

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

**Draft guidance comments form**

**Consultation on the draft guidance document – deadline for comments** 5pm on Thursday 25 May 2023. Please submit via NICE Docs.

	<p>Please read the checklist for submitting comments at the end of this form. We cannot accept forms that are not filled in correctly.</p> <p>The Appraisal Committee is interested in receiving comments on the following:</p> <ul style="list-style-type: none"> <li>• has all of the relevant evidence been taken into account?</li> <li>• are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?</li> <li>• are the provisional recommendations sound and a suitable basis for guidance to the NHS?</li> </ul> <p>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:</p> <ul style="list-style-type: none"> <li>• 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;</li> <li>• could have any adverse impact on people with a particular disability or disabilities.</li> </ul> <p>Please provide any relevant information or data you have regarding such impacts and how they could be avoided or reduced.</p>
<p><b>Organisation name – Stakeholder or respondent</b> (if you are responding as an individual rather than a registered stakeholder please leave blank):</p>	<p>Cardiothoracic Transplant Patient Group at NHS Blood and Transplant</p>

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<p><b>Disclosure</b> Please disclose any funding received from the company bringing the treatment to NICE for evaluation or from any of the comparator treatment companies in the last 12 months. [Relevant companies are listed in the appraisal stakeholder list.] Please state the name of the company, amount, and purpose of funding.</p>	<p>None</p>
<p>Please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry.</p>	<p>None</p>
<p><b>Name of commentator person completing form:</b></p>	<p>Robbie Burns, Cardiothoracic Transplant Patient Group Chair</p>
<p><b>Comment number</b></p>	<p style="text-align: center;"><b>Comments</b></p> <p style="text-align: center;">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.</p>
<p><b>Example 1</b></p>	<p>We are concerned that this recommendation may imply that .....</p>
<p>1</p>	<p>The Cardiothoracic Transplant Patient Group are concerned that the draft recommendations do not include people with an active diagnosis of heart failure and as a result the population with this specific disability are being disadvantaged.</p> <p>The draft recommendations have retained the specific link for access to Niramtrrelvir plus ritonavir treatment to the population defined in the updated McInnes Report. The updated McInnes Report clearly states that it has “identified several cardiovascular diseases, particularly heart failure ... as additional risk factors.” but has not made any “specific recommendations around these conditions...”.</p> <p>The Cardiothoracic Transplant Patient Group consider that NICE must assess the best evidence available for relative severe Covid 19 risk for people with heart failure and draw its own conclusions.</p>

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	<p>The two Omicron era studies referenced in the NICE assessment, Hipplesley – Cox et al (2022) and Agrawal et al (2022) both evidence higher severe Covid 19 risk in people with heart failure compared to some conditions included in the McInnes list, such as the immune mediated inflammatory disorders of rheumatoid arthritis or systemic lupus erythematosus.</p> <p>Hipplesley – Cox et al (2022), demonstrate a relative risk of death from Covid 19 in men from heart failure of 1.41 compared to 1.24 in rheumatoid arthritis or systemic lupus erythematosus and for women 1.63 compared to 1.18.</p> <p>Agrawal et all (2022) demonstrate an adjusted relative risk of hospitalisation or death from Covid 19 in the vaccinated and boosted population of 2.38 for heart failure compared to 2.32 for people with rheumatoid arthritis or systemic lupus erythematosus.</p> <p>The Cardiothoracic Transplant Patient Group believe that there is sufficient evidence for NICE to recommend people with heart failure are included in the groups able to access Nirmatrelvir plus ritonavir for treating mild Covid 19.</p> <p>Failure to include this patient group could discriminate against people with heart failure compared to people who will be able to access this treatment despite having a lower underlying risk of severe Covid 19 disease progression.</p>
2	<p>The Cardiothoracic Transplant Patient Group are concerned at the lack of representation and engagement with the clinical cardiology community.</p> <p>The Cardiothoracic Transplant Patient Group notes that the membership of the McInnes Advisory Group does not include a cardiologist. The group includes members from all clinical specialities that are listed in Box 1 but is lacking direct input from cardiology despite evidence suggesting that people with certain cardiac conditions may have similar or a greater risk of severe Covid 19 to conditions included in the recommendations.</p> <p>The Cardiothoracic Transplant Patient Group recommends that the NICE appraisal process the panel seek the expert opinion from a professional cardiac body, such as The British Society For Heart Failure.</p>
3	
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Insert extra rows as needed

**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

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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.