SUMMARY

bictegravir/emtricitabine/tenofovir alafenamide

BIKTARVY 30 mg/120 mg/15 mg and 50 mg/200 mg/25 mg

film-coated tablet

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 (indication extension)

- HIV infection is a serious, life-threatening disease.
- The proprietary medicinal product BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 50 mg/200 mg/25 mg film-coated tablet aims to prevent and/or correct the immune deficiency induced by HIV infection in patients weighing > 25 kg with HIV-1 infection.
- Based on the extrapolation of efficacy data observed in adults, the efficacy/adverse effects ratio is high in patients with human immunodeficiency virus type 1 (HIV-1) infection without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.
- 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,
- available data that demonstrate a comparable efficacy, safety and resistance profile to TRIUMEQ;
- the fact that BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide), 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 dolutegravir-based strategies currently available (TRIUMEQ or TIVICAY + two NRTIs);
- the lack of expected impact on the organisation of care;

BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 50 mg/200 mg/25 mg film-coated tablet is substantial only for the treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients weighing at least 25 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.

The Committee issues a favourable opinion for inclusion of BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 50 mg/200 mg/25 mg film-coated tablet in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use only for the treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients weighing at least 25 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir 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 BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 30 mg/120 mg/15 mg film-coated tablet aims to prevent and/or correct the immune deficiency induced by HIV infection in patients weighing at least 14 kg to less than 25 kg with HIV-1 infection.
- ➔ Based on the extrapolation of efficacy data observed in adults, the efficacy/adverse effects ratio is high in patients with human immunodeficiency virus type 1 (HIV-1) infection without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.
- ➔ 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,
- available data that demonstrate a comparable efficacy, safety and resistance profile to TRIUMEQ;
- the fact that BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide), 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 dolutegravir-based strategies currently available (TRIUMEQ or TIVICAY + two NRTIs);
- the lack of expected impact on the organisation of care;

BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 30 mg/120 mg/15mg film-coated tablet is substantial only for the treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients at least 2 years of age and weighing at least 14 kg to less than 25 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.

The Committee issues a favourable opinion for inclusion of BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 30 mg/120 mg/15 mg film-coated tablet in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use only for the treatment of human immunodeficiency virus-1 (HIV-1) infection in paediatric patients at least 2 years of age and weighing at least 14 kg to less than 25 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir 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 (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 (non-comparative study, with a small sample size) in children weighing at least 25 kg with HIV infection, suggesting an efficacy and safety profile comparable to that described in adults,
- its good safety, good palatability and ease of administration (dosing without requirements in terms of food),

the Committee deems that, as in adults, BIKTARVY (bictegravir/emtricitabine/tenofovir alafenamide) 50 mg/200 mg/25 mg film-coated tablet provides no clinical added value (CAV V) in the current care pathway for paediatric patients weighing at least 25 kg with HIV-1 infection without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.

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 (non-comparative study, with a small sample size) 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,
- its good safety, good palatability and ease of administration (dosing without requirements in terms of food),

the Committee deems that BIKTARVY bictegravir/emtricitabine/tenofovir alafenamide) 30 mg/120 mg/15 mg film-coated tablet (provides no clinical added value (CAV V) in the current care pathway for paediatric patients at least 2 years of age and weighing at least 14 kg to less than 25 kg without present or past evidence of viral resistance to the integrase inhibitor class, emtricitabine or tenofovir.