Cardiothoracic Transplant Patient Group

NHS Blood and Transplant

13 February 2024

Dr Mark Chakravarty

Lead Non-executive Director NICE Appeals – Technology Appraisals and Highly Specialised Technologies

National Institute for Health and Care Excellence

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Dear Dr Chakravarty,

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

Thank you very much for your letter dated 1 February 2024. We appreciate that you have taken the time to consider our points of appeal and personally respond to us.

We are two lay patients, who have both undergone heart transplants, trying to advocate for fellow patients who are going through similar health journeys. We know from personal experience that heart failure and the heart transplant journey is tough. Heart failure is horrid, and you become extremely vulnerable to any illness that compounds your circulatory inadequacies. As has been proven heart failure is a clear risk factor for poor outcomes from Covid 19 and we are grateful to NICE for recognising this and including heart failure as an indication for Nirmatrelvir plus ritonavir.

We do understand that NICE can only make decisions based on the evidence presented at a specific point in time. Some of our appeal points relate to what we as patients could reasonably have expected NHSE to have undertaken or previously implemented. Our disappointment fundamentally lies with NHSE and their request to apply a significant funding variation to this guidance.

There are a few points we would like to make further comments on, and we would leave it to your expert judgment to decide whether they warrant referral to the Appeal Panel.

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.**

We completely appreciate the points you raise as to why this is not an arguable appeal point for NICE to consider. We would, however, be grateful if you could ask NHSE to outline to us what actions they took to prepare the wider the NHS for further rollout of Nirmatrelvir plus ritonavir. Giving specific regard to the clinical evidence that emerged in 2022 and the Edmunds report published in March 2023.

2) **NHSE estimate on the number of patients requesting test kits, reporting positive tests, and requiring treatment is likely to be an extreme overestimate.**

We note from the NHSE variation to the funding period submission that their treatment estimates are based on 2022/23 activity and the number of test kits is estimated as a box of 5 per eligible person per year. We fundamentally believe that the use of this source data by NHSE and accepted by NICE is inadequate for a decision of this magnitude.

We believe that it would be reasonable for NICE to request NHSE provide recent information on Covid 19 assessment and treatment numbers (i.e. since the devolution to ICBs in June 2023) and test kit requirements (i.e. since the move to community pharmacy provision in Nov 2023). NHSE have stated that information on the uptake of test kits would be available from January 2024 (point 24, page 44 of the Committee Papers).

This may of course endorse the demand estimates already central to NHSE's submission, but it may not. This process would ensure that NICE are taking the decision to grant the funding variation period based on actual recent demand numbers and not historical estimates.

The CTPG could obtain this information through Freedom of Information requests, however, that would not have been feasible approach within the timescales for this appeal.

3) Lack of consideration by NICE and NHSE for alterative variation period phasing

We are really struggling to understand the NHSE rationale and accepted by NICE that the further roll out of Paxlovid in areas able to do so before the end of the funding variation period would be inequitable and "such an approach would mean access was based on where someone lives".

It would seem to us that this argument is being used for the purpose of delay and not based on any fundamental consistently applied principle.

We will cite a few examples of where access to treatment is entirely dependent on where you live in England.

a. Primary Percutancoues Coronary Intervention (PPCI) for ST-Elevation Myocardial Infarction (STEMI).
   Across England access to PPCI for a STEMI is entirely dependent on where you live, which emergency department you present to, what time of the day or day of the week the event occurs.
b. Thrombectomy for blood clot removal in some strokes.
   The same situation applies to this treatment, where access is entirely dependent on where you live, which emergency department you present to, what time of the day or day of the week the event occurs.

Both treatments are commissioned within England. Why are these interventions not subject to the same equity of access principle as cited by NHSE in the roll out of Nirmatrelvir plus ritonavir for treating COVID-19. The argument put forward by NHSE appears flawed based on known inequity of provision of countless therapies.

Another example would be access to Sotrovimab for treatment Covid 19. As you are aware NICE published guidance, TA878, on 29 March 2023. This guidance recommends Nirmatrelvir plus ritonavir as the first line treatment for mild Covid 19 with Sotrovimab next for people where Nirmatrelvir plus ritonavir is contraindicated. People who have had an organ transplant and are taking immunosuppressants, which interact with Nirmatrelvir plus ritonavir, would be a good example of an applicable group of patients. The Cardiothoracic Transplant Patient Group are receiving regular reports of post-transplant patients being

denied Sotrovimab for Covid 19, with some patients being informed, “we have no access to infusion services in our area”. Other patients are receiving Sotrovimab quickly and efficiently. There are clear inequities based on geography.

We would be grateful if you could ask NHSE to comment on these experiences and why some patients are being denied access to a NICE approved treatment? We would also value advice from NHSE for patients who are experiencing difficulties accessing Sotrovimab in their areas.

A member of the CTPG who attends the Specialised Healthcare Alliance meetings informed us that Lord Markham’s team updated the group that three significant Covid 19 waves were expected in 2024.

We believe that NHSE have a responsibility to explore every available option to deliver NICE approved treatments in a timely manner.

We would ask that NICE formally request NHSE explore options to implement a next phased step before the end of the full funding variation period. This could include our pragmatic suggestion of the wider heart failure population or people aged 80-85. We note that NHSE state they aim to collect six months data (Jan – Jun 24) and share this with NICE to assist with next steps in planning and decision making (point 26, page 44 Committee Papers).

A logical next step would be for NICE and NHSE to schedule a meeting for summer 2024 to discuss the six months data and options to expand the eligible cohort further before the winter 2024/25 season is upon us.

We wish to point out that phased introduction by patient cohort would obviate NHSE's objection, in that it would not involve geographical variation, indeed NHSE has already chosen to phase its initial implementation in this way. It was unreasonable for NHSE not to consider any further expansion for 12 months rather than consider defining manageable groups that could be included earlier, and NHSE's assertion that implementing all the other patients in one go at the end of the year will be easier for ICBs than a phased implementation defies logic. Again, we would like to point out that it is NHSE's duty to implement NICE guidance as fast as possible, and while we appreciate NICE's position that it should not assume it knows better than NHSE, it is surely NICE's duty to challenge NHSE and insist on it providing a proper timetable, rather than to rubber-stamp NHSE's wish for such a long delay with no further implementation, particularly when it involves another winter season.

We note that it was NHSE's obligation to consider both the severity and acuity of the condition, and the impact on patients of delayed treatment. We do not consider that NHSE fairly or properly considered this, especially since it is well known and accepted that heart failure patients already have a serious illness which is particularly vulnerable to exacerbation and decompensation by concurrent viral infections, and it is also well-known and accepted that Covid 19’s cardiac effects are deleterious.

Thank you very much for your consideration and we would be happy to discuss this matter further.

Yours sincerely,

Robbie Burns (Chair) & Brian Golding (Member)

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