

Cardiothoracic Transplant Patient Group

NHS Blood and Transplant

24 January 2024

Dr Mark Chakravarty

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

National Institute for Health and Care Excellence

2nd Floor

2 Redman Place

London E20 1JQ

Dear Dr Chakravarty,

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

The Cardiothoracic Transplant Patient Group (CTPG) at NHS Blood and Transplant would like to appeal the decision of NICE to grant the extension of the funding variation period until June 2025 for the wider heart failure population.

The CTPG consider the recommendation is unreasonable in the light of the evidence submitted to NICE.

Firstly, we would like to thank NICE and NHSE for acknowledging the urgent need of the patients on an organ transplant waiting list or with a VAD, and for including them in the variation period roll out. By appealing on behalf of the wider heart failure community the CTPG does not want to do anything to delay the implementation for transplant waiting list and VAD patients, or indeed any of the groups identified for the initial roll out.

The CTPG consider the following issues to be reasons why the recommendation is unreasonable.

- 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.**

Initially the eligibility criteria for access to treatments to prevent progression to severe Covid 19 were derived largely based on clinical expertise rather than large volume studies. This is entirely reasonable as the evidence base simply did not exist. However, studies produced in 2022 and cited by NICE within this appraisal, such as Hippisley-Cox et al (August 2022) and Agrawal et al (October 2022) indicated other clinical conditions, such as heart failure, were at higher risk of severe COVID 19 than some currently included in the eligibility criteria.

As such in winter 2022, the COVID 19 Antivirals and Therapeutics Taskforce specifically commenced work for the wider deployment of antivirals against Covid-19. This work included the Therapeutics Clinical Review Panel (TCRP) to consider further high risk groups that could benefit from anti-viral treatment. Below is a background to this work,

“In winter 2022, the COVID-19 Antivirals and Therapeutics Taskforce was planning for the potential wider deployment of antivirals against COVID-19, should there be new evidence of the drug's effectiveness in a wider cohort. As part of this work the Therapeutics Clinical Review Panel (TCRP) was required to consider whether there are further high-risk patient groups that could benefit from antiviral treatment - in particular, whether there are groups that have a risk that is at least as high as those that are already eligible for treatment.” (DHSC, 2023).

This report (Edmunds) was published on 31 March 2023, and specifically outlined heart failure as a cohort of patients that may have a risk of severe Covid 19 at least as high as some of the patient groups already eligible for anti-viral treatments.

NHS England have responsibility for not only commissioning healthcare for their population but also for planning for their future provision. It would be reasonable to assume that NHS England, Integrated Care Boards, and other NHS organisations should have been planning for a much wider roll out of Nirmatrelvir plus ritonavir for treating COVID-19 for at least the last 12-18 months.

The CTPG consider that NHSE's request and NICE's approval to delay rollout until June 2025 for heart failure patients to be unreasonable. This date would be 27 months after the publication of the Edmonds report.

2. Delaying the rollout will lead to considerable waste of expired doses of Nirmatrelvir plus ritonavir

The delayed timing of the rollout will lead to wasting large quantities of expired doses of Nirmatrelvir plus ritonavir. As a public body, NICE would have been expected to have given this factor due consideration in its deliberations to grant approval for the delayed roll out.

NICE has concluded further groups of patients will derive cost effect benefit from the drug. Thus, to grant approval for its delay, denying access to this drug for many of these patients, whilst knowingly wasting public funds would seem unreasonable.

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

NHSE have requested the funding variation period as they have estimated the expansion of population will lead to a demand in test kits, treatment assessment and delivery that cannot be fulfilled. The CTPG consider these estimates to be overly prudent (high), as they are based on historical data from the very highest risk patient groups. These groups had easy access to test kits, proactive contacting when reporting a positive test and during a period where Covid 19 was a more prominent feature in daily life.

The CTPG believe evidence exists and could be obtained which would show a much lower level of demand. Devolved (ICB led) out of hospital Covid 19 treatment has been in place

since June 2023 and the community-based test kit provision from November 2023. Given the unprecedented nature of the delay requested by NHSE, the CTPG consider it unreasonable that NICE have not requested, and NHSE have not provided, contemporary demand figures for test kit requests and out of hospital Covid 19 treatments delivered.

Trial and anecdotal evidence would also indicate the demand is likely to be much lower.

The Panoramic trial is open to over double the number of even the expanded cohort, yet despite great efforts at encouraging recruitment, it only randomised 30,000 patients over 2 years - a great number for a trial, but low given that it was the only way for most patients to get antivirals.

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

Heart failure patients form the most seriously ill group of the expansion cohort. The risks of Covid-19 to the heart, both at the time of infection and the greater long-term risk, are well established, as is the known continued cardiac excess deaths risk. These are especially detrimental to heart failure patients who are often easily decompensated by concurrent illness. Avoiding this decompensation is also in the interests of NHSE in view of the burden it places on the NHS in both primary and secondary care.

The CTPG 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. The CTPG 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.

5. Lack of consideration by NICE and NHSE for alternative variation period phasing

NHSE have outlined groups that will be eligible for Nirmatrelvir plus ritonavir during the variation period, as detailed in 4.2 of the Final Draft Guidance, with most of the cohort not becoming eligible for a further 12 months.

This two-step approach does not seem to be in the best interests of patients (ensuring timely access to a NICE approved treatment) or clinical teams around the country where a multi phased approach would provide teams the opportunity to scale and refine operational delivery.

The CTPG considers it unreasonable that NHSE have not proposed, and NICE have not requested a more refined phased approach.

6. NICE and NHSE may not have considered all the evidence from professional groups

The CTPG would request NICE and NHSE engage with British Society for Heart Failure to ensure their professional opinion is voiced and considered before formalising the roll out delay.

Conclusion

The CTPG does recognise and witness that clinical teams across the whole of the NHS are stretched. It appreciates that taken at face value the immediate increase of eligibility to Nirmatrelvir plus ritonavir from 3.9million people to 15million people may seem overwhelming.

The CTPG have outlined reasons why the increase was predictable and should have been planned for, but that the actual demand is likely to be much less than modelled.

The CTPG wishes to seek a pragmatic and deliverable compromise for the roll out of Nirmatrelvir plus ritonavir for the heart failure population. Heart failure has been proven to be at higher risk of severe Covid 19 in large scale studies in 2022 and was specifically highlighted in the DHSC Edmunds Report of March 2023.

The CTPG would propose that heart failure patients become eligible at a pre agreed date during the funding variation phase, but before winter 2024/25. This population of approx. 1 million people will provide a reasonable operational step for clinical teams in preparation for the much larger cohort at the end of the variation period. It will also provide a valuable Covid treatment option for Covid 19 to the vulnerable heart failure population before the next winter season.

Thank you for your consideration and the CTPG would be very happy to discuss this matter further. The CTPG would also be willing to make further written statements or oral representations.

Yours sincerely,

Robbie Burns (Chair) & Brain Golding (Member)

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