



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
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2025028166

Date 15 December 2025
Re: Expansion of additional conditions for bempedoic acid (Nilemdo®) and bempedoic acid in combination with ezetimibe (Nustendi®) for hypercholesterolaemia

This is a corrigendum to the letter dated 5 December 2025 (reference 2025028166). In the List 2 conditions for Nustendi®, it was inadvertently stated that a patient is eligible if the LDL-C target value is not reached with a statin alone. However, this is a treatment with both a statin and ezetimibe. The condition has been adjusted accordingly.

Dear Mr Bruijn,

The National Health Care Institute advises you on the expansion of the reimbursement conditions of bempedoic acid (Nilemdo®) and bempedoic acid in combination with ezetimibe (Nustendi®) for the treatment of certain patients with hypercholesterolaemia in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 12 August 2025 (CIBG-25-08558). The National Health Care Institute advises you to adjust the additional conditions of bempedoic acid and bempedoic acid in combination with ezetimibe.

In hypercholesterolaemia, there is too much cholesterol in the blood. This can lead to constricted blood vessels and, consequently, to myocardial infarction, kidney damage or stroke. This means that an elevated cholesterol level is an important risk factor for cardiovascular disease. In the Netherlands, there are approximately 1.6 million people with a lipid metabolism disorder, including hypercholesterolaemia. Most patients can be treated with statins and ezetimibe. PCSK9 inhibitors, such as evolocumab and alirocumab, may also be used in certain patients whose cholesterol levels (LDL-C) remain too high despite statin and/or ezetimibe treatment.

Background

The National Health Care Institute in 2022 stated that bempedoic acid can be reimbursed in certain patients who are not eligible for a PCSK9 inhibitor whose LDL-C level remains too high despite treatment with statins and/or ezetimibe. At the time of that assessment, a limited role for bempedoic acid was recognised, as PCSK9 inhibitors were considered more potent in lowering LDL-C. Since then, PCSK9 inhibitors have become known to be effective in the prevention of cardiovascular events, but, due to the high price, among other things, physicians are currently cautious about prescribing them. In patients with elevated LDL-C where the LDL-C is relatively close to the target value, the professional

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association has indicated that they would prefer to use the cheaper bempedoic acid instead of the more expensive PCSK9 inhibitor, as part of the appropriate care approach, even though a patient might qualify for a PCSK9 inhibitor. However, the use of bempedoic acid in patients where the LDL-C is relatively close to the target value is not possible at the moment, due to the current reimbursement conditions. Since the results of the hard-outcomes study of bempedoic acid have become available, the National Health Care Institute has now reassessed the reimbursement conditions for bempedoic acid.

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Registered indications

Bempedoic acid is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:

- In combination with a statin or a statin together with other lipid-lowering therapies in patients unable to reach their low-density lipoprotein cholesterol (LDL-C) targets with the maximum tolerated dose of a statin, or,
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant or for whom a statin is contraindicated.

Bempedoic acid is also indicated for use in adults with established or high risk atherosclerotic cardiovascular disease to reduce cardiovascular risk by lowering LDL-C levels, in addition to the correction of other risk factors:

- in patients with a maximum tolerated dose of a statin with or without ezetimibe or,
- alone or in combination with ezetimibe in patients who are statin-intolerant or for whom a statin is contraindicated.

Bempedoic acid is registered as a single-agent preparation (180 mg) under the brand name Nilemdo® and as a combination preparation with ezetimibe (180/10 mg) under the brand name Nustendi®. Both are being reimbursed in accordance with the following additional conditions:

Claim by the marketing authorisation holder

The addition of bempedoic acid to standard therapy has therapeutic added value over current standard treatment with statins and/or ezetimibe in patients who do not meet LDL-C target values.

The marketing authorisation holder therefore requests that the additional conditions are decommissioned. The current additional conditions are set out in the Annex.

Advisory report

The National Health Care Institute recommends that the additional conditions for bempedoic acid and bempedoic acid/ezetimibe in List 2 of the GVS be amended as follows:

List 2 conditions for bempedoic acid

Only for an insured person with hypercholesterolaemia or mixed dyslipidaemia who does not reach the LDL-C target with a statin and ezetimibe at the maximum tolerated dose.

List 2 conditions for bempedoic acid/ezetimibe

Only for an insured person with hypercholesterolaemia or mixed dyslipidaemia who does not reach the LDL-C target with a statin and ezetimibe at the maximum tolerated dose.

We have explained below how we reached this advisory report.

