HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
02 OCTOBER 2019

glecaprevir/pibrentasvir
MAVIRET 100 mg/40 mg, film-coated tablet

New indication

Key points

Favourable opinion to reimbursement in the treatment of chronic hepatitis C virus (HCV) infection in adults and adolescents age 12 to 18 years.

What therapeutic improvement?

Slight therapeutic improvement in management.

Role in the care pathway?

Where treatment is required in adolescents from 12 to 18 years, direct acting antivirals (DAAs) are now the conventional treatment. MAVIRET is a first-line therapeutic option as an alternative to the other options with MA available in France (SOVALDI and HARVONI).

Its use is not recommended in patients with moderate liver failure (Child-Pugh B) and is contraindicated in patients with severe liver failure (Child-Pugh C).

Special recommendations

The Committee recalls that the decision to treat a chronic HCV infection in adolescents from 12 to 18 years must be discussed on a case-per-case basis in a multidisciplinary review meeting.

COMMITTEE'S CONCLUSIONS

Actual benefit

Extension of indication in the paediatric population age 12 to 18 years

◗ Hepatitis C is a viral disease of which the severity is related to the potential long-term complications of its chronicisation: cirrhosis, hepatocellular carcinoma.
HCV infection is rare in children and generally asymptomatic. The outcome of the disease is not identical to in adults, as time to progression is longer.
Hepatitis C in children is therefore a non-serious disease in most cases.

◗ MAVIRET, pangenotypic treatment, used alone, without adjuvant ribavirin, is a curative treatment.

◗ The efficacy/adverse effects balance, is high.

◗ This proprietary medicinal product is part of first-line treatment.

◗ There are therapeutic alternatives (SOLVADI, HARVONI) for the treatment of hepatitis C in adolescents age 12 to 18 years.

Public health benefit

Considering:
the lack of severity of HVC infection in children in most cases due to slow progression,
the low prevalence of HCV infection in adolescents,
the medical need already met by SOVALDI and HARVONI in the paediatric population,
the fact that MAVIRET is likely to provide a response to the medical need identified in adolescents, with a shorter treatment period for certain patients and no need to add ribavirin to the therapy,
the uncertainty of the impact on morbidity-mortality of the antiviral treatment in adolescents, due to the little progressive nature of the disease and without impact on development and quality-of-life in most cases,
MAVIRET is not likely to have an impact on public health in extension of the indication to adolescents age 12 to 18 years.

Considering all these elements, the Committee deems that the actual benefit of MAVIRET (glecaprevir/pibrentasvir) is significant in the MA indication.

The Committee issues a positive opinion for both hospital and retail formulary listing of reimbursed pharmaceutical products approved for use by market authorization and dosages.

Recommended reimbursement rate: 65 %

Clinical added value

Considering:

- **the data available in adults demonstrating significant virological efficacy,**
- **the data available (phase 2 study) in adolescents age 12 to 18 years, suggesting an efficacy and safety profile comparable to that described in adults,**
- **currently available alternatives (SOVALDI and HARVONI),**

the Committee considers that MAVIRET (glecaprevir/pibrentasvir) brings, as in adults, minor clinical added value (IACB IV) in the treatment of chronic Hepatitis C in adolescents age 12 to 18 years.