SUMMARY

foslevodopa/foscarbidopa

SCYOVA 240 mg/mL + 12 mg/mL

solution for infusion

Initial inclusion

Original French opinion adopted by the Transparency Committee on 10 January 2024

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Parkinson's disease is a neurodegenerative disease with multi-systemic involvement characterised by symptoms of insidious onset and intermittent progression. It progresses towards disability and major impairment of quality of life.
- The proprietary medicinal product SCYOVA (foslevodopa/foscarbidopa) is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a medicinal option in the treatment of advanced levodopa-responsive Parkinson's disease with motor fluctuations and hyperkinesia or severe dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.

Public health benefit

Considering:

- the severity of the disease in patients at an advanced stage, and its prevalence,
- the partially met medical need,
- the partial response to the identified need, due to:
  - the lack of any demonstrated additional impact on morbidity compared to the available alternatives, given the superiority demonstrated in terms of efficacy only versus oral levodopa/carbidopa and the absence of any comparison with the second-line treatments available,
  - the lack of an additional impact in terms of quality of life in the absence of robust data,

- the absence of any demonstrated additional impact on the organisation of care, despite this being expected due to its continuous subcutaneous administration compared to the reference medicinal product, DUODOPA (levodopa/carbidopa), which is administered by continuous intestinal infusion and requires a surgical procedure (percutaneous endoscopic gastrostomy) for the insertion of a permanent tube,
- the lack of additional impact on the care and/or life pathway,

SCYOVA (foslevodopa/foscarbidopa) 240 mg/mL + 12 mg/mL solution for infusion is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of SCYOVA (foslevodopa/foscarbidopa) 240 mg/mL + 12 mg/mL solution for infusion is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of SCYOVA (foslevodopa/foscarbidopa) 240 mg/mL + 12 mg/mL solution for infusion 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 only versus oral levodopa/carbidopa after 12 weeks of treatment on:
  - change in average daily normalised “on” time without troublesome dyskinesia (primary endpoint): 2.72 hours versus 0.97 hours, i.e. a mean difference of 1.75 hours (p = 0.0083),
  - change in average normalised “off” time (key secondary endpoint): -2.75 hours versus -0.96 hours, i.e. a mean difference of -1.79 hours (p = 0.0054),
- the absence of comparison versus the available second-line treatments for Parkinson’s disease, in particular apomorphine as continuous subcutaneous infusion, despite this being possible,
- the lack of quality of life evidence, in the absence of robust data,
- the safety profile of foslevodopa/foscarbidopa, marked by specific cutaneous adverse reactions,

the Committee deems that SCYOVA (foslevodopa/foscarbidopa) 240 mg/mL + 12 mg/mL solution for infusion provides no clinical added value (CAV V) in the care pathway in the treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyperkinesia or dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results.