Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

cladribine

MAVENCLAD 10 mg

tablets

Reassessment at the request of the TC

Adopted by the Transparency Committee on 14 May 2025

Summary of opinion

Favourable opinion for maintenance of reimbursement in the treatment of adult patients with highly active relapsing multiple sclerosis (MS) defined by clinical or imaging (MRI) features.

Transparency Committee's Conclusions

Clinical Benefit

- Multiple sclerosis (MS) is a progressive and disabling, serious chronic neurological disease. It corresponds to inflammation and selective, chronic demyelination of the central nervous system. It has multiple manifestations: motor and sensory dysfunction, sensory, bladder-sphincter, sexual, cognitive and mood dysfunction. They can considerably reduce patients' autonomy and impair their quality of life. Disease severity is highly variable, ranging from mild forms to forms resulting in significant disabilities within a few years.
- This is a medicinal product to prevent active episodes and progression of disability.
- In highly active forms of RMS, the efficacy/adverse effects ratio of MAVENCLAD (cladribine) remains inadequately established in view of the clinical data available and, in particular, due to the methodological weaknesses of efficacy and safety data in the population retained by the MA.
- MAVENCLAD (cladribine) remains a treatment option in patients with highly active RMS in view of the therapies available. The Committee recommends reserving the use of MAVENCLAD for patients who have failed or are ineligible for these alternative treatments.

Public health benefit

Considering:

- the seriousness of highly active forms of RMS,
- the size of the target population, estimated to be 4,670 patients in France,

- the partially met medical need,
- the lack of additional response to the identified need given:
  - the absence of an additional impact on morbidity and mortality,
  - the lack of evidence of an additional impact on quality of life,
  - the lack of evidence of an additional impact on the organisation of care,
  - the lack of evidence to support an improvement in the care and/or life pathway,

MAVENCLAD (cladribine) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of MAVENCLAD (cladribine) remains low in the MA indication.

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

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

Clinical Added Value

The Committee deems that the data provided in the context of this reassessment are not likely to modify the assessment of the clinical added value expressed in the previous opinion of 27 May 2020.

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