

Acoramidis for treating transthyretin amyloidosis with cardiomyopathy

Technology appraisal guidance

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www.nice.org.uk/guidance/ta1121

Your responsibility

The recommendations in this guidance represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take this guidance fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this guidance is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to provide the funding required to enable the guidance to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should [assess and reduce the environmental impact of implementing NICE recommendations](#) wherever possible.

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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.
- 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.

NICE has produced tools and resources to support the implementation of this guidance.

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 (Beyonttra, 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](#). This makes acoramidis available to the NHS with a discount. The size of the discount is commercial in confidence.

Sustainability

- 2.5 For information, the Carbon Reduction Plan for UK carbon emissions is published on [Bayer's webpage on sustainability](#).

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.

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