SUMMARY

fondaparinux

ARIXTRA 2.5 mg/0.5 ml,

solution for injection, pre-filled syringe

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 7 June 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Superficial vein thrombosis (SVT), generally a condition that is not usually serious, can be complicated by venous thromboembolic events (symptomatic DVT or PE), which may be life-threatening (potentially fatal pulmonary embolism) or have serious sequelae (post-thrombotic syndrome). However, this complication remains rare.
- This is a curative medicinal product.
- In view of the uncertainties that persist in terms of morbidity and mortality in this indication in patients with a low risk of thrombosis and haemorrhage and the difference observed on clinically relevant complications (symptomatic DVT and PE), the efficacy/adverse effects ratio remains moderate.
- This is a first-line treatment in the absence of any available therapies (the therapeutic benefit of LMWH used off-label in this indication remains inadequately established).

Public health benefit

Considering:

- the seriousness and incidence of isolated superficial vein thrombosis, which are considered to be low [limited incidence of complications (DVT, PE)] and the smaller number of patients concerned;
- the medical need to have access to an effective and well-tolerated treatment for SVT using an anticoagulant for which the efficacy on clinically relevant thromboembolic complications has been demonstrated;

- the still partial response to the identified need, with an additional impact on morbidity observed, but considering the methodological limitations of these data;
- the lack of demonstrated impact on mortality and quality of life;
- the absence of an additional impact on the organisation of care,

ARIXTRA (fondaparinux) 2.5 mg/0.5 ml solution for injection, pre-filled syringe is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ARIXTRA (fondaparinux) 2.5 mg/0.5 ml solution for injection, pre-filled syringe remains moderate in the reassessed MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of ARIXTRA (fondaparinux) 2.5 mg/0.5 ml solution for injection, pre-filled syringe in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 30%**

Clinical Added Value

The Committee confirms the absence of any clinical added value (level V, no clinical added value) in the care pathway given the uncertainty concerning the clinical benefit of treatment prolonged to 45 days in a heterogeneous population of patients with SVT.