NICE National Institute for Health and Care Excellence

Therapeutics for people with COVID-19 [ID4038]

Draft Guidance comments form

Consultation on the Draft Guidance document – deadline for comments 5pm on Wednesday 7 December 2022. Please submit via NICE Docs.

	Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly. The Appraisal Committee is interested in receiving comments on the following: • has all of the relevant evidence been taken into account? • are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence? • are the provisional recommendations sound and a suitable basis for guidance to the NHS? NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the preliminary recommendations may need changing in order to meet these aims. In particular, please tell us if the preliminary recommendations: • could have a different impact on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology; • could have any adverse impact on people with a particular disability or disabilities. Please provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced**.**
Organisation name – Stakeholder or respondent (if you are responding as an individual rather than a registered stakeholder please leave blank):	Cardiothoracic Transplant Patient Group (Under the governance of the Organ Donation and Transplantation Directorate at NHS Blood and Transplant) Response formally approved at Cardiothoracic Transplant Patient Group Meeting on 7 December 2022
Disclosure Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.	None

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Name of commentator person completing form:	Robert Burns, Cardiothoracic Transplant Patient Group Chair
Comment number	**Comments** Insert each comment in a new row. Do not paste other tables into this table, because your comments could get lost – type directly into this table.
Example 1	We are concerned that this recommendation may imply that ……..
1	The Cardiothoracic Transplant Patient Group is concerned that the preliminary recommendations could have an adverse impact on those individuals whose life is sustained with a donor heart and / or lung. That the preliminary recommendations will discriminate against this group. In section 3.24 the committee noted that nirmatrelvir plus ritonavir would not be a viable option for some patient groups due to the contraindication for concomitant use. This would apply to all heart and / or lung transplant recipients due to their immunosuppressant drug regimes. The Cardiothoracic Transplant Patient Group recognise that the committee acknowledged this issue and considered alternative treatments (such as Sotrovimab) but concluded that they "had substantially higher Incremental Cost Effectiveness Ratios and were not considered a cost-effective use of NHS resources". The Cardiothoracic Transplant Patient Group would like to formally raise concerns that the Incremental Cost Effectiveness Ratios have been calculated for the McInnes defined high risk patient group and suggest these figures should be calculated for the subgroups of heart and lung transplant. During such an exercise the following considerations should be taken into account; • The lack of viability of nirmatrelvir plus ritonavir for this patient group • The very high Covid severe disease risk with heart and lung transplant patients. This is exemplified by the latest Covid 19 mortality figures published by NHS Blood and Transplant (monthly-report-on-covid-19-nhsbt-16-march-2022.pdf (windows.net)), which shows mortality rates of 15.5% and 7.5% for lung and heart transplant respectively. The Cardiothoracic Transplant Patient Group was pleased to note that in 3.25 the committee stated that "in theory it would be willing to accept an Incremental Cost Effectiveness Ratios slightly more than what is usually acceptable if it addressed such health inequalities (people with protected characteristics disproportionately)". In summary, the Cardiothoracic Transplant Patient Group appreciate that the committee has considered the potential for the guidance to discriminate against people with certain disabilities. However, it does not believe that the committee has specifically analysed the impact of the draft guidance on heart and / or lung transplant patients to be confident that this patient group is not being discriminated against.

