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BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

TRIUMEQ (dolutegravir/abacavir/lamivudine), fixed-dose combination of antiretrovirals

No clinical benefit demonstrated when compared with taking the different components separately.

Main points

- TRIUMEQ has Marketing Authorisation in the treatment of Human Immunodeficiency Virus (HIV)-infected adults and adolescents from 12 years of age weighing at least 40 kg and non-carriers of the HLA-B*5701 allele.
- TRIUMEQ enables treatment simplification when prescription of the abacavir + lamivudine + dolutegravir triple therapy is considered in treatment-naive or pre-treated patients, in whom the virus does not possess the resistance mutation to integrase inhibitors and the two NRTIs: abacavir and lamivudine.

Therapeutic use

Medicinal products containing abacavir must only be used in patients who are non-carriers of the HLA-B*5701 allele.

Abacavir/lamivudine/dolutegravir triple therapy is part of the preferential treatment options recommended in the management of patients infected with HIV.

Given that the recommended dosage of dolutegravir is 50 mg twice daily in patients with resistance to the class of integrase inhibitors, the use of TRIUMEQ is not recommended in these patients.

Clinical data

- The clinical data are mainly based on one study (SINGLE) belonging to the dolutegravir clinical development programme and which studied the free combination of this proprietary medicinal product with abacavir/lamivudine (KIVEXA). This study revealed the non-inferiority then superiority of the free combination of dolutegravir + abacavir/lamivudine compared with tenofovir/emtricitabine/efavirenz (ATRIPLA).
- The subgroup analyses of two other studies (SPRING-2 and FLAMINGO) revealed the non-inferiority of dolutegravir compared with raltegravir (INSENTRESS) or darunavir/ritonavir (PREZISTA/ritonavir), coadministered with abacavir/lamivudine (KIVEXA) or tenofovir/emtricitabine (TRUVADA).
- In pre-treated patients, in whom the virus does not possess the resistance mutation to integrase inhibitors, the efficacy of the fixed-dose abacavir/lamivudine/dolutegravir combination (TRIUMEQ) was extrapolated from efficacy data which were already known for its components because no clinical data are available for this fixed-dose combination in this population.
- In terms of resistance, the results of the *in vitro* studies and of the clinical studies show that the genetic barrier to dolutegravir resistance is higher than that of raltegravir and efavirenz. The abacavir and lamivudine resistance profiles are well-known and are not likely to change when combined with dolutegravir.
- The observed data with the fixed-dose combination are consistent with the adverse effect profiles observed with each individual component (dolutegravir, abacavir and lamivudine).

Special prescribing conditions

Initial annual hospital prescription
Unrestricted renewal

Benefit of the medicinal product

- The actual benefit* of TRIUMEQ is substantial.
- TRIUMEQ does not provide clinical added value** (CAV V) compared with taking the different components of the fixed-dose combination separately.

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This document was created on the basis of the Transparency Committee Opinion of 17 December 2014 (CT-13894) and is available at **www.has-sante.fr**

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[i]* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".