HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
2 DECEMBER 2020

The legally binding text is the original French opinion version

sofosbuvir/velpatasvir
EPCLUSA 400 mg/100 mg film-coated tablets
EPCLUSA 200 mg/50 mg film-coated tablets

New indication
and
Availability of a new form

Key points

Favourable opinion for reimbursement in the treatment of chronic hepatitis C virus (HCV) infection in patients aged 6 years and older and weighing at least 17 kg.

Favourable opinion for reimbursement in the new form, EPCLUSA (sofosbuvir/velpastasvir) 200 mg/50 mg film-coated tablets.

What therapeutic improvement?

Therapeutic improvement in the management of the disease.

Role in the care pathway?

The reference treatment for chronic hepatitis C in adults and adolescents (from 12 years of age) is now based on direct-acting antiviral combinations. These combinations usually enable a sustained virological response (> 90%) to be obtained, including in cirrhosis patients. The majority of patients can now benefit for 8 to 12 weeks of treatment with ribavirin-free pangenotypic direct-acting antiviral combinations. These pangenotypic regimens are recommended preferentially since they reduce the needs for genotyping or resistance tests to guide treatment decisions.

In children aged under 12 years, due to the slow-progressing nature of the infection in paediatric patients, the guidelines recommend delaying the initiation of treatment pending the availability of pangenotypic combinations: EPCLUSA (sofosbuvir/velpatasvir) and MAVIRET (pibrentasvir/glecaprevir), which are reference options.

Role of the medicinal product in the care pathway

In children who meet the treatment criteria, EPCLUSA (sofosbuvir/velpatasvir) is a reference treatment option, in the same way as MAVIRET (pibrentasvir/glecaprevir), due to its pangenotypic efficacy, shortening the treatment duration (12 weeks) and simplifying treatment (reduced need for genotyping or resistance tests).

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

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

◗ EPCLUSA (sofosbuvir/velpatasvir) is a curative treatment.

◗ The efficacy/adverse effects ratio of this medicinal product is high in this indication.

◗ There are therapeutic alternatives in the treatment of hepatitis C, in particular MAVIRET (pibrentasvir/glecaprevir).

◗ This proprietary medicinal product is a first-line treatment.

Public health impact

Considering:

- the seriousness of the disease and its prevalence,
- the medical need to have access to new antivirals with improved efficacy, safety, drug interaction and resistance profiles, opening up new treatment opportunities, particularly in terms of reducing the treatment duration or simplifying treatment,
- the fact that EPCLUSA (sofosbuvir/pibrentasvir) is likely to provide a response to the identified medical need:
    - in terms of eradication of HCV, with a shorter treatment duration (12 weeks for all patients) and the absence of any need to add ribavirin to the therapy,
    - an expected impact on morbidity and mortality in treated patients,
    - the expected impact on the care and life pathway (reduction in the treatment duration and the need for genotyping or resistance tests),

EPCLUSA (sofosbuvir/velpatasvir) is likely to have an additional impact on public health.

Given all these elements, the Committee deems that the clinical benefit of EPCLUSA (sofosbuvir/velpatasvir) is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of EPCLUSA (sofosbuvir/velpatasvir) proprietary medicinal products in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the new indication and at the MA dosages.

◗ **Recommended reimbursement rate: 100%**

Clinical Added Value

Considering:

- **the data available in adults, demonstrating high pangenotypic virological efficacy,**
- **the data available (phase 2 study) in children aged from 6 years, suggesting an efficacy and safety profile comparable to that described in adults,**
- **the need to have access to new oral pangenotypic antiviral-based treatment regimens in children that are highly effective and can be administered as short courses,**

the Committee considers that, as in adults, EPCLUSA (sofosbuvir/velpatasvir) provides a minor clinical added value (CAV IV) in the treatment of chronic hepatitis C virus (HCV) infection in children aged 6 years and older and weighing at least 17 kg.