

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Final draft guidance

# Acoramidis for treating transthyretin amyloidosis with cardiomyopathy

## 1 Recommendations

- 1.1 Acoramidis can be used, within its marketing authorisation, as an option to treat wild-type or hereditary transthyretin amyloidosis with cardiomyopathy in adults. Acoramidis can only be used if the company provides it according to the commercial arrangement (see [section 2](#)).
- 1.2 Use the least expensive option of the suitable treatments (including acoramidis and tafamidis), having discussed the advantages and disadvantages of the available treatments with the person with the condition. Take account of administration costs, dosages, price per dose and commercial arrangements.

### What this means in practice

Acoramidis must be funded in the NHS in England for the condition and population in the recommendations, if it is considered the most suitable treatment option. Acoramidis must be funded in England within 30 days of final publication of this guidance.

There is enough evidence to show that acoramidis provides benefits and value for money, so it can be used routinely across the NHS in this population.

### Why these recommendations were made

Usual treatment for transthyretin amyloidosis with cardiomyopathy is tafamidis. Acoramidis works in a similar way to tafamidis and would be offered to the same population.

Clinical trial evidence suggests that acoramidis is more effective than placebo. Acoramidis has not been directly compared in a clinical trial with tafamidis, but an indirect comparison suggests that they are likely to have similar clinical effectiveness. There are uncertainties with the clinical-effectiveness evidence, including:

- how effective acoramidis is in people with severe heart failure, and
- that some people in the trial had both acoramidis and tafamidis.

But these uncertainties are unlikely to have affected the overall results.

A cost comparison suggests that the costs for acoramidis are similar to or lower than those for tafamidis. So, acoramidis can be used.

For all evidence see the [committee papers](#). For more information on NICE's evaluation of tafamidis, see the committee discussion section in [NICE's technology appraisal guidance on tafamidis for treating transthyretin amyloidosis with cardiomyopathy](#).

## 2 Information about acoramidis

### Marketing authorisation indication

- 2.1 Acoramidis (Beyontra, Bayer) is indicated for the 'treatment of wild-type or variant transthyretin amyloidosis in adult patients with cardiomyopathy (ATTR-CM)'.

### Dosage in the marketing authorisation

- 2.2 The dosage schedule is available in the [summary of product characteristics for acoramidis](#).

## Price

- 2.3 The list price of acoramidis is £8,547.60 for 120 x 356-mg tablets (excluding VAT; company submission).
- 2.4 The company has a commercial arrangement (a simple discount patient access scheme). This makes acoramidis available to the NHS with a discount. The size of the discount is commercial in confidence.

## Carbon Reduction Plan

- 2.5 Information on the Carbon Reduction Plan for UK carbon emissions for Bayer will be included here when guidance is published.

## 3 Implementation

- 3.1 Section 7 of the [National Institute for Health and Care Excellence \(Constitution and Functions\) and the Health and Social Care Information Centre \(Functions\) Regulations 2013](#) requires integrated care boards, NHS England and, with respect to their public health functions, local authorities to comply with the recommendations in this evaluation within 90 days of its date of publication. Because acoramidis has been recommended through the [cost-comparison process](#), NHS England and integrated care boards have agreed to provide funding to implement this guidance 30 days after publication.
- 3.2 The Welsh ministers have issued directions to the NHS in Wales on implementing NICE technology appraisal guidance. When a NICE technology appraisal guidance recommends the use of a drug or treatment, or other technology, the NHS in Wales must usually provide funding and resources for it within 60 days of the first publication of the final draft guidance.
- 3.3 When NICE recommends a treatment ‘as an option’, the NHS must make sure it is available within the period set out in the paragraphs above. This means that, if a patient has transthyretin amyloidosis with cardiomyopathy

and the healthcare professional responsible for their care thinks that acoramidis is the right treatment, it should be available for use, in line with NICE's recommendations.

## **4 Evaluation committee members and NICE project team**

### **Evaluation committee members**

The highly specialised technologies committee is a standing advisory committee of NICE. This topic was considered as a cost comparison by the chair, vice chair and a lead team of the [highly specialised technologies committee](#).

Committee members are asked to declare any interests in the technology being evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

### **Chair**

#### **Paul Arundel**

Chair, highly specialised technologies evaluation committee

### **NICE project team**

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

#### **Giacomo De Guisa**

Technical lead

#### **Lizzie Walker**

Principal technical adviser

#### **Thomas Feist**

Project manager

**Richard Diaz**

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