



> Return address PO Box 320, 1110 AH Diemen

Minister of Medical Care  
PO Box 20350  
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2024017678

Date 15 May 2024  
Re: package advice codeine

Dear Ms Dijkstra,

In the Netherlands, we aim to provide good healthcare for everyone, now and in the future. However, our healthcare system is under pressure. The increasing demand for healthcare, leading to higher care expenditure, puts pressure on solidarity and crowds out other important collective spending.

Usually, package advice is about (very) expensive healthcare for people with a high burden of disease, such as in case of cancer where the discussion focusses on what we as a society can collectively afford. With the question of 'care that necessarily needs to be insured', we focus on the lower limit of what we as a society want to pay. Package management includes making responsible choices between collectively insured care and care that can be considered the responsibility of the individual. By looking critically at the lower limit of the package, we contribute to the sustainability of care.

In the letter of 9 March 2023, your predecessor asked the National Health Care Institute to apply the decision framework for care that necessarily needs to be insured that was recently developed by the National Health Care Institute in stages to a certain group of medicinal products. These are medicinal products included in the Medicine Reimbursement System (GVS) for which there are (virtually) equivalent alternatives that can be purchased over the counter, and for which the costs may be borne by the insured person.

The National Health Care Institute applied the evaluation framework to the medicinal product codeine. Codeine tablets can be used for the symptomatic relief of non-productive cough, for the symptomatic relief of diarrhoea after inadequate loperamide treatment, or for the treatment of acute moderate pain. Our considerations are set out in the attached report, which also takes into account the ACP advisory report and stakeholder responses.

#### **National Health Care Institute advice**

On the basis of the review of the package criteria, the National Health Care Institute recommends limiting the entitlement to codeine by setting further conditions for the reimbursement of codeine. Codeine can be placed on List 2 of the Health Insurance Regulation with the

#### **National Health Care Institute**

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#### **Case number**

2024002887

#### **Our reference**

2024017678

#### **Your reference**

3537770-10444456-Z

#### **Your letter of**

09 March 2023

following conditions:

### Codeine

Only for an insured person with chronic diarrhoea who cannot be treated with loperamide because loperamide has been insufficiently effective or because loperamide cannot be used due to a contraindication or intolerance.

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### **Outcome of the assessment**

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- 1 After evaluation of the package criteria, the National Health Care Institute determines that treatment with codeine for the symptomatic relief of cough, pain and acute diarrhoea should no longer be included in the GVS. The burden of disease associated with these various indications is low to very low (less than or around 0.1), the average cost of the short-term treatment is less than €22 per person per year including pharmacy service fee and VAT, there is an over-the-counter medicinal product with codeine available for the symptomatic relief of dry cough, and these uses of codeine are not recommended by the guidelines because its effectiveness has not been demonstrated while the medicinal product has side effects and may lead to dependence. 86% of codeine tablet users use this medicinal product for a short period of time.
- 2 After weighting of the package criteria, the National Health Care Institute concludes that the use of codeine as a chronic treatment for the symptomatic relief of diarrhoea, after insufficient results with loperamide, should remain in the GVS. Due to the long-term nature of the treatment of codeine, the associated costs are high (hundreds to thousands of euros per person per year). Furthermore, this application is recommended by current guidelines.
- 3 According to the GIP-databank, the total reimbursement amount for codeine tablets in 2022 was over €20 million, including pharmacy service fee and VAT. For the group that uses this product for a short period of time, the reimbursement amount including pharmacy service fee and VAT was almost €11 million. The National Health Care Institute notes that the material costs (i.e. the reimbursement for the tablets themselves) are in fact lower because health insurers have made price agreements with the suppliers. However, the amount of this discount has not been made public.

### **Other considerations**

- During the consultation, a supplier of codeine tablets indicated that they need time to adjust their stocks, an amount that is required by law, to the new reimbursement reality. The National Health Care Institute advises that the package measure should not be implemented directly, but that a transitional period should be observed in consultation with the suppliers.
- Despite the fact that the use of codeine is, in many cases, being discouraged by the guidelines, this medicinal product is widely used in practice. In 2022, there were 590,620 users of codeine tablets, of which 86% were short-term users. The National Health Care Institute wonders to what extent this can be considered appropriate care. We call on the parties to ensure that only appropriate care is provided.
- Codeine is an opium alkaloid that is metabolised to morphine in the body. Given the potential for dependence and in light of the responsible use of medicinal products, maintaining the prescription requirement for codeine tablets is a condition.

For the next evaluation of the decision framework for care that necessarily needs

to be insured, the National Health Care Institute intends to discuss 'medicinal products for allergy'. This includes products covered by part 35 of List 2 of the Health Insurance Regulation.

Yours sincerely,

Sjaak Wijma  
*Chairperson of the Executive Board*

Annex: Report 'Package advice for codeine'

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