Substantive assessment

Therapeutic value

Bempedoic acid meets the established medical science and medical practice in adults with heterozygous familial and non-familial hypercholesterolaemia or mixed dyslipidaemia at (very) high cardiovascular risk who do not reach the LDL-C target according to current CVRM guideline with maximally tolerated oral lipid-lowering therapy (statin/ezetimibe).

In the randomised CLEAR Outcomes study, bempedoic acid was compared with placebo in patients with hypercholesterolaemia and a (very) high cardiovascular risk. The study shows that bempedoic acid reduces cholesterol levels in patients and reduces the risk of cardiovascular events.

Based on the above, the National Health Care Institute concludes that bempedoic acid may be an appropriate option for patients with heterozygous familial and non-familial hypercholesterolaemia or mixed dyslipidaemia with a (very) high cardiovascular risk for whom it is likely that they can achieve the target values by adding bempedoic acid to statin/ezetimibe treatment.

Budget impact analysis

The National Health Care Institute estimates that a maximum of 34,519 patients in year 3 will be treated with bempedoic acid for the above indication after inclusion in the basic health care package. The total cost per patient per year comes to €657, based on the list price. This results in possible macro costs of €21.3 million in the third year. When substitution of PCSK9 inhibitors for 2,026 patients is also considered, the budget impact will be €13.4 million in year 3. It should be noted that financial arrangements have been made for both bempedoic acid and PCSK9 inhibitors, so the actual budget impact will be much lower. There is uncertainty about the number of patients who will actually be treated with bempedoic acid.

It should be noted that the estimation of the number of patients eligible for bempedoic acid - also with the expansion of additional conditions - is still lower than initially estimated by the National Health Care Institute in the 2022 assessment. The financial risk of adjusting the current reimbursement conditions appears, therefore, limited.

The National Health Care Institute would like to emphasize that there is a high financial risk if bempedoic acid is already used before a patient has tried a statin and ezetimibe. In the Netherlands, there are more than 2 million people who use a statin and/or ezetimibe according to the GIP database. In consultation with the healthcare insurers, it has therefore been decided to apply List 2 conditions, but to simplify them.

Cost-effectiveness

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The National Health Care Institute already determined the cost-effectiveness of bempedoic acid in 2022. That cost-effectiveness analysis did not differentiate between patients eligible and those ineligible for PCSK9 inhibitors. The results therefore also apply to the population for which reimbursement is now being requested. On the basis of that assessment, a 50% price reduction for bempedoic acid was recommended and a financial arrangement was concluded.

Should you need any further information, please do not hesitate to contact us. The assessment reports have been added as annexes (pharmacotherapeutic report and budget impact analysis).

Yours sincerely,

M.J. Janssen
Chair of the Executive Board

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Annex

Current List 2 condition for bempedoic acid

Only for an insured person with *non-familial hypercholesterolaemia or mixed dyslipidaemia with a (very) high cardiovascular risk*, if a maximum tolerated statin in combination with ezetimibe does not achieve the treatment objective in accordance with the guidelines accepted by the relevant professional associations in the Netherlands; *and the patient is not eligible for treatment with a PCSK9 inhibitor*, bempedoic acid can be applied as follows:

1. In combination with both a statin and the maximum tolerable dose of ezetimibe,
2. in combination with ezetimibe alone in cases of contraindication or documented statin intolerance: statin-associated muscle pain has been determined for at least three different statins according to the flow chart and criteria described by EAS/ESC consensus (European Heart Journal 2015; 36: 1012-1022),
3. in combination with only statin in case of contraindication or documented intolerance to ezetimibe, or
4. as monotherapy if both ezetimibe and statins cannot be used due to contraindication or intolerance. Statin intolerance means statin-associated muscle pain for at least three different statins determined according to the flowchart and criteria described by EAS/ESC consensus (European Heart Journal 2015; 36: 1012-1022).

Current List 2 conditions for bempedoic acid/ezetimibe

Condition:

Only for an insured person with *non-familial hypercholesterolaemia or mixed dyslipidaemia with a (very) high cardiovascular risk*, if a maximum tolerated statin in combination with ezetimibe does not achieve the treatment objective in accordance with the guidelines accepted by the relevant professional associations in the Netherlands; *and the patient is not eligible for treatment with a PCSK9 inhibitor*, bempedoic acid can be applied as follows:

1. in combination with a statin in a daily dose or;
2. not in combination with a statin in cases of documented statin intolerance: statin-associated muscle pain has been determined for at least three different statins according to the flow chart and criteria described by EAS/ESC consensus (European Heart Journal 2015; 36: 1012-1022).

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