SUMMARY

nifedipine

MAPAKNA LP 20 mg,

prolonged-release tablet

Initial inclusion

Adopted by the Transparency Committee on 8 November 2023

The legally binding text is the original French opinion version

Transparency Committee's Conclusions

Clinical Benefit

- Preterm delivery, on account of its frequency, is a public health problem. It remains the leading cause of neonatal mortality and sequelae-related morbidity. Tocolytic treatment delaying delivery by at least 48 hours makes it possible to set up glucocorticoid therapy (foetal maturation) and organise transfer of the patient and the infant in utero to an intensive care unit.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment.

- **Public health benefit**

In view of:

- the seriousness of the condition, its prevalence and incidence;
- the medical need partially met by atosiban;
- the partial response to the identified need with a lack of expected additional impact on maternofoetal morbidity-mortality or quality of life;
- the lack of evidence of an impact on delivery of care, even though the oral administration of MAPAKNA LP (nifedipine) is an advantage in relation to the intravenous administration of atosiban;

MAPAKNA LP (nifedipine) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of MAPAKNA LP 20 mg (nifedipine), prolonged-release tablet, is substantial in the MA indication.

The Committee approves inclusion of MAPAKNA LP 20 mg (nifedipine), prolonged-release tablet, in the list of covered drugs for inpatients for the indication and at the MA dosages.

Clinical Added Value

In view of:

- the lack of clinical study conducted with the proprietary medicinal product MAPAKNA LP (nifedipine) in threatened preterm delivery;
- the clinical data available on nifedipine in TPD based on a literature review, with in particular 3 identified comparative studies with a low level of evidence as they are not free from limitations and bias, which do not allow an assessment of a potential difference in the effect size of nifedipine in relation to atosiban;
- the well-established and recommended use of nifedipine in threatened preterm delivery and the follow-up available from its off-label use in this indication;
- the known safety profile of nifedipine,
- the medical need for an alternative to intravenously administered atosiban, the oral administration of nifedipine being an advantage in this context of use among pregnant women with threatened preterm delivery;

the Committee deems that MAPAKNA LP 20 mg (nifedipine), prolonged-release tablet provides no clinical added value (CAV V) in the current therapeutic strategy including atosiban.