SUMMARY

glibenclamide

AMGLIDIA 0.6 mg/mL and 6 mg/mL,

oral suspension with syringe

Reassessment

Original French opinion adopted by the Transparency Committee on 24 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Approval of reimbursement for "AMGLIDIA oral suspension is indicated for the treatment of neonatal diabetes mellitus, for use in newborns, infants and children.

Sulphonylureas like AMGLIDIA have been shown to be effective in patients with mutations in the genes coding for beta-cell ATP-sensitive potassium channel and chromosome 6q24-related transient neonatal diabetes mellitus."

Transparency Committee's Conclusions

Clinical Added Value

In view of:

- the initial assessment of AMGLIDIA (glibenclamide) based in particular on a study of the acceptability and tolerance of the switch from glibenclamide tablets to AMGLIDIA (glibenclamide) oral solution on 10 patients, and on the Committee's finding of the lack of robust data on the impact of AMGLIDIA (glibenclamide) on neurological symptoms of the disease,
- new data to support the impact of AMGLIDIA (glibenclamide) on neurological symptoms of the disease based solely on a literature review with a low level of evidence suggesting a neurological benefit, but with no probative value of this benefit,
- uncertainties about the long-term efficacy of AMGLIDIA (glibenclamide) in the absence of data capable of supporting it,
- the updated safety profile of AMGLIDIA (glibenclamide) which appears to be favourable,

- the medical benefit of having a medicine in a dosage form which is suitable for the paediatric population and which facilitates its administration, in this rare and serious disease,

the Committee deems that AMGLIDIA 0.6 mg/mL and 6 mg/mL (glibenclamide) oral suspension with syringe provides minor clinical added value (CAV IV) in the current therapeutic strategy.