SUMMARY

dolutegravir/abacavir/lamivudine

TRIUMEQ 5 mg/60 mg/ 30 mg

dispersible tablets

Indication extension

Adopted by the Transparency Committee on 11 September 2024

Summary of opinion

Favourable opinion for reimbursement in "the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infected children at least 3 months of age and weighing at least 6 kg to less than 25 kg, not carrying the HLAB*5701 allele and with no evidence of previous or current resistance to any of the antiretroviral classes represented in the dolutegravir/ abacavir/lamivudine fixed-dose combination, i.e. integrase inhibitors (INIs) and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs)"

Transparency Committee's conclusions

Clinical Benefit

- HIV infection is a serious, life-threatening disease.
- The proprietary medicinal product TRIUMEQ (dolutegravir/abacavir/lamivudine) 5 mg/60 mg/ 30 mg dispersible tablets aims to prevent and/or correct the immune deficiency induced by HIV infection in children weighing from 6 kg to less than 14 kg with HIV infection.
- Based on the extrapolation of efficacy data observed in adults, the efficacy/adverse effects ratio is high in patients not carrying the HLAB*5701 allele and in whom the virus has no mutations leading to resistance to INIs and NRTIs.
- There are medicinal alternatives.
- This is a first-line treatment.

Public health benefit

Considering:

- the frequency and seriousness of the infection concerned,
- the medical need to have access to new antiretrovirals with improved efficacy, safety and drug interaction profiles,

- the available data in adults and adolescents demonstrating a relatively satisfactory efficacy and safety profile,
- the fact that TRIUMEQ (dolutegravir/abacavir/lamivudine) provides no response to the identified medical need in the absence of any expected additional impact on morbidity and mortality and/or on quality of life compared to the non-fixed combination of abacavir (ZIAGEN), lamivudine (EPIVIR) and dolutegravir (TIVICAY),
- the lack of expected impact on the organisation of care,

TRIUMEQ (dolutegravir/abacavir/lamivudine) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of TRIUMEQ (dolutegravir/abacavir/lamivudine) 5 mg/60 mg/30 mg dispersible tablets is substantial only in the treatment of children at least 3 months of age weighing from 6 kg to less than 14 kg with HIV-1 infection not carrying the HLAB*5701 allele and in whom the virus has no mutations leading to resistance to integrase inhibitors (INIs) and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs).

The Committee issues a favourable opinion for inclusion of TRIUMEQ (dolutegravir/abacavir/lamivudine) 5 mg/60 mg/30 mg dispersible tablets in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use only in the treatment of children at least 3 months of age weighing from 6 kg to less than 14 kg with HIV-1 infection not carrying the HLAB*5701 allele and in whom the virus has no mutations leading to resistance to integrase inhibitors (INIs) and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs), and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%**

Clinical Added Value

Considering:

- very limited efficacy and safety data in children based almost exclusively on extrapolation of the results observed in adults and adolescents,
- the available data (phase 1/2 study) in children weighing at least 6 kg to less than 14 kg with HIV infection, suggesting an efficacy and safety profile comparable to that described in adults and adolescents,
- its good safety, good palatability and ease of administration (dosing without requirements in terms of food),

the Committee deems that TRIUMEQ (dolutegravir/abacavir/lamivudine) 5 mg/60 mg/30 mg dispersible tablets provides no clinical added value (CAV V) compared to separate doses of the different components of the fixed-dose combination in children at least 3 months of age weighing from 6 kg to less than 14 kg with HIV-1 infection not carrying the HLAB*5701 allele and in whom the virus has no mutations leading to resistance to integrase inhibitors (INIs) and nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs).