HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
22 APRIL 2020

ibrutinib
IMBRUVICA 140 mg hard capsules

New indication

Key points

Unfavourable opinion for reimbursement in the treatment of adult patients with Waldenström's macroglobulinaemia (WM) in combination with rituximab.

Role in the care pathway?

The strategy for the first-line treatment of Waldenström's macroglobulinaemia (WM) is based on a combination of rituximab with an alkylator or proteasome inhibitor.

The second-line treatment strategy for WM (relapsed patients) depends on the time to relapse and is based either on rituximab-based chemo-immunotherapy or single-agent therapy with IMBRUVICA (ibrutinib).

Role of the medicinal product in the care pathway

IMBRUVICA (ibrutinib) in combination with rituximab has no role in the treatment of adult patients with Waldenström's macroglobulinaemia.

01 COMMITTEE'S CONCLUSIONS

01.1 Clinical benefit

◗ Waldenström's macroglobulinaemia (WM) is a rare disease that is life-threatening, particularly following the failure of several treatment lines.
◗ This is a curative treatment.
◗ The efficacy/adverse effects ratio of IMBRUVICA (ibrutinib) in combination with rituximab in adult patients with Waldenström's macroglobulinaemia has not been established in the absence of clinical data versus a good comparator.
◗ There are therapeutic alternatives, in particular the combination of rituximab with an alkylator or a proteasome inhibitor.
◗ IMBRUVICA (ibrutinib) in combination with rituximab has no role in the care pathway for adult patients with Waldenström's macroglobulinaemia (see section 09 of the opinion).

Public health impact

Considering:
- the seriousness of Waldenström's macroglobulinaemia,
- the low incidence of this disease,
- the medical need that is partially met,
- 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 IMBRUVICA (ibrutinib) in combination with rituximab to the identified partially met need,
- the lack of expected impact on the organisation of care,

IMBRUVICA (ibrutinib) in combination with rituximab is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that, on the basis of currently available data, the clinical benefit of IMBRUVICA (ibrutinib) in combination with rituximab is insufficient to justify its funding by the French national health insurance system in the treatment of adult patients with Waldenström's macroglobulinaemia.

The Committee issues an unfavourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the treatment of adult patients with Waldenström's macroglobulinaemia in combination rituximab and at the MA dosages.

01.2 Clinical Added Value

Not applicable.