HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
17 FEBRUARY 2021

The legally binding text is the original French opinion version

almitrine bismesylate
VECTARION, lyophilisate and solution for injection

Reevaluation

Key points

Unfavourable opinion for reimbursement in supportive treatment in addition to mechanical ventilation in the most serious cases of acute respiratory distress syndrome (ARDS) with refractory hypoxemia and hypercapnia despite optimised artificial respiratory support (protective ventilation, ventral decubitus, etc.), and/or in the absence of another accessible appropriate respiratory support device (e.g.: CO2 removal, veno-venous ECMO, etc.)

◗ Role in the care pathway?

The treatment of ARDS primarily consists of mechanical ventilation and, if necessary or if mechanical ventilation fails, supportive therapies for the most serious cases. These therapies may be non-pharmacological (ventral decubitus, high-frequency ventilation and extracorporeal oxygenation methods) or pharmacological (primarily inhaled nitric oxide [Noi], although this is used off-label).

Role of the medicinal product in the care pathway

Considering:
- the absence of robust and recent new data having demonstrated an efficacy of almitrine in the recently modified MA indication;
- its safety profile, marked, in particular, by peripheral neuropathies (important potential risk with the injectable formulation), and its mechanism of action, involving potential harmful effects on the pulmonary circulation;
- current French recommendations that do not mention this drug in the management of ARDS;

The Committee considers that VECTARION (almitrine) no longer has a role in the care pathway in view of the alternatives.

COMMITTEE'S CONCLUSIONS

Clinical benefit

◗ Acute respiratory distress syndrome is a medical emergency that is life-threatening.
◗ The proprietary medicinal product VECTARION (almitrine bismesylate) is a curative medicinal product.
◗ Considering the absence of robust and recent new data having demonstrated an efficacy of almitrine, its safety profile, marked, in particular, by peripheral neuropathies (important potential risk with the injectable formulation), and in view of its mechanism of action and its potentially harmful effects on the pulmonary circulation, the efficacy/adverse effects ratio has not been adequately established.
◗ There is a recommended alternative (nitric oxide), although it does not have an MA.
◗ VECTARION (almitrine bismesylate) no longer has a role in the care pathway in view of the existing alternatives.

Public health impact

Considering:
- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the lack of response to the identified need, due to the lack of demonstrated impact on morbidity and mortality in the absence of a robust clinical study, and the absence of an additional impact on the organisation of care,

VECTARION (almitrine bismesylate) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VECTARION (almitrine bismesylate) is insufficient to justify public funding cover in the MA indication in view of the available alternatives.

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