse effects ratio of ADECTRIS in combination with doxorubicin, vinblastine and dacarbazine (AVD) in patients with CD30+ Stage IV Hodgkin lymphoma (HL) has not been adequately established given the numerous methodological limitations of the study and the associated uncertainties (in particular, open-label study, choice and clinical relevance of the primary outcome measure, data derived from an exploratory subgroup analysis, imbalance between the groups concerning prophylaxis with myeloid growth factor, transposability of results not guaranteed and lack of consideration of an intermediate PET scan-guided treatment strategy).
- ▶ In the first-line treatment of patients with CD30+ Stage IV HL there are therapeutic alternatives.
- ▶ ADCETRIS in combination with doxorubicin, vinblastine and dacarbazine (AVD) has no role in the first-line treatment of adult patients with CD30+ Stage IV Hodgkin lymphoma (HL) (see section 08 of the opinion).

▶ Public health impact

Considering:

- the seriousness of CD30+ Hodgkin lymphoma,
- its low incidence,
- the medical need considered to be partially met by first-line chemotherapy protocols,
- the lack of any expected impact on morbidity and the lack of any demonstrated impact on mortality and quality of life,
- the lack of response of ADECTRIS to the identified partially met need,
- the lack of expected impact on the organisation of care,

ADCETRIS is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ADCETRIS is insufficient in view of the available alternatives to justify its funding by the French national health insurance system in the treatment of adult patients with previously untreated CD30+ Stage IV Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD).

The Committee issues an unfavourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the MA indication extension and dosages.

Clinical Added Value

Not applicable