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Minister for Health,
Welfare and Sport
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2023043152

Date 1 December 2023
Re: monitoring the vitamin D package measure

Dear Mr Kuipers,

In May 2022, the National Health Care Institute issued an additional package advice on the reimbursement of medicinal products containing vitamin D.¹ At the time, the National Health Care Institute indicated that the practical effects of the withdrawal of the reimbursement of vitamin D should be monitored in the context of cyclical package management. For this purpose, the National Health Care Institute tendered a study.

The results of the study, carried out by the Netherlands Institute for Health Services Research (Nivel), have since become available. This letter is to inform you about the main findings of this and how the National Health Care Institute interprets them.

Conclusion of the National Health Care Institute

In its 2022 advisory report, the National Health Care Institute indicated that the vast majority of users of prescription medicines containing vitamin D can switch to a daily dose of self-care product and that only a small proportion of users will stop taking them.

The results of the study confirm the expectations in the 2022 advice. The argument of the National Health Care Institute not to reimburse vitamin D from the Medicine Reimbursement System (GVS) therefore remains unchanged. The savings realised here (some €129 million in 2021) could be better spent on care that cannot be self-funded and self-managed. Of course, we also recognise that people in poverty cannot afford the relatively low cost of vitamin D over the counter. It would be good if a solution could be found to this, outside the health care insurance.

In addition, we advise to repeat and improve the information on the correct use of vitamin D. When you decided to stop the compensation of vitamin D at the end of 2022, you informed the public about this through a public campaign.² However,

¹ National Health Care Institute. 2022. Additional package advice vitamin D To be consulted via <https://www.zorginstituutnederland.nl/publicaties/adviezen/2022/05/09/pakketadvies-vitamine-d>

² Flyer with 9 translations: <https://www.rijksoverheid.nl/documenten/brochures/2022/12/23/flyer-vitamine-d> and video: <https://www.rijksoverheid.nl/documenten/videos/2022/12/22/vitamine-d-animatie> ; <https://www.rijksoverheid.nl/onderwerpen/geneesmiddelen/vraag-en-antwoord/wordt-vitamine-d-vergoed-door-mijn-zorgverzekering>

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for people with limited health literacy or a limited capacity to act, it is still difficult to choose an appropriate product. We recommend that you direct the public's attention to this once again, including through healthcare professionals and healthcare providers.

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We explain how we came to this conclusion below.

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Nivel study

Detailed information about the design and results of the study can be found in the Nivel report attached.³

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The aim of the study was to gain insight into whether and how the acquisition of vitamin D (cholecalciferol) and patient compliance have changed following the withdrawal of the reimbursement for higher doses of vitamin D and what the underlying mechanisms and reasons are.

This study has a focus on vulnerable groups in particular. According to healthcare professionals, the term "vulnerable" includes: people with difficulty keeping oversight of their medicines, people with osteoporosis, people with a language barrier or an immigration background, people with a low level of education, people with low socio-economic status, people with poor general health, people with limited health literacy and low literacy. Vitamin D users with at least one of the above characteristics have been merged into one vulnerable group for the study. This is because people often have multiple characteristics. This broad approach resulted in 69% of the vitamin D users participating in the study being identified as vulnerable.

The study consisted of a quantitative analysis based on online questionnaires. A total of 9,594 people completed the questionnaire: 4,016 respondents were recruited through the Nivel Consumer Panel on Health and 5,578 people responded through an open link. In addition, a focus group with six people with low-level literacy was organised (qualitative analysis).

Key study findings⁴

What are vulnerable vitamin D users doing in 2023?

- 65% will continue to take vitamin D at their own expense. These people recognize the need for its use.
Within this group:
 - four out of ten take the same vitamin D as in 2022;
 - two out of ten take another product with vitamin D than in 2022, i.e. one in a different dose or dosage, usually bought without a prescription.
- In the low-level literacy focus group, a similar picture emerges as in the quantitative analysis: all six participants who were interviewed still use vitamin D in 2023 and they indicated that they need it for their health.
- About 5% of the respondents of the questionnaire stopped taking vitamin D.
Within this group:
 - five out of ten say that they cannot afford to pay for the vitamin D product themselves;
 - three out of ten say that they don't want to pay for it themselves;

³ <https://www.nivel.nl/en/publicatie/effecten-van-de-pakketmaatregel-vitamine-d-eindrapportage-met-een-focus-op-kwetsbare>

⁴ See Annex 2 | Nivel Infographic

- two out of ten say that they don't know which vitamin D product to choose.
- Approximately 20% of respondents still have a supply of vitamin D. Within this group:
 - the majority indicated they intend to continue using vitamin D after their supply is exhausted;
 - about 6-7% indicated that they intend to stop when their supply runs out, with the most frequently mentioned argument that they do not want or cannot pay for the product themselves.
- 10% of respondents did not provide any useful information in the questionnaire.
- Patient compliance in the group of vulnerable vitamin D users is (and was) not optimal. Within this group:
 - approximately 40-50% of the users intermittently forget to take their vitamin D;
 - most people who are (still) taking the same product indicate their use of vitamin D remains unchanged compared to the year before. This seems to indicate that in 2022, patient compliance for vitamin D was not optimal.
- The affordability of vitamin D is not a big issue for most people who are currently taking this (same) product (or another). 7% (Dutch Healthcare Consumer Panel) to 16% (open link) of respondents report having difficulty paying for vitamin D themselves.

