**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Proposed Multiple Technology Appraisal**

### Therapeutics for people with COVID-19 ID4038

### Consultee and commentator comment form

Please use this form for submitting your comments on the draft remit, draft scope and provisional list of stakeholders.

**Enter the name of your organisation here: Faculty of Pharmaceutical Medicine**

**Comments on the draft remit and draft scope**

The draft remit is the brief for an appraisal. Appendix B contains the draft remit. The draft scope, developed from the draft remit outlines the question that the appraisal 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 appraisal, 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 **Thursday 03 February 2022**. If using NICE docs is not possible please return via email to scopingta@nice.org.uk If you have any questions please contact Michelle Adhemar, Project Manager on 44 (0)20 7045 2239 or Emily Richards, (0)161 413 4070 or via the address above.

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

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**Comment 1: the draft remit**

| **Section** | *Notes* | Your comments |
| --- | --- | --- |
| Appropriateness | *It is important that appropriate topics are referred to NICE to ensure that NICE guidance is relevant, timely and addresses priority issues, which will help improve the health of the population. Would it be appropriate to refer this topic to NICE for appraisal?* |       |
| 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.* | The clinical indications of treatments currently licenced for COVID-19 are diverse from mild disease to treatment of severe disease. These may well increase in diversity to include pre- and/or post-exposure prophylaxis, depending on the time frame for the appraisal and progression through licensing. The range of therapeutics covered by the draft remit is also diverse, covering 3 different ATC codes ATC J06, J05 and L04). This means that the comparisons between different medicines for use in different situations will need to be carefully considered. As such the remit should reflect this complexity.  |
| Timing Issues | *What is the relative urgency of this appraisal to the NHS?* |       |
| Any additional comments on the draft remit       |

**Comment 2: the draft scope**

| **Section** | *Notes* | Your comments |
| --- | --- | --- |
| Background information | *Consider the accuracy and completeness of this information.* | The background does not cover the full range of potential therapeutic uses, such as pre- and post-exposure prophylaxis.  |
| The technology/ intervention | *Is the description of the technology or technologies accurate?*  | The description does not distinguish the different classes of medicines adequately.The description does not include information on pre- and post-exposure prophylaxis trials to date, nor regulatory approvals for these indications. |
| Population | *Is the population defined appropriately? Are there groups within this population that should be considered separately?* | Specific populations to be considered:Pregnant womenThose who could benefit from pre-exposure prophylaxis e.g. patients requiring ongoing cancer treatment, for whom a COVID infection would interrupt life-impacting careThose who could benefit from post-exposure prophylaxisKey workers at risk of exposure (e.g. healthcare workers) |
| Comparators | *Is this (are these) the standard treatment(s) currently used in the NHS with which the technology should be compared? Can this (one of these) be described as ‘best alternative care’?* |       |
| Outcomes  | *Will these outcome measures capture the most important health related benefits (and harms) of the technology?* |       |
| Economic analysis | *Comments on aspects such as the appropriate time horizon.* |       |
| 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 proposed remit and scope may need changing in order to meet these aims.  In particular, please tell us if the proposed 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.* | As noted above, pregnant women are at risk of being full considered.Patients with other medical conditions who require protection from COVID in order to access the treatment they need are at risk of being discriminated against with the current approach. |
| Other considerations | *Suggestions for additional issues to be c**overed by the appraisal are welcome.* | Data sources must include evaluation of the significant amounts of real-world evidence available such as ISARIC and ICNARIC.  |
| Innovation | *Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a ‘step-change’ in the management of the condition)?**Do you consider that the use of the technology can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?* *Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.* |       |
| Questions for consultation |  *Please answer any of the questions for consultation if not covered in the above sections****.*** *If appropriate, please include comments on the proposed process this appraisal will follow (please note any changes made to the process are likely to result in changes to the planned time lines).* |       |
| Any additional comments on the draft scope      |

**Comment 3: provisional stakeholder list of consultees and commentator****s**

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

As NICE is committed to promoting equality and eliminating unlawful discrimination Please let us know if we have missed any important organisations from the lists contained within the stakeholder 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: [ ]

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| Comments on the provisional stakeholder list of consultees and commentators     Additional consultees should include the UK Pandemic Ethics Accelerator |

**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 marketing authorisation |  *What are the current indications for the technology?* |       |
| *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 ERG, will investigate whether the requested software is acceptable, and establish if you need to provide NICE and the ERG with temporary licences for the non –standard software for the duration of the appraisal. NICE reserves the right to reject economic models in non-standard software* |       |

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