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2	The Cardiothoracic Transplant Group would like to raise concerns that the hospitalisation rates used for calculating the Incremental Cost Effectiveness Ratios, are a likely significant underestimate of actual rates experienced by heart and / or lung recipients. The maximum rate used for calculating the ICERs was 2.79% (DISCOVER-NOW). However, Shields et al. 2022 report 18.4% for people with primary or secondary immunodeficiency and known Covid mortality rates for lung and heart transplant recipients are 15.5% and 7.5% respectively (monthly-report-on-covid-19-nhsbt-16-march-2022.pdf (windows.net)). The Cardiothoracic Transplant Patient Group acknowledge that the committee recognised the uncertainty around hospitalisation rates for some patient groups, citing transplant recipients as an example. However, the Cardiothoracic Patient Transplant Group do not consider that the committee have investigated the available evidence in sufficient detail to assure itself that the draft guidance would not cause discrimination to people with a protected characteristic. It is difficult to conclude that 2.79% is a sufficient hospitalisation rate ceiling for a patient group with known publicly available mortality figures of 15.5% and 7.5% (monthly-report-on-covid-19-nhsbt-16-march-2022.pdf (windows.net)) In summary the Cardiothoracic Transplant Patient Group consider that the hospitalisation rates selected for the Incremental Cost Effectiveness Ratios will almost certainly have discriminated against those individuals whose life is sustained with a donated heart and / or lung.
3	The Cardiothoracic Transplant Patient Group is concerned that the committee may have not received all relevant evidence relevant to cardiothoracic transplant recipients due to the lack of stakeholder inclusion and engagement from the cardiothoracic transplant patient and clinical communities. The extensive list of patient carer groups included most disease types within the Independent Advisory Group defined list of highest risk patients. However, apart from Pulmonary Fibrosis no other patient carer group relating to cardiothoracic transplant was involved.
4	The Cardiothoracic Transplant Patient Group are concerned that the time allocated to the External Advisory Group was insufficient for them to consider the impacts on individuals with certain protected characteristics such as those whose life is sustained by a donor heart and / or lung. The External Advisory Group Assessment report specifically highlights this issue in 1.4.5 stating, “Due to time constraints, the only subgrouping considered was related to whether oxygen was required upon admission to hospital entry… The External Advisory Group is aware that other possible criteria for selecting subgroups includes but are not limited to age; immune system competence; comorbidities; seroprevalence; vaccination status; and the predominant SAR-CoV-2 variant but did not have time to explore the impact of these characteristics.” The consequence has been that the preliminary recommendations are only based on hospitalisation rate data from PANORAMIC or DISCOVER-NOW which the Cardiothoracic Transplant Patient Group believe is a significant underestimate of the actual rates for their patient population. The preliminary recommendations will have an adverse impact on people with a donor heart and / or lung.
5	The Cardiothoracic Transplant Patient Group believe that the preliminary recommendations are not sound and suitable guidance to the NHS as they remove many treatment options for heart and lung transplant recipients. The primary recommendation of nirmatrelvir plus ritonavir is known to be clinically unsuitable for this patient group.
6	The Cardiothoracic Transplant Patient Group would like to highlight new evidence to the Appraisal Committee. An observational study published in the BMJ (BMJ 2022;379:e071932) comparing the effectiveness of sotrovimab and molnupiravir for prevention of severe covid-19 outcomes in patients in the community suggested, “sotrovimab was associated with a lower risk of severe covid-19 outcomes than molnupiravir, including in those patients who were fully vaccinated”.

Insert extra rows as needed

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Checklist for submitting comments

- Use this comment form and submit it as a Word document (not a PDF).
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Combine all comments from your organisation into 1 response. We cannot accept more than 1 set of comments from each organisation.
- Do not paste other tables into this table – type directly into the table.
- Please underline all confidential information, and separately highlight information that is 'commercial in confidence' in turquoise and information that is 'academic in confidence' in yellow. If confidential information is submitted, please submit a second version of your comments form with that information replaced with the following text: 'academic / commercial in confidence information removed'. See the NICE Health Technology Evaluation Manual (section 5.4) for more information.
- Do not include medical information about yourself or another person from which you or the person could be identified.
- Do not use abbreviations.
- Do not include attachments such as research articles, letters or leaflets. For copyright reasons, we will have to return comments forms that have attachments without reading them. You can resubmit your comments form without attachments, it must send it by the deadline.
- If you have received agreement from NICE to submit additional evidence with your comments on the draft guidance document, please submit these separately.

Note: We reserve the right to summarise and edit comments received during consultations, or not to publish them at all, if we consider the comments are too long, or publication would be unlawful or otherwise inappropriate.

Comments received during our consultations are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the comments we received, and are not endorsed by NICE, its officers or advisory committees.

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