SUMMARY

dolutegravir/abacavir/lamivudine

TRIUMEQ 50 mg/600 mg/300 mg and 5 mg/60 mg/30 mg

film-coated tablets and dispersible tablets

Indication extension and inclusion of a new presentation in a new indication

Original French opinion adopted by the Transparency Committee on 10 May 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

In paediatric patients weighing at least 25 kg to less than 40 kg (indication extension)

- HIV infection is a serious, life-threatening disease.
- The proprietary medicinal product TRIUMEQ (dolutegravir/abacavir/lamivudine) 50 mg/ 600 mg/300 mg film-coated tablets aims to prevent and/or correct the immune deficiency induced by HIV infection in children weighing at least 25 kg to less than 40 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 product 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) 50 mg/600 mg/300 mg film-coated tablets is substantial only in the treatment of paediatric patients weighing at least 25 kg to less than 40 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 reverse transcriptase inhibitors (NRTIs).

The Committee issues a favourable opinion for inclusion of TRIUMEQ (dolutegravir/abacavir/lamivudine) 50 mg/600 mg/300 mg film-coated tablets in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use only in the treatment of paediatric patients weighing at least 25 kg to less than 40 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 reverse transcriptase inhibitors (NRTIs), and at the MA dosages.

➔ Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 100%

In paediatric patients weighing at least 14 kg to less than 25 kg (inclusion of a new presentation)

- ➔ 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 at least 14 kg to less than 25 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 product 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 paediatric patients weighing at least 14 kg to less than 25 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 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 hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use only in the treatment of paediatric patients weighing at least 14 kg to less than 25 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 reverse transcriptase inhibitors (NRTIs), and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 100%**

Clinical Added Value

In paediatric patients weighing at least 25 kg to less than 40 kg (indication extension)

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 25 kg to less than 40 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, as in adults and adolescents, TRIUMEQ (dolutegravir/ abacavir/lamivudine) 50 mg/600 mg/300 mg film-coated tablets provides no clinical added value (CAV V) compared to separate doses of the different components of the fixed-dose combination in paediatric patients weighing at least 25 kg to less than 40 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 reverse transcriptase inhibitors (NRTIs).

In paediatric patients weighing at least 14 kg to less than 25 kg (inclusion of a new presentation)

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 14 kg to less than 25 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 paediatric patients weighing at least 14 kg to less than 25 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 reverse transcriptase inhibitors (NRTIs).