Zorginstituut Nederland

Letermovir (Prevymis®) in cases of adult CMV-seropositive recipients of an allogenic haemotopoietic stem cell transplant (HSCT)

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 27 November 2018.

Zorginstituut Nederland has carried out an assessment of the medicinal product Letermovir (Prevymis®), whereby the following conclusion was drawn.

In a letter dated 13 August 2018 (CIBG-18-06754) the Minister of Health Welfare and Sport (WVS) asked *Zorginstituut Nederland* to assess whether letermovir (Prevymis®) is interchangeable with a medicinal product already included in the Medicine Reimbursement System (GVS). The *Zorginstituut* has completed its assessment

Letermovir is an orphan drug and is registered for the prophylaxis of cytomegalovirus (CMV)-reactivation and disease in adult CMV-seropositive recipients of an allogenic haematopoietic stem cell transplant (HSCT). Letermovir is available as 240 mg or 480 mg film-coated tablets. The recommended dose of letermovir is 480 mg once daily.

Assessment of interchangeability
No other medicinal products are included in the GVS that are eligible for assessing the interchangeability of letermovir.
Based on the above, letermovir (Prevymis®) cannot be placed on List 1A. What has to be examined is whether letermovir is eligible for placing on List 1B.

Therapeutic value
Zorginstituut Nederland, advised by the Scientific Advisory Board (WAR), concluded that for the prophylaxis of CMV reactivation and disease in adult CMV-seropositive recipients of an allogenic HSCT, the therapeutic added value of letermovir added to CMV-DNA-control and, if necessary, pre-emptive therapy, is higher than that of CMV-DNA-control alone, and, where necessary, pre-emptive therapy.

Budget impact analysis
Taking into account the assumptions mentioned in the budget impact analysis, including letermovir (Prevymis®) on List 1B of the GVS will be accompanied by additional costs to the pharmacy budget of €1.99 million in the third year.

Uncertainty exists regarding a number of aspects, such as the distribution of patients receiving allogenic HSCT in high-risk and low-risk groups in Dutch treatment centres and the actual market penetration of letermovir for both high-risk and low-risk patients.

On the grounds of the estimated budget impact, the product was exempted from performing a pharmacoeconomic analysis.

Advice
Letermovir (Prevymis®) is not interchangeable with any product included in the GVS. Based on the above-mentioned considerations, the *Zorginstituut* advised the Minister to include letermovir (Prevymis®) on List B of the Health Insurance

Decree. Inclusion on List 1B will involve additional costs.

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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.