HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
08 JANUARY 2020

Iorlatinib
LORVIQUA tablets

First assessment

Key points

Favourable opinion for reimbursement in the treatment of patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC) whose disease has progressed after alectinib or ceritinib as the first ALK tyrosine kinase inhibitor (TKI) therapy, or crizotinib and at least one other ALK TKI.

What therapeutic improvement?

No clinical added value.

Role in the care pathway?

The therapeutic arsenal for lung cancer has recently been expanded following the addition of specific treatments targeting this genome abnormality, as first-line therapy: ALECENSA (alectinib), ZYKADIA (ceritinib) and XALKORI (crizotinib) and as second-line therapy: ALECENSA (alectinib), ZYKADIA (ceritinib).

Role of LORVIQUA in the care pathway:

On the basis of currently available data, the Committee considers that LORVIQUA is a second or third-line treatment option. In the absence of comparative data, its precise role in the care pathway remains to be defined.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Non-small cell lung cancer (NSCLC) is a serious, life-threatening condition.
◗ LORVIQUA proprietary medicinal products are part of a specific curative treatment regimen for ALK-positive NSCLC.
◗ The efficacy/adverse effects ratio is low.
◗ It is a second or third-line treatment option for ALK+ NSCLC.

◗ **Public health impact**

Considering:
- the seriousness of the disease and its low incidence,
- the medical need, which is considered to be partially met,
- an impact on morbidity that is difficult to quantify in the absence of comparison with the available alternatives and given the limitations of the study provided,
- the lack of demonstrated impact on mortality and quality of life compared to current alternatives,
- an impact on the organisation of the healthcare system (hospitalisations avoided, transfer of care to consultations), which is not documented, in the same manner as oral chemotherapy,

LORVIQUA is unlikely to have an impact on public health.

Considering these elements, the Committee considers that the clinical benefit of LORVIQUA is low, as the dossier currently stands.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication(s) and dosages.

Clinical Added Value

Considering:
- **available data based on 3 cohorts among 7 derived from a phase 1/2 non comparative study in a heterogeneous population in second, third or later-line treatment,**
- **the difficulty of precisely determining the effect size and role of this proprietary medicinal product in the treatment of advanced ALK+ lung cancer,**

the Committee considers that LORVIQUA provides no clinical added value (CAV V) in the treatment of advanced ALK+ lung cancer.