**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: Faculty of Pharmaceutical Medicine**

**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](mailto: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.

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**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 highly specialised technology evaluation).* | The Faculty of Pharmaceutical Medicine (FPM) welcomes the proactive approach to early review of AZD3152 within its likely marketing authorisation. The immunocompromised population recommended is unlikely to respond to covid vaccines and remains vulnerable to severe disease and death. FPM considers prevention to be preferable to waiting until these individuals become ill and then implementing antiviral treatment, as currently recommended, as the use of antiviral treatment in this population risks the potential emergence of viral variants resistant to these treatments, which threatens the health of other vulnerable populations in the UK. This risk may be reduced by considering the use of combination antiviral treatment with both a MAb and a small molecule antiviral, as the Mab will enhance viral clearance within the immunocompromised population.  FPM notes the extended eligibility for antiviral treatment recommended in the IAG’s March 2023 report, However, FPM suggests that influenza and covid, which can co circulate, may adversely impact the same groups of individuals and it is preferable for treatment recommendations for covid to match those for influenza antiviral therapy. A uniform approach could further reduce risk of hospitalisation/death and it would greatly simplify delivery of care to make these recommendations consistent across both disorders. |
| 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.* | Whilst we acknowledge that the recent PreP report is quoted in the introduction to Appendix B, which takes into account a wider public health perspective, the disadvantage of the approach proposed is that it fails to take a population health approach to both the prevention and treatment of covid in the UK.  In addition, the change of disease pattern which has accompanied disease caused by omicron variants would warrant a revised assessment of the rates of hospitalisation and death which have significantly decreased since 2020. This can be used as a means of comparing to the data generated in the ongoing clinical trial (which is being conducted internationally with a limited range of UK centres participating) and also to set the baseline assumptions for cost effectiveness modelling based on trial outcomes. |
| Timing Issues | *What is the relative urgency of this evaluation to the NHS?* | Although covid is no longer considered a health emergency of international concern, the disease has not disappeared and in the UK currently causing 3-4000 hospital admissions and 3-400 deaths weekly (UKHSA Weekly report May 25 2023). These admissions and deaths may be significantly reduced by appropriate use of targeted chemoprophylaxis/treatment. |
| 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 information is based on data which is 3 years out of date and no longer reflects disease severity as observed in current practice. This will result in discrepant data to that generated in a clinical trial which is currently underway and impact cost effectiveness assessment whatever the outcome of a clinical trial. |
| Population | *Is the population defined appropriately?* | The population for chemoprophylaxis is appropriately defined in the IAG group report of March 2023. |
| 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 IAG group has identified sub populations of interest.  If a correlate of immunity were found this may enable a means to identify patients at greatest risk and also patients with pre-existing immunity at a level likely to be protective. This might be particularly relevant for patients in receipt of regular immunoglobulin treatment for their disease condition. |
| Comparators | *Are the comparators listed considered to be the standard treatments currently used in the NHS with which the technology should be compared? Have all relevant comparators been included?* | The clinical trial randomises patients to prophylaxis with AZD3152 or Evusheld. While Evusheld is licensed it has not been widely used for chemoprophylaxis in the UK population. However, as this group are eligible for antiviral treatment of illness, it would also be appropriate to compare outcomes following PrEP with outcomes following treatment of covid. It is unclear whether patients becoming ill with covid in the ongoing clinical trial will be offered antiviral treatment. This should be clarified. A secondary assessment of disease outcomes observed following disease occurring with treatment alone, or chemoprophylaxis plus/minus treatment of breakthrough infection should be conducted – this may utilise up to date outcomes among the UK population currently eligible for antiviral treatment. |
| Outcomes | *Are the outcomes listed appropriate? Will these outcome measures capture the most important health related benefits (and harms) of the technology?* | While the outcomes are generally appropriate, there is no consideration of the risk of asymptomatic infection or spread to contacts in the home or hospital setting. An important additional benefit of such treatment may be reduction in nosocomial transmission or, alternatively, harm may occur due to failure to recognise asymptomatic infection with risk of prolonged viral replication causing increased risk of disease in contacts. |
| 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 restriction of use to immunosuppressed individuals may disadvantage individuals at risk of severe disease for whom vaccination is not appropriate (eg previous vaccine reactions/contraindications). |
| Other considerations | *Suggestions for additional issues to be c**overed by the evaluation are welcome.* |  |
| Questions for consultation | *Please answer any of the questions for consultation if not covered in the above sections****.*** | **Where do you consider AZD 3152 will fit into the existing care pathway for prevention of COVID-19?**  See above – chemoprophylaxis for immunosuppressed patients  **Which populations would AZD 3152 be used in?**  The patient group recommended in the IAG March 2023 report, with the possible exclusion of those receiving chronic immunoglobulin transfusions.  **How many people in England would be eligible for treatment with AZD 3152?**  Based on QCovid publications potential max 1.5% of UK population or approx. 975,000  **How would these people be identified in practice?**  All are under chronic medical care. Many will be listed as eligible for antiviral treatment currently.  **Are the subgroups listed appropriate? Are there any other relevant subgroups that should be considered?**  If a population health approach were to be utilised there would be a reassessment of potential extension of the groups permitted access to antiviral treatment to include the population recommended for influenza antivirals.  **Would AZD 3152 be used in both primary and secondary care settings? If so, about what proportion of use would you expect in each setting?**  As it is administered IM it could be prescribed/administered in any setting including community pharmacy  **Would AZD 3152 be used at vaccination centres?**  If these continue to be used this is an option, but it would likely be preferable to administer this during a hospital visit (all of these patients regularly attend) or via GP/community pharmacy services  **Would AZD 3152 be a candidate for managed access?**  Yes – as is currently the case for antiviral treatment within the same population  **Do you consider that the use of AZD3152 can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?**  It is possible that use of this treatment within the population concerned would reduce the risk of spread of disease within a hospital/contact setting provided that there is no increase in risk of asymptomatic infection.  **Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.**  It is not clear that this is being evaluated within the ongoing clinical trial. AZ could be asked to consider assessing this additional outcome in the phase III portion of the ongoing SUPERNOVA study. |
| Any additional comments on the draft scope | | |

**Comment 3: provisional stakeholder list**

The provisional stakeholder list (Appendix C) is a list of organisations that we haveidentified 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:x

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| Comments on the provisional stakeholder list  We would suggest an additional stakeholder group be included: the National Clinical Expert Group for immunocompromised patients. This is the largest national clinical expert group representing >200 clinicians across 4 nations and 17 medical specialities led by Dr Lennard Lee. |

**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 EAG, will investigate whether the requested software is 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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