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FAO Mr R Burns and Mr B Golding
Cardiothoracic Transplant Patient Group
NHS Blood and Transplant

1 February 2024

Dear Mr Burns and Mr Golding

Re: Final Draft Guidance 2 — Nirmatrelvir plus ritonavir for treating COVID-19 (Partial Rapid Review of TA878) [ID6262]

Thank you for your letter of 24 January 2024, lodging an appeal against the above Final Draft Guidance (FDG).

Introduction

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

Preliminary points

I make two preliminary points.

First, your appeal letter states that you do not wish to delay the implementation for any of the patient groups identified for the initial roll out. NICE does not issue final guidance to the NHS until after the resolution of any appeal. This means that if I refer your appeal to the appeal panel there will be a relatively short period of delay before final guidance is published in order for the appeal to be determined.

Your appeal will not otherwise impact the position in respect of the groups already identified at 4.2 of the FDG.

Secondly, I note that your appeal relates exclusively to NICE's decision to grant an extension of the funding variation period for the wider heart failure population (i.e. those eligible under paragraph 1.1 of the FDG but are not resident in a care home or hospitalised, per paragraph 4.2 of the FDG).

I therefore hope it assists to note that NICE is required by law to specify in the FDG that its recommendation must be complied with within 3 months from the date of publication, save that NICE must, if it considers it appropriate, specify a longer period for compliance if:

> *"(a)the health technology cannot be appropriately administered until—*
>
> *(i) training is,*
>
> *(ii) certain health service infrastructure requirements including goods, materials or other facilities are, or*
>
> *(iii) other appropriate health services resources, including staff, are,*
>
> *in place; or*
>
> *(b) the health technology is not yet available in England."* [1]

Where NICE specifies a longer period this is described as "varying the funding requirement". NICE's Manual provides more detail on when and how NICE may vary the funding requirement.[2]

I consider the decision to vary the funding requirement (as set out in section 4 of the FDG) forms part of NICE's recommendation so falls within the scope of NICE's appeals process.[3]

Initial View

I assess each of your points in turn.

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

Appeal point 2.1: "Expanded the cohort of patients who would benefit from Nirmatrelvir plus ritonavir for treating COVID-19 was entirely predictable and should have been appropriately planned for."

I am not minded to refer this appeal point to the Appeal Panel.

I understand that this appeal point is made on the basis that there was evidence available, including Hippisley-Cox et al, Agrawal et al and the Edmunds report cited in your appeal letter, which should have led NHS England, Integrated Care Boards (ICBs), and other NHS organisations to have been planning for a wider roll out of Nirmatrelvir plus ritonavir for treating COVID-19 for at least the last 12-18 months.

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[1] Regulation 7(2)-(5) of the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (the '2013 Regulations')

[2] https://www.nice.org.uk/process/pmg36/chapter/developing-the-guidance#varying-the-funding-requirement-to-take-account-of-net-budget-impact-technology-appraisals-and See paragraph 5.10 and in particular 5.10.2 and 5.10.25-5.10.34 on how NICE handles requests for a funding variation.

[3] https://www.nice.org.uk/process/pmg41/chapter/making-an-appeal See paragraph 4.2 (scope).

In light of this evidence, you consider that NICE's decision to delay rollout until June 2025 for wider heart failure patients to be unreasonable.

I do not consider this to be an arguable appeal point. That is because it appears to be based on whether other NHS organisations (not NICE itself) should have predicted a wider roll out and prepared accordingly. This is not a matter for NICE when considering funding variation requests in accordance with the law and guidance I've explained above. In my view it would be unreasonable for NICE to make a decision based on what the position would or might have been had another NHS organisation taken alternative action, rather than based on the position of the NHS as it finds it. On this basis I consider that the evidence you cite relating to heart failure patients and the state of preparedness in other parts of the NHS system cannot arguably support a valid appeal point that NICE's decision to vary the funding period was unreasonable.

Appeal point 2.2: "Delaying the rollout will lead to considerable waste of expired doses of Nirmatrelvir plus ritonavir"

I am not minded to refer this appeal point to the Appeal Panel.

I understand this appeal point to be on the basis that NICE failed to give appropriate weight to the fact that delaying the time for compliance will lead to considerable waste of expired doses of Nirmatrelvir plus ritonavir that have already been purchased by the NHS, as raised by the company in consultation (see pages 25 and 32 of the Committee Papers).

I note NICE's appeal process guide explains (at section 4.3) that an appellant may appeal under ground 2 if they consider that the recommendations in the final draft guidance cannot reasonably be justified from the evidence, such that the guidance is obviously and unarguably wrong, illogical, or 'does not add up'.

The FDG at section 4 explains why NICE considered the criteria for granting a funding request (as set out above) were met.

Your appeal letter does not explain how you consider NICE ought to have considered the issue of wasted dosages when applying the criteria to vary the funding requirement or why the evidence on wasted dosage renders that decision unreasonable. I therefore see no arguable appeal point under ground 2.

Appeal point 2.3: "NHSE estimate on the number of patients requesting test kits, reporting positive tests, and requiring treatment is likely to be an extreme overestimate".

I am not minded to refer this appeal point to the Appeal Panel.

I understand this appeal point to be on the basis that the funding variation submission from NHS England overestimates the demand for test kits, treatment assessment and treatment delivery as it relies on historical data from the highest risk patient groups. I note you consider "evidence exists and could be obtained" which would show a much lower level of demand and that this is indicated by "trial and anecdotal evidence", citing the Panoramic trial, such that it is "unreasonable that NICE have not requested, and NHSE have not provided, contemporary demand figures."

