­Sent by email to: XXXXXXXXXXXXXXXXXXXXXXXXXXX

XX XXXXX XXXXXXXX,

Chair,

British Society for Heart Failure,

33 Cavendish Square,

London

W1G 0PW

14 January 2021

Dear XX XXXXXXXX

**Re: Final Appraisal Determination – Heart failure (reduced ejection fraction) - dapagliflozin [ID1656]**

Thank you for your letter of 12 January 2021, 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

As a general observation: the right of appeal against a FAD is created by Regulation 9 of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, which reads:

*9.—(1) A person aggrieved by a recommendation described in paragraph (2) may bring an appeal against the recommendation on grounds described in paragraph (3).*

*(2) A recommendation against which an appeal may be brought is—*

*(a) a technology appraisal recommendation, or*

*(b) a highly specialised technology recommendation.*

*(3) The grounds on which an appeal may be brought are that—*

*(a) in making the assessment that preceded the recommendation, NICE—*

*(i) failed to act fairly, or*

*(ii) exceeded its powers; or*

*(b) the recommendation is unreasonable in the light of the evidence submitted to NICE.*

The important point is that an appeal can only be brought against a recommendation (and not as such against any part of a FAD). NICE would not read this restrictively, so that in fact appeals are frequently brought which take issue with something said in an FAD that is not part of the recommendation, but in every case the part of the FAD appealed against must be capable of bearing on the recommendation and the appellant must disagree with (“*be aggrieved by*”) the recommendation itself. In this case you have very fairly made clear that you agree with the recommendation and so I do not think the point you raise can be dealt with through the appeal process.

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

Moving on to the specific ground of appeal, you are concerned with the use of the term ‘comparator’ in relation to sacubitril valsartan. Your concern is that the two treatments should not be seen as either/or options.

This appraisal was concerned only with making recommendations for the use of dapagliflozin. It should not be seen as recommending any particular use of sacubitril valsartan. I would agree, for present purposes, that using sacubitril valsartan as a comparator implies that the committee considered that there are at least some patients who, if they were not to be treated with dapagliflozin would be treated with sacubitril valsartan, but that does not amount to a recommendation or encouragement to regard the treatments as mutually exclusive alternatives. Nor was this the only treatment scenario considered.

As a second point, sacubitril valsartan was specifically referred to as a comparator in the scope for this appraisal. (As you will be aware scopes are published in draft for comment, and the final scope sets the parameters for an appraisal.) Committees are obliged to address the comparators in a scope and may be appealed if they do not.

Finally, I do not think the recommendation could result in the displacement of other treatments that would benefit patients. The recommendation is for use as an add on to optimised standard care and it seems that the committee considered the use of dapagliflozin as an add on to the standard care based on sacubitril valsartan (the last part of FAD 3.21) and concluded that this would be cost effective. So I think you may not be disagreeing with the committee on this point?

For all of these reasons at present I would not be minded to refer this to an appeal panel, but if you feel I have misunderstood your concerns please do respond to me within the next ten working days, by no later than **Thursday 28 January 2020** and I will reach a final decision. Alternatively if you are now content with the guidance and wish to withdraw your appeal letter it would be very helpful if you could confirm this.

Many thanks

Yours sincerely

XXXXXXXXXX

Tim Irish

Vice Chair

National Institute for Health and Care Excellence