



> Return address PO Box 320, 1110 AH Diemen

To the Minister of Health, Welfare and Sport
P.O. Box 20350
2500 EJ THE HAGUE

2025015592

Date 8 July 2025
Re: GVS advice acoramidis (Beyontra®) for transthyretin amyloidosis with cardiomyopathy

National Health Care Institute

Research, Development and Medicinal Products
Medicinal Products Team

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Contact

P. Bloemen
warcq@zinl.nl

Our reference

2025015592

Dear Ms Jansen,

The National Health Care Institute advises you on the inclusion of acoramidis (Beyontra®) for the treatment of wild-type or hereditary variant transthyretin amyloidosis in adult patients with cardiomyopathy in the Medicine Reimbursement System (GVS). This advice was prompted by your request in the letter of 17 March 2025 (CIBG-25-08008).

The National Health Care Institute advises you to include acoramidis (Beyontra®) for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with NYHA class I and II cardiomyopathy (ATTR-CM) on List 1A of the GVS in a new cluster with tafamidis (Vyndaqel®) with the same additional condition as tafamidis. The net price of acoramidis on the basis of the equivalent value may not exceed the net price of tafamidis 61 mg.

Transthyretin amyloidosis cardiomyopathy (ATTR-CM) is a progressive and potentially fatal heart disease. The protein transthyretin, which normally circulates in the bloodstream, accumulates mainly in the heart, causing thickening and increased stiffness of the cardiac wall. This is called cardiomyopathy and can lead to heart failure. Examples of symptoms of the disease are shortness of breath at rest or with minimal exertion, fatigue, swelling and numbness in extremities, reduced ability to make physical efforts. The severity of heart failure is indicated by the New York Heart Association (NYHA) classification and ranges from I to IV, with IV being the most severe. In the Netherlands, an estimated 3,700 people suffer from this disease. The average life expectancy after diagnosis and without treatment is 3 to 5 years. A higher NYHA classification leads to a poorer life expectancy but the exact prognosis depends on several factors, such as age, gender, other medical conditions and response to treatment. In Dutch expertise centres, patients with reasonable life expectancy and NYHA class I and II are now treated with tafamidis, which has a similar mechanism of action to acoramidis.

Registered indication

Acoramidis (Beyontra®) is indicated for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM) and is available in 356 mg film-coated tablets in a package containing 120 tablets.

Claim by the marketing authorisation holder

Acoramidis (Beyontra®) for the treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (NYHA classes I and II) has an equivalent value to tafamidis 61 mg.

The marketing authorisation holder requests the inclusion in List 1A of the Health Insurance Regulation for this indication.

Advice

The National Health Care Institute has concluded that for this indication, acoramidis is interchangeable with tafamidis 61 mg in NYHA Class I and II. The National Health Care Institute advises you to include acoramidis (Beyontra®) for wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy with NYHA classes I and II in List 1A of the GVS in a new cluster to be formed together with tafamidis (Vyndaqel®) with the List 2 condition mentioned below, stating that the net price of acoramidis, based on the equal value, should not exceed the net price of tafamidis 61 mg.

Condition acoramidis (Beyontra®)

Only for insured patients aged 18 and older with wild-type or hereditary transthyretin amyloidosis with cardiomyopathy and NYHA class I or II.

We explain the preparation of this advice below.

Substantive assessment

Assessment of interchangeability

Based on the criteria for interchangeability, the National Health Care Institute concludes that acoramidis is interchangeable with tafamidis 61 mg and can therefore be included in List 1A in the Health Insurance Regulation in a newly formed cluster. In the absence of a DDD for acoramidis by the WHO, we have set the standard dose at 1424 mg per day. The WHO-defined DDD for tafamidis is 20 mg daily based on the treatment of polyneuropathy as a result of transthyretin amyloidosis. However, the main indication for the cluster is cardiomyopathy due to transthyretin amyloidosis because its prevalence is higher than the prevalence of polyneuropathy due to this disease. The standard dose of tafamidis for transthyretin amyloidosis cardiomyopathy is 61 mg (equivalent to 80 mg tafamidis meglumine).

Therapeutic value

The National Health Care Institute concluded that acoramidis for the mentioned indication meets the established medical science and medical practice and as such has an equivalent value to tafamidis 61 mg for NYHA classes I and II. Due to the lack of a direct comparative study between the medicinal products, an indirect comparison of the ATTRIBUTE-CM study (acoramidis) and ATTR-ACT study (tafamidis) has been assumed. For key endpoints such as survival and hospitalisation, they show a similar effect. The same applies to the adverse effects and the number of discontinuations due to adverse effects.

Cost-effectiveness

Based on the conclusion that acoramidis and tafamidis 61 mg have an equal value and should be clustered in 1A, an assessment of the cost-effectiveness of acoramidis is not required. On the basis of the equal value conclusion, the net

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Date
8 July 2025

Our reference
2025015592

price of acoramidis should not exceed the net price of tafamidis 61 mg. In these calculations, the negotiated price of tafamidis is leading. See the tafamidis package advice¹.

National Health Care Institute
Research, Development and Medicinal Products
Medicinal Products Team

Appropriate care

Appropriate use agreements have been made with the Dutch Working Group on Cardiac Amyloidosis to standardise diagnostics and treatment and to streamline joint scientific research. This has led to the formation of the Amyloidosis Expertise Network. The purpose of the appropriate use arrangement is to stimulate and ensure appropriate use of tafamidis by formulating clear start and stop criteria and by agreeing on data collection and reporting. The National Health Care Institute advises that these appropriate use arrangements should also apply to acoramidis and is already discussing this with the professional group.

Date
8 July 2025

Our reference
2025015592

Specifics

In the assessment of tafamidis, the National Health Care Institute previously concluded that tafamidis appears to increase the risk of cardiovascular hospitalisation in NYHA class III. Therefore, there is no reimbursement of tafamidis for this patient subgroup. As standard treatment is not available for these patients at this time, the National Health Care Institute also looked into the effects of acoramidis in NYHA class III in this assessment. Based on the current subgroup analyses from the assessed study, it is not possible to determine whether this subgroup could experience a treatment benefit with acoramidis. The advice is therefore not to reimburse acoramidis for NYHA class III.

Finally, the National Health Care Institute notes that the medicinal product vutrisiran has also recently been registered for this indication².

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

Yours sincerely,

M.J. Janssen
Chairperson of the Executive Board

¹ <https://www.zorginstituutnederland.nl/publicaties/adviezen/2021/08/11/gvs-advies-tafamidis-vyndaqel-bij-de-behandeling-van-attr-cm>

² <https://www.ema.europa.eu/en/medicines/human/EPAR/amvuttra>