HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
27 MAY 2020

carbetocin
PABAL 100 µg/ml solution for injection

New indication

Key points

Favourable opinion for reimbursement in the prevention of postpartum haemorrhage due to uterine atony following vaginal delivery.

What therapeutic improvement?

No clinical added value in the current strategy for prevention of postpartum haemorrhage due to uterine atony.

Role in the care pathway?

The French National Association of Gynaecologists and Obstetricians (CNGOF) and the World Health Organisation (WHO) recommend the administration of preventive uterotonic agents such as oxytocin in the prevention of postpartum haemorrhage following vaginal delivery, although oxytocin has no MA in this preventive indication.

Role of the medicinal product in the care pathway

PABAL (carbetocin) is a first-line treatment option in the same way as products containing oxytocin (although off-label) in the prevention of postpartum haemorrhage due to uterine atony following vaginal delivery.

01 COMMITTEE'S CONCLUSIONS

01.1 Clinical benefit

◗ Uterine atony remains the main cause of postpartum haemorrhage. It is life-threatening.
◗ This is a preventive treatment for postpartum haemorrhage due to uterine atony.
◗ The efficacy/adverse effects ratio is high.
◗ There are recommended alternatives based on oxytocin, such as SYNTOCINON and its generics, although these do not have an MA specifically in the prevention of uterine atony (see **Erreur ! Source du renvoi introuvable.** Clinically relevant comparators).
◗ PABAL (carbetocin) is a first-line treatment option in the same way as products containing oxytocin (although off-label) in the prevention of postpartum haemorrhage due to uterine atony following vaginal delivery.

Public health impact

Considering:
- the seriousness of postpartum haemorrhage, which is life-threatening,
- its occurrence in around 5% to 10% of deliveries,
- the medical need already met by oxytocin, which is recommended despite not having an MA as a preventive treatment,
- the absence of data demonstrating an improvement in the care pathway or the organisation of care for this proprietary medicinal product, which can be stored at room temperature,
- the lack of additional response to the met need, in particular in view of the non-inferiority demonstrated compared to oxytocin,

PABAL (carbetocin) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of PABAL (carbetocin) is high in the prevention of postpartum haemorrhage due to uterine atony following vaginal delivery.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the prevention of postpartum haemorrhage due to uterine atony following vaginal delivery and at the MA dosages.

01.2 Clinical Added Value

Considering:
- **demonstration of a non-inferiority of PABAL (carbetocin) compared to oxytocin in a phase III study and data from a meta-analysis suggesting a comparable efficacy between carbetocin and oxytocin overall,**
- **the relevance of the primary endpoints used in these studies, i.e., postpartum blood loss ≥ 500 mL or ≥ 1000 mL or use of additional uterotonics,**
- **the absence of data demonstrating a superiority of PABAL (carbetocin) compared to oxytocin whereas this analysis was scheduled,**
- **the medical need already met by oxytocin,**

the Transparency Committee considers that PABAL (carbetocin) provides no clinical added value (CAV V) in the strategy for prevention of postpartum haemorrhage due to uterine atony.