I accept that capacity of the system to copy with demand is central to NHS England's submission and the decision to vary the funding requirement, as recognised at 4.1 of the FDG.

I note NHS England's submission and response to consultation explains the estimates it has made and acknowledges uncertainty around, in particular, the number of tests needed and associated costs, and the need to keep this under review (see pages 17-20 of the Committee papers).

The consultation afforded stakeholders an opportunity to comment on this issue; I note the company did so but CTPG did not.

NICE explains its approach to the company and NHS England's evidence at 4.4-4.5 of the FDG.

Whilst I accept it may be possible that NHS England overestimated demand, your appeal does not appear to argue that NICE's approach or its decision as set out in the FDG was unreasonable in light of the totality of the evidence put to NICE. I can therefore see no arguable ground 2 appeal point here.

Appeal point 2.4: Failure of NICE and NHSE to compare the overall NHS resource implications of delaying the roll out of Nirmatrelvir plus ritonavir for the heart failure population

I am not minded to refer this appeal point to the Appeal Panel.

I note you "consider it unreasonable that NHSE have not modelled the risk / benefit analysis and overall resource implications of delaying access to Nirmatrelvir plus ritonavir for the heart failure population" and you "believe that NICE should request this information from NHSE and appraise it before approving a 12-month delay for heart failure patients to access this treatment for Covid 19".

I understand your point to be that the decision to delay roll out to the wider heart failure population is unreasonable because NICE did not go behind NHS England's submission that Nirmatrelvir plus ritonavir cannot be appropriately administered until resources are in place (and the groups to which access can be expanded sooner) and carry out its own costs resource modelling and sensitivity analysis for each eligible patient group (per 1.1 of the FDG).

I note that cost savings were raised by the company in consultation (page 21 of the Committee papers). However no evidence appears to have been submitted by any consultee regarding heart failure patients. As your appeal identifies no evidence that was put to NICE that arguably renders NICE's reliance on NHS England's submissions unreasonable, I see no arguable ground 2 appeal point here.

Appeal point 2.5: Lack of consideration by NICE and NHSE for alternative variation period phasing

I am not minded to refer this appeal point to the Appeal Panel.

I understand you consider it "unreasonable that NHSE have not proposed, and NICE have not requested a more refined phased approach".

I'm mindful that NICE's Manual states that when requesting a variation to the funding requirement, NHS England should provide the duration of, and the justification for, the proposed variation, and that it did so at section 5 of its request (page 3 of the Committee papers). Further, applications need to contain proposals for a phased allocation of funding, which NHS England addressed at section 9 of its request and in its further submission to NICE (from page 39 of the Committee papers).

I note that the company commented on NHS England's position in consultation and raised the issue of scalability (page 19 of the Committee papers).

Following consultation, NICE accepted NHS England's explanation that Nirmatrelvir plus ritonavir could not be appropriately administered under a more refined phased approach. Its decision making is explained at 4.5 of the FDG:

> "*NICE put to NHS England the question raised in consultation of whether ICBs that did consider they could implement the full recommendations sooner than the end of the funding variation period would be able to do so. NHS England responded that it did not consider that an approach during the variation, which sees some areas providing access sooner than others, is equitable or practicable. Such an approach would mean access was based on where someone lives. This could lead to confusion for patients and clinicians and would likely lead to an avoidable increase in pressure on services. In addition, access to testing would not be available. In the short term, NHS England is extending the arrangements already in place for the highest risk cohort, but will need to introduce new models to allow access for the full population. This will take the time requested in the funding variation and cannot be done in a phased way. NICE accepts these explanations."*

As I explained above, ground 2 allows appellants to argue that NICE's recommendations are unreasonable in light of the evidence.

It seems to me that your appeal does not identify evidence that was put to NICE during consultation that might arguably render its decision unreasonable or elaborate on why in light of the evidence you consider it was unreasonable to support the proposed funding variation. Therefore I currently see no arguable ground 2 appeal point here.

Appeal point 2.6: NICE and NHSE may not have considered all the evidence from professional groups

I am not minded to refer this appeal point to the Appeal Panel.

The British Society for Heart Failure (BSHF) was a consultee and was given the opportunity to comment in NICE's consultation on the funding variation decision. I understand that it sought to do so but did not successfully provide its comments to NICE within the consultation period. I do not consider it arguable that proceeding in the absence of comments from BHSF in these circumstances could arguably render NICE's decision unreasonable under appeal ground 2 (or indeed procedurally unfair under ground 1(a)).

Conclusion

The above sets out above my initial views on all of your appeal points.

In respect of your points which I am not minded to refer on you are entitled to submit further clarification and/or evidence to me within the next 10 working days, and I will then give a final decision on the points to put before an appeal panel.

Once I have made my final decision, and where there is more than one appellant, each appellant will receive the valid appeal points of the other appellants and their redacted appeal letter. This is to enable appellants to avoid duplication at the hearing where there are overlapping appeal points. If the appeal letter and/or responses to scrutiny contain confidential information please ensure you have provided a version with this information redacted by 22 February 2024.

Ordinarily appeals are conducted on the basis of the appellants' written appeal letters, and the material generated during the appraisal process. Use of additional written material is discouraged, and the panel

cannot receive any new evidence. If, exceptionally, you feel there is written material that will not be before the panel that you would wish to rely on you must let the NICE Appeal team know by return of letter, indicating what the material is, why it is desirable to submit it, and when it will be available, by no later than 16 February 2024. Please note that the appeal panel cannot accept papers that are tabled late or ad hoc, as this affects the preparation of the panel and other parties for the appeal.

Yours sincerely

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence