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2023015736

National Health Care Institute
Care
Medicinal Products

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Our reference
2023015736

Date 13 July 2023
Re: Additional GVS advice nirmatrelvir/ritonavir (Paxlovid®)

Dear Mr Kuipers,

In your letter of 27 September 2022 (CIBG-22-04456), you asked National Health Care Institute to assess whether the medicinal product nirmatrelvir/ritonavir (Paxlovid®) could be included in the Medicine Reimbursement System (GVS). On 27 October 2022, the National Health Care Institute recommended this medicinal product to be placed on List 1B of the GVS.

At the time, during the exceptional situation of the coronavirus pandemic, a provisional exemption from the pharmacoeconomic analysis was granted, to ensure the rapid availability of nirmatrelvir/ritonavir in the Netherlands. Following the results of the budget impact analysis (BIA) of September 2022, showing a budget impact over €10 million,[I] the marketing authorisation holder has been working on a pharmaco-economic analysis in the past months. This pharmaco-economic analysis was submitted to the National Health Care Institute on 17 February 2023.

Developments coronavirus pandemic
The latest advice from the Outbreak Management Team (OMT) to the Ministry of Health, Welfare and Sport (VWS) of 22 February 2023 [0011/2023 LCI/JVD/tl/sf] indicates a new phase in the coronavirus pandemic. Due to accumulated immune response after vaccination and/or infection, infections are currently mild on average.. It was advised that COVID-19-specific measures could be discontinued. The onset of this new phase in the coronavirus pandemic prompted the National Health Care Institute to re-examine the BIA for nirmatrelvir/ritonavir.

Budget impact
In the BIA performed in 2022, the National Health Care Institute calculated several scenarios to estimate the possible budget impact of nirmatrelvir/ritonavir over the first three years after inclusion in the basic health care package. In these scenarios, several assumptions were made regarding the number of infections per year and the risk group in which nirmatrelvir/ritonavir would actually be used. All of these scenarios showed a budget impact of more than €10 million.

In June 2023, the number of infections decreased significantly. In addition, the latest (not yet published) GIP data shows that the number of claims for

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nirmatrelvir/ritonavir is far below the estimated BIA numbers. In the first quarter of 2023, claims were submitted for approximately 200 packages of nirmatrelvir/ritonavir for the registered indication. Based on these numbers, it is expected that approximately 800 courses of nirmatrelvir/ritonavir will be distributed throughout 2023. This is well below the minimum scenario of 27,097 patients potentially eligible for treatment with nirmatrelvir/ritonavir, estimated in the BIA of October 2022 .

The price of a course of nirmatrelvir/ritonavir is € 1,242.00. On the basis of the recent claim data, the National Health Care Institute expects the actual budget impact to be well below €10 million in the coming years.

Evaluation of pharmacotherapy reassessment
The GVS advisory report of 27 October 2022 stated that in one year, the National Health Care Institute would evaluate the need for a pharmacotherapeutic reassessment of nirmatrelvir/ritonavir. Based on the current COVID-19 situation and the low number of claims for nirmatrelvir/ritonavir, the National Health Care Institute is delaying this evaluation until at least January 2024.

Conclusion and advice
On the basis of the above, the provisional exemption for a pharmaco-economic analysis is extended at least until 1 January 2024. At that time, the National Health Care Institute will evaluate whether a reassessment and/or pharmaco-economic analysis of nirmatrelvir/ritonavir is required.

Based on the recent claim data, the National Health Care Institute recommends that nirmatrelvir/ritonavir remains included in the GVS under the current conditions.

Yours sincerely,

Peter Siebers
Acting Chairperson of the Executive Board

[I] The National Health Care Institute's threshold for a pharmaco-economic analysis is €10 million. If the budget impact is more than €10 million, a pharmaco-economic analysis is always required.