SUMMARY

apomorphine hydrochloride

KYNMOBI 10 mg, 15 mg, 20 mg, 25 mg, 30 mg and treatment initiation pack

sublingual film

Initial inclusion

Original French opinion adopted by the Transparency Committee on 31 January 2024

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Parkinson's disease is characterised by progression towards disability and/or a marked deterioration in quality of life.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is high.

  This is a therapeutic option in the intermittent treatment of "OFF" episodes in adult patients with Parkinson's disease (PD) which are not sufficiently controlled by oral anti-Parkinson medication, in view of the available therapies.
- **Public health benefit**

Considering:

- the seriousness of the condition and its prevalence,
- the partially met medical need,
- the lack of additional response to the identified need due to:
  - the lack of any demonstrated additional impact on morbidity, given the statistically non-significant result for the superiority of apomorphine SL compared to apomorphine SC (reference medicinal product) in terms of improvement of motor function, not enabling a conclusion to be reached that the two treatments are equivalent,
  - the lack of a demonstrated additional impact on quality of life, in the absence of robust data,

- the absence of a demonstrated impact on the care and/or life pathway, despite this being expected due to its sublingual administration, compared to the reference medicinal product, which is administered subcutaneously. However, this sublingual administration presents specific oropharyngeal adverse reactions to be taken into consideration.

KYNMOBI (apomorphine hydrochloride) sublingual film and treatment initiation pack are unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of KYNMOBI (apomorphine hydrochloride) 10 mg, 15 mg, 20 mg, 25 mg, 30 mg sublingual film and treatment initiation pack is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of KYNMOBI (apomorphine hydrochloride) 10 mg, 15 mg, 20 mg, 25 mg, 30 mg sublingual film and treatment initiation pack 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: 65%**

Clinical Added Value

Considering:

- demonstration of the superiority of apomorphine SL compared to placebo for the mean change from pre-dose in the MDS-UPDRS Part III score at 30 minutes after dosing at Week 12 (primary endpoint): -11.1 points versus -3.5 points, Δ: -7.6 points (95% CI [-11.5; -3.7]; p = 0.0002),
- the absence of demonstration of the superiority of apomorphine SL compared to apomorphine SC (reference medicinal product) for the mean change from pre-dose in the MDS-UPDRS Part III score at 90 minutes after dosing at the end of each 4-week sequence (primary endpoint): -13.5 points versus -13.8 points, Δ: 0.3 points (95% CI [-3.16; 3.62]; p = NS), not enabling a conclusion to be reached that the two treatments are equivalent,
- the lack of quality of life evidence, in the absence of robust data,
- the safety profile of apomorphine SL, marked by specific oropharyngeal adverse reactions,

the Committee deems that KYNMOBI (apomorphine hydrochloride) 10 mg, 15 mg, 20 mg, 25 mg, 30 mg sublingual film and treatment initiation pack provide no clinical added value (CAV V) compared to the reference medicinal product, APOKINON (apomorphine hydrochloride) 30 mg/3 mL solution for injection in pre-filled pen.