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Reflection on the study results

Methodological limitations of the study

Following the motion of Mohandis and co⁵, you informed the House of Representatives about the design and implementation of this study in a timely manner.⁶ Because the study was intended to get results in the short term for the largest possible group of users, an online questionnaire was chosen. The study therefore has a number of methodological limitations that are important for a correct interpretation of its findings, namely:

- The data was collected five to six months after the package measure entered into effect. At that time, a significant proportion of patients (20%) still had a supply; the results of this subgroup only relate to their intentions.
- Long-term effects have not been researched due to the limited lead time (5-6 months) of the study.
- Although the response is high, there is a risk of bias through self-reporting. For example, the vulnerable group can be both underrepresented and overrepresented. On the one hand, people who have stopped taking vitamin D may be less inclined to participate in this study. On the other hand, people who disagree with the package measure may be more willing to fill in the questionnaire.
- Filling in the online questionnaire requires the necessary skills of the respondents, which prevented part of the vulnerable group from participating in the study. This was taken into consideration beforehand, which is why a focus group meeting was held for those participants with low-level literacy.

⁵House of Representatives, meeting year 2021–2022, 29 477, no. 771.
<https://zoek.officielebekendmakingen.nl/kst-29477-771.html>

⁶Letter to the House of Representatives dated 7 December 2022. Information approach monitor vitamin D from basic health care package. <https://www.rijksoverheid.nl/documenten/kamerstukken/2022/12/07/kamerbrief-over-informatie-aanpak-monitor-vitamine-d-uit-basispakket>

Similar experiences and arguments emerged from this focus group as from the quantitative questionnaire study. However, the actual size of the group not reached by the online questionnaire cannot be estimated.

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Missing data

Information is available for 70% of respondents: 65% continues to take vitamin D at their own expense and 5% stopped taking it. Of the remaining 30%, the research results do not show what they (will) do as a result of the package measure: 20% say they have a supply and 10% have not entered any useful information.

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Patient compliance is not optimal

Patient compliance for taking vitamin D is not optimal. Almost half of the people using it forget to take it and part of them consciously takes it differently. However, this suboptimal compliance is no different than in 2022. In fact, almost all respondents say that they take their vitamin D in the same way as in 2022.

Half the stoppers indicate they cannot afford the product

About 5% of the vulnerable group report that they have stopped taking vitamin D, half of them because they cannot afford it.

- The study includes 25 respondents from the Dutch Healthcare Consumer Panel of Nivel and 139 respondents from the open link who checked the answer 'I cannot afford this'.
- If this is extrapolated to the Dutch situation, it affects about 25,000 vulnerable people who are forgoing vitamin D because of the costs (available over the counter from less than 10 euros per person per year).

Advice from the Insured Package Advisory Committee (ACP)

The results shows the effects of no longer reimbursing vitamin D for the vulnerable group and the patient compliance. Due to methodological limitations, these conclusions are limited. The committee expects that such methodological limitations will still exist when repeating this or another type of study at a later date.

The vast majority of the committee sees no reason to reconsider the earlier advice on the basis of the study results. The committee member who indicated in the earlier advice that it was undesirable to stop reimbursing vitamin D for a group that really needs vitamin D from a medical point of view and that is vulnerable, also agrees with the committee's view.

If a vulnerable group of persons will continue to have issues as a result of the package measure, the committee recommends looking at another, more practical way to reach the vulnerable group, for example with an easy accessibility of vitamin D.

The committee considers the information provision in a broad sense (to users and healthcare providers) to be a point of special interest. For example, healthcare professionals and patients are often unaware that for severe metabolic diseases (such as cystic fibrosis, CF), food supplements (such as vitamin D) can be reimbursed from medical specialist care. The complete ACP advice can be found in Annex 3.

Considerations of the National Health Care Institute

The results of the Nivel study give a global picture of the practical effects on vulnerable groups, six months after the introduction of the package measure for vitamin D.

The results did not lead to new insights that were not known during the 2022 consultation. The questionnaire survey also did not reveal any distressing situations.

In its 2022 advisory report, the National Health Care Institute indicated that the vast majority of users of prescription medicines can switch to a daily dose of self-care product. Some of the users will continue to use the prescription product and that only a small proportion of users will stop taking them. And that is also the picture that emerges from this study. The results do not give the National Health Care Institute any reason for a different assessment of the arguments than in our 2022 advice.¹

As for the ACP remark about the reimbursement of vitamin D from medical specialist care, the following needs mentioning. Patients with cystic fibrosis have deficits of fat-soluble vitamins such as vitamins A, D, E and K. CF patients are currently reimbursed for these vitamins through hospital pharmacies at their CF Centres on the basis of 'Reimbursement of nutritional supplements for severe metabolic diseases'.⁷ The treating physicians are aware of this arrangement for CF.⁸

With this letter and the study, the National Health Care Institute provides insight into the practical effects of the withdrawal of the reimbursement for vitamin D. We also made a number of recommendations at the beginning of the letter. We trust that this will provide you with a good basis for the further implementation of this package measure.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

Annexes:

1. Nivel 2023. Effects of the vitamin D package measure. With a focus on vulnerable groups.
2. Nivel infographic.
3. ACP advice on monitoring the vitamin D package measure.

⁷ National Health Care Institute 2012. Information approach monitor vitamin D from basic health care package. <https://www.rijksoverheid.nl/documenten/kamerstukken/2022/12/07/kamerbrief-over-informatie-aanpak-monitor-vitamine-d-uit-basispakket>

⁸ Dutch Cystic Fibrosis Foundation, via <https://ncfs.nl/vitamine-d-verwijderd-uit-verzekerd-basispakket-vergoeding-blijft/>

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