Zorginstituut Nederland

Tenofovir alafenamide (Vemlidy®) for the treatment of chronic hepatitis B infection

Summary of recommendations by *Zorginstituut Nederland* dated 26 April 2017

Zorginstituut Nederland carried out an assessment of the medicine tenofovir alafenamide (Vemlidy®), whereby they reached the following conclusion.
Based on the criteria of the Medicines Reimbursement System (GVS), tenofovir alafenamide fumarate (TAF) is interchangeable with tenofovir disoproxil fumarate (TDF), which is included on List 1B of the GVS.

In a letter dated 10 April 2017 (CIBG-17-04265), the Minister of Health, Welfare and Sport asked *Zorginstituut Nederland* to perform an assessment of the medicine tenofovir alafenamide (Vemlidy®).

Registered indication

Tenofovir alafenamide is registered for the treatment of chronic hepatitis B in adults and adolescents (aged 12 years and older with body weight at least 35 kg). Each (film-coated) Vemlidy® tablet contains tenofovir alafenamide fumarate (TAF) equivalent to 25 mg of tenofovir alafenamide. The recommended dose is 1 tablet once daily. The optimum treatment duration is not known. This is usually at least 6 to 12 months, but it can last many years.

Tenofovir alafenamide belongs to the pharmacotherapeutic group of antiviral products for systemic use, namely the group of nucleoside and nucleotide reverse transcriptase inhibitors (NRTIs). Tenofovir alafenamide is a prodrug. TAF is phosphorylated in the body, via several steps, into the pharmacologically active metabolite tenofovir diphosphate. Another prodrug for tenofovir diphosphate is tenofovir disoproxil fumarate (TDF). Both TDF and TAF can be used for several indications: in addition to chronic hepatitis B infection, TAF and TDF can also be used to treat an HIV-1 infection.

Tenofovir alafenamide is not inferior to tenofovir disoproxil fumarate for the treatment of either chronic hepatitis B infection or an hiv-1 infection. The favourable and unfavourable effects of tenofovir alafenamide are the same as those of tenofovir disoproxil fumarate.

Conclusion on interchangeability

Based on current criteria, TAF is interchangeable with TDF, whereby its use for HIV-1 infection is the main indication. Tenofovir disoproxil fumarate (Viread®) has been included on List 1B of the GVS.

Since 2000, HIV-inhibiting drugs have been given a special place in the GVS. On 30 March 2000, a past Minister of Health, Welfare and Sport stated that, in principle, all antiretroviral drugs for the treatment of HIV infection would be eligible for inclusion on list 1B of the GVS. No pharmacoeconomic assessment is required for these products.

Our conclusion on interchangeability between TAF and TDF is not in line with the exceptional reimbursement policy for HIV-inhibiting products. If this policy is not altered, then Vemlidy® will also be

eligible for placing on List 1B.

The marketing authorisation holder (MAH) of Vemlidy®, who is also MAH of Viread®, has indicated that the price of Vemlidy® will be similar to that of Viread®. The purchase price of Vemlidy has been fixed at €322.23 per 30 pcs (exclusive 6% VAT; Gilead file dated 13 March 2017), which is the same as that of Viread® 245 mg (Taxe March 2017); €322.22 per 30 pcs.). This means that including Vemlidy® on List 1B of the GVS will not result in additional costs.

Zorginstituut Nederland's advice

Based on the above, Zorginstituut Nederland advises the inclusion of tenofovir alafenamide (Vemlidy®) on List 1B of the GVS.

Specific reimbursement conditions for antiretroviral products (section 8 of List 2 of the GVS) also apply to TAF.

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The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.