NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single Technology Appraisal

AZD 3152 for preventing COVID-19 ID6282

Stakeholder comment form

Please use this form for submitting your comments on the draft remit, draft scope and provisional list of stakeholders. It is important that you complete and return this form even if you have no comments otherwise we may chase you for a response.

Enter the name of your organisation here: Cardiothoracic Transplant Patient Group (CTPG), NHS Blood and Transplant

Comments on the draft remit and draft scope

The draft remit is the brief for an evaluation. Appendix B contains the draft remit. The draft scope, developed from the draft remit outlines the question that the evaluation would answer.

Please submit your comments on the draft remit and draft scope using the table below. **Please take note of any questions that have been highlighted in the draft scope itself** (usually found at the end of the document).

If you have been asked to comment on documents for more than one evaluation, please use a separate comment form for each topic, even if the issues are similar.

Please complete this form and upload it to NICE Docs by **Monday 19 June 2023.** If using NICE docs is not possible, please return via email to scopingta@nice.org.uk If you have any questions please contact Emily Richards, Project Manager on (0)161 413 4070 or at the above email address.

If you do not have any comments to make on the draft remit and draft scope, please state this in the box below.

Comment 1: the draft remit and proposed evaluation route

Section	*Notes*	**Your comments**
Appropriateness of an evaluation and proposed evaluation route	*NICE welcomes comments on the appropriateness of evaluating this topic and the evaluation route proposed (single technology appraisal, multiple technology appraisal or*	The CTPG considers AZD 3152 for preventing COVID-19 to be an appropriate topic to evaluate and the proposed route also be appropriate.

Section	*Notes*	Your comments
	highly specialised technology evaluation).	
Wording	*Does the wording of the remit reflect the issue(s) of clinical and cost effectiveness about this technology or technologies that NICE should consider? If not, please suggest alternative wording.*	Yes
Timing Issues	*What is the relative urgency of this evaluation to the NHS?*	The CTPG consider that the evaluation should be undertaken as rapidly as possible as there is a continuing and ongoing need for an effective treatment to prevent COVID-19. Many patients that the CTPG represent remain susceptible to poor outcomes from COVID-19 despite vaccination and many still have poor quality of life as they continue to "shield".
Any additional comments on the draft remit None		

Comment 2: the draft scope

Section	*Notes*	Your comments
Background information	*Consider the accuracy and completeness of this information.*	The CTPG consider this to be appropriate
Population	*Is the population defined appropriately?*	Yes
Subgroups	*Are there groups within the population that should be considered separately? For example, are there subgroups in which the technology is expected to be more clinically or cost effective? If subgroups have been suggested in the scope, are these appropriate?*	The CPTG consider that the subgroups of heart and lung transplant recipients should be considered separately. Numerous studies demonstrate these patients remain at high risk of poor outcomes from COVID-19 and hence any effective treatment would derive a greater cost effectiveness.
Comparators	*Are the comparators listed considered to be the standard treatments currently used in the NHS with which the technology should be*	The CTPG consider these to be appropriate

Section	*Notes*	Your comments
	compared? Have all relevant comparators been included?	
Outcomes	*Are the outcomes listed appropriate? Will these outcome measures capture the most important health related benefits (and harms) of the technology?*	The CTPG consider these to be appropriate
Equality	*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 draft remit and scope may need changing in order to meet these aims. In particular, please tell us if the draft remit and scope:* •*could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which [the treatment(s)] is/are/will be licensed;* •*could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. 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 tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.*	The CTPG consider that patient populations with shared protected characteristics should be appraised separately. This will prevent people who would derive a cost-effective benefit from the treatment if they were solely appraised in a wider patient population being excluded. The CTPG consider that heart and lung transplant recipient would be good examples of such defined patient populations.

Section	*Notes*	Your comments
Other considerations	*Suggestions for additional issues to be covered by the evaluation are welcome.*	No further considerations
Questions for consultation	*Please answer any of the questions for consultation if not covered in the above sections.*	No further questions
Any additional comments on the draft scope No further comments		

Comment 3: provisional stakeholder list

The provisional stakeholder list (Appendix C) is a list of organisations that we have identified as being appropriate to participate in this evaluation. If you have any comments on this list, please submit them in the box below.

NICE is committed to promoting equality and eliminating unlawful discrimination. Please let us know if we have missed any important organisations from the list, and which organisations we should include that have a particular focus on relevant equality issues.

If you do not have any comments to make on the provisional stakeholder list of consultees and commentators, please cross this box: ☐

Comments on the provisional stakeholder list The CTPG consider that NHS Blood and Transplant should be included as a consultee.

Comment 4: regulatory issues (to be completed by the company that markets the technology)

Section	*Notes*	Your comments
Remit	*Does the wording of the remit reflect the current or proposed marketing authorisation? If not, please suggest alternative wording.*	
Current or proposed	*What are the current indications for the technology?*	

Section	*Notes*	Your comments
marketing authorisation	*What are the planned indications for the technology?*	
	FOR EACH PLANNED INDICATION:	
	Which regulatory process are you following?	
	What is the target date (mm/yyyy) for regulatory submission?	
	What is the anticipated date (mm/yyyy) of CHMP positive opinion (if applicable)?	
	What is the anticipated date (mm/yyyy) of EU regulatory approval?	
	What is the anticipated date (mm/yyyy) of UK regulatory approval if different to Europe?	
	What is the anticipated date (mm/yyyy) of UK launch?	
	Please indicate whether the information you provide concerning the proposed marketing authorisation is in the public domain and if not when it can be released. All commercial in confidence information must be highlighted and underlined.	
Economic model software	*NICE accepts executable economic models using standard software, that is, Excel, DATA, R or WinBUGs. Please indicate which software will be used. If you plan to submit a model in a non-standard package, NICE, in association with the EAG, will investigate whether the requested software is*	

Section	*Notes*	Your comments
	acceptable, and establish if you need to provide NICE and the EAG with temporary licences for the non – standard software for the duration of the evaluation. NICE reserves the right to reject economic models in non-standard software	

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