NICE National Institute for Health and Care Excellence

2nd Floor
2 Redman Place
London
E20 1JQ
United Kingdom

+44 (0)300 323 0140

Sent by e-mail only: robertwburns@tiscali.co.uk

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

22 February 2024

Dear Mr Burns and Mr Golding

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

Thank you for your letter of 13 February 2024 responding to my initial scrutiny views. This is my final decision on initial scrutiny.

I assess each of your points in turn. Before doing so I would like to acknowledge your position and the concerns you share at the start of your letter. Thank you for explaining your experience and perspective. Your engagement in the appeal process is sincerely appreciated.

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

Appeal point 2.1: "Expanding 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."

In my initial scrutiny letter of 1 February 2024 I explained why I was not minded to refer this point to the Panel. In your letter you acknowledge my reasons why this is not a valid appeal point and do not seek to make any additional arguments. I therefore confirm this point will not be referred.

You have requested that I ask NHS England to outline what actions they took to prepare the wider NHS for further rollout of Nirmatrelvir plus ritonavir taking into account certain clinical evidence. Whilst I understand your concerns and the reasons for your request, it is not within my remit or that of the NICE's internal appeals process to put questions to NHS England. I therefore cannot fulfil your request, however I will share a full copy of your letter with NICE's executive leadership to consider any appropriate actions that NICE may wish to take.

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

I explained in my letter of 1 February 2024 why I am not minded to refer this point to the Panel. I note you have provided no further arguments in support of this appeal point and I therefore confirm it will not be referred to the Panel.

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."

Thank you for your further comments in respect of this point in your letter of 13 February 2024. Having considered your additional arguments I remain of the view that this is not a valid appeal point so should not proceed to appeal.

I explained at initial scrutiny that I did not consider your original appeal to present an arguable case under appeal ground 2 that NICE's decision as set out in the FDG was unreasonable in light of the totality of the evidence submitted to NICE.

In your letter of 13 February 2024, you point to information that NHS England said would become available from January 2024 to provide a more reliable demand estimate than evidence from 2022/23 activity. However, as this information was neither available nor provided to NICE at the time of the funding decision it could not be taken into account. NICE could only consider evidence submitted to it at the relevant time. On this basis I cannot see an arguable point under ground 2.

You have requested that NICE ask NHS England to provide recent information on Covid 19 assessment and treatment numbers (since the devolution to ICBs in June 2023) and test kit requirements (since the move to community pharmacy provision in Nov 2023). Whilst again it is not within my remit or that of the NICE's appeal process to make requests of stakeholders, I will share a copy of your letter with NICE's executive leadership for consideration.

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 explained in my letter of 1 February 2024 why I am not minded to refer this point to the Panel. I note you have provided no further arguments in support of this appeal point and I therefore confirm it will not be referred to the Panel.

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

Thank you for your further comments in respect of this point in your letter of 13 February 2024. Having considered your additional arguments I remain of the view that this is not a valid appeal point so should not proceed to an oral hearing.

NICE's appeal process guide explains an appeal under ground 2 allows an appellant to argue that NICE's recommendation cannot reasonably be justified from the evidence presented to it.

Therefore, for this to be a valid appeal point I would need to be persuaded that it is *arguable* that it was unreasonable, in light of the evidence put to NICE, to accept NHS England's proposed approach, i.e. that this is obviously and unarguably wrong, illogical, or 'does not add up'.

I noted in my initial scrutiny letter that challenges to NHS England's proposal were raised during consultation, specifically by suggesting that some geographical areas / ICBs could provide access sooner than others based on readiness. NICE's reasoning on that point is explained at paragraph 4.5 of the FDG. I understand that you disagree with NICE's conclusion on this point, particularly given geographical variation in access to some other treatments, but I don't consider you have put forward argument or evidence to support an arguable appeal point that NICE's rationale and conclusion on this point is unreasonable in the sense explained above.

You go on to suggest an alternative phasing approach of "defining manageable groups that could be included earlier" than the 12 month period proposed by NHS England, which "could include [your] pragmatic suggestion of the wider hearth failure population or people aged 80-85". I note this was not raised during consultation and that you have not identified specific evidence that was before NICE that supports this proposal. I therefore am not persuaded that this is a valid appeal point that the approach proposed by NHS England and adopted by NICE was arguably unreasonable on the evidence.

That said, I do appreciate your concerns and interest in whether alternative options can be explored following a review of the data. It is again not within my remit or that of the appeal process to consider this, but I will ensure your comments are referred to NICE for consideration.

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

I explained in my letter of 1 February 2024 why I am not minded to refer this point to the Panel. I note you have provided no further arguments in support of this appeal point and I therefore confirm it will not be referred to the Panel.

Conclusion

For the reasons set out above, I will not refer any appeal points for consideration at oral hearing. This letter therefore brings NICE's appeal process to a close and the technology appraisal team will take forward publication of the guidance.

Thank you for your comments and engagement in the appeals process.

Yours sincerely

Dr Mark Chakravarty

Lead Non-Executive Director for Appeals & Vice Chairman

National Institute for Health and Care Excellence