SUMMARY

activated eptacog alfa

NOVOSEVEN 1 mg (50 KIU), 2 mg (100 KIU), 5 mg (250 KIU), 8 mg (400 KIU),

powder and solvent for solution for injection

Indication extension

Original French opinion adopted by the Transparency Committee on 19 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Postpartum haemorrhage is the leading cause of severe maternal morbidity and can be life-threatening for the patient.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is low.
- This is an additional treatment given shortly before, during or after a haemostasis hysterectomy or a vascular ligation, B-Lynch suture or embolisation (see 5.1).

Public health benefit

Considering:

- the seriousness of postpartum haemorrhage and its prevalence,
- the partially met medical need,
- the partial response to the identified need with:
  - the lack of demonstration of an additional impact on morbidity and mortality and on quality of life,
  - the lack of demonstration of an additional impact on the care pathway and on the organisation of care,

NOVOSEVEN (activated eptacog alfa) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NOVOSEVEN (activated eptacog alfa) powder and solvent for solution for injection is low in the MA indication.

The Committee issues a favourable opinion for inclusion of NOVOSEVEN 1 mg, 2 mg, 5 mg and 8 mg (activated eptacog alfa) powder and solvent for solution for injection in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the indication and at the MA dosages.

Clinical Added Value

Considering:

- the results of a phase 4 study that compared NOVOSEVEN (activated eptacog alfa) in addition to the standard of care at the time of the study versus a control group having benefited from standard of care alone; with uterine balloon tamponade not being part of the standard of care at the time of implementation of the study and tranexamic acid not having been used in the majority of cases in the study, contrary to current practice,
- since this study is not in line with the current care pathway for severe postpartum haemorrhage, it does not enable NOVOSEVEN (activated eptacog alfa) to be assigned an important and early role in the care pathway for severe postpartum haemorrhage,
- the phase 4 study demonstrated the superiority of activated eptacog alfa compared to standard of care in terms of embolisation and/or ligature rates. However, embolisation is not accessible in all centres, and these two techniques with different characteristics each have a separate and non-interchangeable role in the management of severe postpartum haemorrhage,
- the available data do not enable the effect size of NOVOSEVEN (activated eptacog alfa) to be assessed in the current care pathway for severe postpartum haemorrhage,
- the risk of venous and arterial thromboembolic complications with NOVOSEVEN (activated eptacog alfa) needs to be taken into account in a context of emergency use,
- the mechanism of action on haemostasis of NOVOSEVEN (activated eptacog alfa), which may be of benefit in certain limited critical situations,

the Committee considers that NOVOSEVEN 1 mg, 2 mg, 5 mg and 8 mg (activated eptacog alfa) powder and solvent for solution for injection provides no clinical added value (CAV V) in the current care pathway, which includes the non-medicinal techniques mentioned in paragraph 2.2.