Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

fampridine

FAMPYRA 10 mg,

prolonged-release tablet

Inclusion on list: First listing

Range supplement

Adopted by the Transparency Committee on 23 April 2025

Summary of opinion

Favourable opinion for reimbursement in the indication for the improvement of walking in adult patients with multiple sclerosis with walking disability (EDSS 4-7).

No clinical added value of the new bottle forms of FAMPYRA (fampridine) compared to the forms already available.

Transparency Committee's conclusions

Clinical Benefit

- Multiple sclerosis (MS) is a progressive and disabling, chronic neurological disease.
- This is a symptomatic medicinal product for walking disabilities in patients with MS.
- In view of data confirming the low number of patients responding to FAMPYRA (fampridine) treatment and the at best modest additional effect size compared to placebo (absolute difference of 10%) and the safety profile of this treatment, the efficacy/adverse effects ratio of this proprietary medicinal product is low.
- Treatment with FAMPYRA (fampridine) should only be considered in combination with an appropriate functional rehabilitation program, without delaying the implementation of this as well as walking aids or specific treatments such as those for spasticity.

- **Public health benefit**

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FAMPYRA (fampridine) in bottles is unlikely to have an additional impact on public health compared to the blister forms already available.

The Committee considers that the clinical benefit of FAMPYRA (fampridine) is low in the MA indication.

The Committee issues a favourable opinion for inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 15%**

Clinical Added Value

These medicinal products are range supplements that do not provide any clinical added value (CAV V) compared to the forms already listed.

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