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2023038912

Our reference
2023038912

Date 20 December 2023
Re: Amendment of List 2 conditions for lenacapavir (Sunlenca®)

Dear Mr Kuipers,

With this letter, the National Health Care Institute advises you to amend the List 2 condition for the reimbursement of the medicinal product lenacapavir (Sunlenca®).

Reason
The National Health Care Institute received a request from the chairperson of the Guidelines committee of the Dutch Association of HIV-treating Physicians (NVHB) to adjust the reimbursement condition for lenacapavir to allow treatment with the combination of lenacapavir and fostemsavir (Rukobia®). This combination treatment is now excluded from the List 2 conditions.

The reason for the request is that HIV patients with very extensive resistance are deprived of a potentially effective antiviral combination. It is conceivable that there will be patients for whom the extent of resistance requires the combination of lenacapavir with fostemsavir for a sufficiently effective treatment, as the 2 products have a completely different mechanism/site of action. The NVHB indicates that, unfortunately, they had not noticed this exclusion of the combination in the comments phase and is therefore only now submitting this request.

Background
Registered indication for lenacapavir (Sunlenca®):
Lenacapavir, in combination with other antiretroviral agents, is indicated for the treatment of adult patients with a multi-drug resistant HIV-1 infection who cannot otherwise be treated with a suppressive antiviral regimen.

Current List 2 conditions:
1. with a multi-drug resistant human immunodeficiency virus-1 (HIV-1) infection who cannot otherwise be treated with a suppressive antiviral regimen, and
2: who does not use a combination of fostemsavir with lenacapavir, and
3: who does not use this medicinal product as a pre-exposure prophylaxis to reduce the risk of infection with the human immunodeficiency virus.

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Considerations

The NVHB considers that exclusion of the combination of lenacapavir and fostemsavir is undesirable. And states:

> "It is conceivable that there will be patients for whom the extent of resistance requires the combination of these 2 medicinal product for a sufficiently effective treatment, as the 2 products have a completely different mechanism/site of action. Note that in the assessment you used (CAPELLA study), 11% of the study participants received a treatment combining lenacapavir with fostemsavir.
> Therefore, even if the combination of lenacapavir and fostemsavir is expected to be rarely or never needed in the Netherlands, we ask you to please remove this exclusion ground for reimbursement."

The National Health Care Institute agrees with this request.

Appropriateness agreements

The NVHB will amend the Dutch guidelines that promote appropriate use. Furthermore, the combined use is expected to be very rare. The NVHB has submitted data showing that the need for the combination is very low. There are currently 33 triple-class resistant patients in the Netherlands. Based on the registration study CAPELLA, approximately 10% would be eligible for the combination. This would correspond to approximately 0-3 patients who are eligible for treatment with the combination in the Netherlands.

The NVHB is committed to making the following changes to the guidelines:

- The new medicinal products fostemsavir and lenacapavir can only be applied and are only reimbursed for the treatment of adults with a multi-drug resistant HIV-1 infection who cannot otherwise create a suppressive antiviral regimen in combination with other HIV medicinal products.
- Note: a combination of fostemsavir and lenacapavir is reimbursed only if it is not possible to compose a suppressive regimen without this combination, in combination with other HIV medicinal products.

Budget impact analysis

Adjustment of this condition is accompanied by estimated additional costs of €339,471 after three years. This is a maximum scenario in which 3 patients will use the combination in the next 3 years. Based on the pharmacy purchase price (AIP) of lenacapavir of €3,143 per pack of 5 tablets of 300 mg and €18,858 per pack of 2 vials of 1.5 ml with 464 mg lenacapavir, the costs per patient in the first year are €40,859 (5 tablets of 300 mg plus 4 vials of 1.5 ml), and in subsequent years €37,716 (4 vials of 1.5 ml per year). The total costs of fostemsavir are, based on the purchase price per tablet (600 mg) of €51.67, a daily intake of 2 tablets and a lifetime treatment period, €37,719 (51.67*2*365) per patient per year. The additional costs are 3*3* € 37.719= € 339,471

Advice

Based on the above considerations, we recommend that the List 2 conditions for lenacapavir be adjusted to allow the use and reimbursement of the combination of lenacapavir with fostemsavir. This combination should only be reimbursed in the

rare cases where it is not possible to compose a suppressive regimen without using the combination of fostemsavir and lenacapavir, in combination with other HIV medicinal products. The estimated maximum additional costs associated with this change are €339,471.

Proposal for new List 2 conditions:
1. with a multi-drug resistant human immunodeficiency virus-1 (HIV-1) infection who cannot otherwise be treated with a suppressive antiviral regimen, and
2: who does not use this medicinal product as a pre-exposure prophylaxis to reduce the risk of infection with the human immunodeficiency virus.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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