NICE National Institute for Health and Care Excellence

Consultation COVID-19 technology appraisal recommendations: surveillance and rapid update process statement – deadline for comments 5pm on 5 May 2023.
email: covidsurveillance@nice.org.uk

Checklist for submitting comments.

- Use this comments form and submit it as a **Word document (not a PDF)**.
- **Do not submit further attachments** such as research articles, or supplementary files. We return comments forms that have attachments without reading them. You may resubmit the form without attachments, but it must be received by the deadline. You are welcome to include links to research articles or provide references to them.
- Complete the disclosure about links with, or funding from, the tobacco industry.
- Include **page number and section number** of the text each comment is about.
- Combine all comments from your organisation into 1 response form. **We cannot accept more than 1 response from each organisation**.
- **Do not** paste other tables into this table – type directly into the table.
- Ensure each comment stands alone; **do not** cross-refer within one comment to another comment.
- **Clearly mark any confidential information or other material that you do not wish to be made public with underlining and highlighting. Also, ensure you state in your email to NICE, and in the row below, that your submission includes confidential comments.**
- **Do not name or identify any person or include medical information about yourself or another person** from which you or the person could be identified as all such data will be deleted or redacted.
- Spell out any abbreviations you use.
- **We do not accept comments submitted after the deadline stated for close of consultation.**

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	Please read the checklist above before submitting comments. We cannot accept forms that are not filled in correctly. A process is needed to rapidly update the technology appraisal recommendations on medicines for COVID-19. This may be in response to several triggers including new clinical evidence, a change in the disease that significantly changes hospitalisation or mortality rates or emergence of a new variant of SARS-CoV-2 that affects the effectiveness of a medicine. A process statement has been developed that outlines the methods and process that will be used for surveillance and updates to recommendations. We would like to hear your views on the following questions. **Please include your answers to these questions with your comments in the table below:** 1. **Is the process as outlined a good basis for the committee to make decisions and update recommendations?** 2. **Do you have any concerns about the process and, if so, any suggestions to address those concerns?** 3. **Do you feel there are any gaps in the process or areas that need further consideration?**
Organisation name (if you are responding as an individual rather than a registered stakeholder please specify).	Cardiothoracic Transplant Patient Group at NHS Blood and Transplant
Disclosure (please disclose any past or current, direct or indirect links to, or funding from, the tobacco industry).	No
Confidential comments (Do any of your comments contain confidential information?)	No

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Name of person completing form	Robbie Burns, Cardiothoracic Transplant Patient Group Chair

Comment number	**Page number** **'General'** for comments on whole document	**Section number** **'General'** for comments on whole document	**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. • Include section or recommendation number in this column.
Example	016	1.2.2	We are concerned that this approach may imply that ……..
Example	010	2.4.6	We agree with the timescales listed, and would also like to add ….
1	General		In general, The Cardiothoracic Transplant Patient Group supports the principles within the proposed process as being a good basis to make decisions and update recommendations. However, the Cardiothoracic Transplant Patient Group does have some concerns which will be detailed below.
2	5	2.2.9	The example given in the second bullet point is a binary comparison between Paxlovid and sotrovimab. The Cardiothoracic Transplant Patient Group would like to emphasise that the surveillance process must continue to be multi-comparator between medicines as some agents (for example Paxlovid) are unviable for some high-risk groups. The surveillance process must include those agents which have previously been assessed and not recommended by NICE as well as agents which are currently recommended in the guidance.
3	6	2.2.12	The Cardiothoracic Transplant Patient Group welcomes the inclusion of a stakeholder submission surveillance stream.
4	9	2.4.2	The Cardiothoracic Transplant Patient Group have concerns that the cost recovery requirements have the potential to adversely impact subgroups with certain protected characteristics. As an example, the population size of any potential new subgroup for additional inclusion in recommendations would be a significant factor in the company's decision whether to fund the cost recovery of a rapid COVID-19 review process. This population could have a specific disability which is a protected characteristic. The Cardiothoracic Transplant Patient Group does appreciate the requirement for cost recovery and has three process suggestions which could mitigate the potential for discrimination.

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			1) Basketing - If NICE receive more than one surveillance trigger that relate to different aspects of changing the recommendations for one treatment, then triggers are “basketed” into a single review and hence a single cost recovery charge to the company. 2) Networking stakeholders – In this scenario, NICE receive a surveillance trigger where the company are not willing to fund the review as it relates to a small patient population and hence low potential revenue gains for the company. NICE proactively (and subject to stakeholder approval) link stakeholders with a shared common interest. Stakeholders may then seek to make a wider surveillance trigger case. 3) Tiered rather than single recovery cost – NICE develop a more refined tiered recovery cost structure where review charges that are covered by the company are tiered based on the anticipated size of the patient population and expected number of increased treatment sales generated. This costing structure will mitigate the risk of rarer disabilities being adversely impacted by a single tariff.
5			
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Insert extra rows as needed

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Data protection
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By submitting your data via this form you are confirming that you have read and understood this statement.

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