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Our reference
2022043518

Date 27 October 2022
Regarding GVS advice nirmatrelvir/ritonavir (Paxlovid®)

Dear Mr Kuipers,

In your letter of 27 September 2022 (reference CIBG-22-04456), you asked the National Health Care Institute to assess whether nirmatrelvir/ritonavir (Paxlovid®) can be included in the Medicine Reimbursement System (GVS). The National Health Care Institute has now partially completed the substantive assessment. The considerations are included in the GVS report attached to this letter, with the pharmacotherapeutic report and the budget impact analysis.

Very exceptional situation
Due to the exceptional situation with regard to the (developments of the) coronavirus pandemic, the National Health Care Institute has followed an unusual procedure for the assessment of nirmatrelvir/ritonavir. According to the National Health Care Institute, it is desirable that, due to the exceptional situation, this medicinal product should be made available as soon as possible to designated patients. The assessment shows that nirmatrelvir/ritonavir only has a clinically relevant effect for patients without SARS-CoV-2 antibodies. The physicians' associations (the Dutch College of General Practitioners and the Foundation Working Group for Antibiotics Policy) currently only see a place for this medicinal product in a (very) limited group of patients. Therefore, the recommended further conditions limit the prescription of nirmatrelvir/ritonavir to the patients designated according to the guidelines. If the development of the coronavirus pandemic should result in expanding (or further narrowing) the guidelines, the reimbursement conditions will be adjusted accordingly.
The National Health Care Institute will evaluate in a year's time whether a pharmacotherapeutic reassessment of nirmatrelvir/ritonavir is necessary.

Nirmatrelvir/ritonavir
Nirmatrelvir/ritonavir is indicated for the treatment of coronavirus infection 2019 (COVID-19) in adults who do not require oxygen supplementation and are at increased risk of developing severe COVID-19.

It is available as a combination package that contains a 5-day treatment course. Each pink film-coated tablet contains 150 mg of nirmatrelvir (listed in the SmPC as PF-07321332); each white film-coated tablet contains 100 mg of ritonavir. The recommended dosage is 300 mg of nirmatrelvir (two 150 mg tablets) along with

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100 mg of ritonavir (one 100 mg tablet). The three tablets must be taken orally every 12 hours for 5 days. Nirmatrelvir/ritonavir should be administered as soon as possible after diagnosis of COVID-19 and within 5 days of the onset of symptoms.

The market authorisation holder is asking for inclusion on List 1B of the Health Insurance Regulation (Rzv).

Outcome of the assessment

Review of interchangeability
In assessing whether nirmatrelvir/ritonavir is interchangeable with medicinal products already included in the GVS, we concluded that this is not the case.

Therapeutic value
The National Health Care Institute has found that nirmatrelvir/ritonavir meets the established medical science and medical practice in the treatment of COVID-19 in adults who do not need oxygen supplementation and are at a very high risk of developing severe COVID-19, as defined by the applicable treatment guidelines. The National Health Care Institute concludes, on the basis of the data, that nirmatrelvir/ritonavir has an added value compared to the placebo, when added to the best possible supportive care.

Budget impact analysis
The marketing authorisation holder has indicated that the price for nirmatrelvir/ritonavir will be € 1242 per treatment. The National Health Care Institute has noticed that this amount is much higher than the prices abroad mentioned in the media (for example, one treatment would cost the US government $500).
Taking into account assumptions about the number of (symptomatic) infections, the percentage of people at an increased risk of severe COVID-19 eligible for treatment with this medicinal product, and market penetration, inclusion in List 1B of the GVS of nirmatrelvir/ritonavir for COVID-19 will result in additional costs charged to the pharmaceutical budget of €33.7 to €74.3 million in year 1 and €8.4 to €74.3 million in year 3.
The National Health Care Institute does not exclude that in practice, patients at a lower risk and/or patients with a suspected positive serology status, will also be prescribed nirmatrelvir/ritonavir.
The National Health Care Institute emphasizes that the assumptions, calculations and outcomes in this budget impact analysis are extremely uncertain. It is therefore not possible to identify the most realistic scenario.

Pharmacoeconomic analysis
For a rapid availability of nirmatrelvir/ritonavir in the Netherlands in the present exceptional situation, a **provisional** exemption for a pharmacoeconomic analysis has been granted. Following the results of the budget impact analysis, a pharmacoeconomic analysis analysis is currently being conducted. The National Health Care Institute will advise you about this in the future.

Advice

The National Health Care Institute recommends you to include nirmatrelvir/ritonavir (Paxlovid®) in List 1B of the Health Insurance Regulation.
The National Health Care Institute hereby recommends the following

reimbursement condition:
Nirmatrelvir/ritonavir condition
Only for insured persons that fall into a medical high-risk group and have been designated in accordance with the Dutch guidelines drafted by the physicians' associations.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

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