

Sent by email to: [REDACTED]

[REDACTED]
[REDACTED], British Society for Heart Failure, on behalf of the Board of Trustees,
British Society for Heart Failure,
33 Cavendish Square,
London
W1G 0PW

9 November 2020

Dear [REDACTED]

**Re: APPEAL AGAINST THE FINAL APPRAISAL DETERMINATION FOR
TAFAMIDIS FOR TREATING TRANSTHYRETIN AMYLOIDOSIS WITH
CARDIOMYOPATHY**

Thank you for your letter of 28 October 2020, lodging the British Society for Heart Failure's appeal against the above Final Appraisal Document (FAD).

Introduction

The Institute's appeal procedures provide for an initial scrutiny of points that an appellant wishes to raise, to confirm that they are at least arguably within the permitted grounds of appeal ("valid"). The permitted grounds of appeal are:

- 1(a) NICE has failed to act fairly, or
- 1(b) NICE has exceeded powers;
- (2) the recommendation is unreasonable in the light of the evidence submitted to NICE

This letter sets out my initial view of the points of appeal you have raised: principally whether they fall within any of the grounds of appeal, or whether further clarification is required of any point. Only if I am satisfied that your points contain the necessary information and arguably fall within any one of the grounds will your appeal be referred to the Appeal Panel.

You have the opportunity to comment on this letter in order to elaborate on or clarify any of the points raised before I will make my final decision as to whether each appeal

point should be referred on to the Appeal Panel.

Initial View

I assess each of your points in turn and then summarise the appeal points that I am presently minded to refer at the end of this letter. .

Ground 1(a): In making the assessment that preceded the recommendation, NICE has failed to act fairly

1.1 Failures in engaging with the BSHF as a consultee

I agree this is a valid appeal point.

Ground 1(b): NICE has exceeded its powers

No grounds advanced.

Ground 2: the recommendation is unreasonable in the light of the evidence submitted to NICE

2.1 The conclusion ‘But clinical benefit varies across different types and stages of ATTR-CM. is unreasonable

A valid appeal point.

2.2 The conclusion “The measure used to assess how severe ATTR-CM is, has limitations. This makes it difficult to clearly identify who benefits from tafamidis and whether they should continue treatment.” Is unreasonable.

A valid appeal point.

As I agree all of your proposed points are valid there is no need to reply to this letter unless you wish to do so. An oral appeal will be held, although under current circumstances this is likely to be held remotely in part or in whole. Other appeals have been received and NICE will in due course share details of the points being advanced with you (and share your appeal with other appellants) so that the appeal can be prepared for efficiently

Many thanks

Yours sincerely

Tim Irish

Vice Chair

National Institute for Health and Care Excellence