Updating technology appraisal recommendations for COVID-19 medicines

# Response to consultation and finalised process

Following the second consultation on the surveillance and update of technology appraisal recommendations for COVID-19 medicines that took place between 27 June and 25 July 2023, NICE has considered the consultation comments. The consultation comments can be found in full in appendix 1 of this document.

This document is structured as follows: 1. What we heard in the consultation, 2. Final process for updating technology appraisal recommendations for COVID-19 medicines, Appendix 1 – consultation comments.

# What we heard in the consultation

* Support for the change to publishing surveillance decisions. Referencing the line that “NICE expects that consultations will not be needed routinely.", suggestion that a consultation would be appropriate, if there is any dispute between NICE, the surveillance evidence submitter, and any other relevant stakeholder.

**NICE response:** This is appropriate and broadly how we would approach this.

* Request for detailed criteria on what would trigger a surveillance review.

**NICE response:** NICE does not have set criteria when deciding whether to review technology appraisal guidance and it would not be possible to construct a detailed list for COVID-19 medicines. Decisions will be made on a case by case basis by the NICE team. However, as described above, if there is disagreement between NICE and a stakeholder about whether the new evidence warrants a review, NICE will set out its rationale and hold a consultation.

* Broad support for revised process, especially additional steps for stakeholder submissions and participation

**NICE response:** These steps will be maintained

* Some respondents asked for clarity on whether there would be scoping or decision-problem steps.

**NICE response:** The aim of this process is to pick up where the original appraisal left off, to ensure rapid review of new evidence, so these steps are not included. If circumstances mean these steps are required, then this would need to be as part of a full STA review.

* Mixed views on 4 week submission timeframe
  + Some stakeholders considered that 4 weeks was too long and that 2 weeks would be more appropriate
  + Others felt 4 weeks will provide stakeholders with enough time to develop a robust evidence submission in most cases, but may not be long enough in others.

**NICE response:** The 4 week submission timeframe will be maintained. However, as with all appraisals, NICE will engage with the companies at the start of the update. If a company considers it needs less than 4 weeks to make a submission, this could potentially speed the timeline up, as the EAG review could be moved forward (while still allowing other stakeholders 4 weeks for their submissions).

* Mixed views on 4 week draft guidance consultation timeframe
  + Some stakeholders considered this was appropriate noting “this is the most time-intensive for stakeholders to complete”
  + Others thought 4 weeks was too long and that 2 weeks would be more appropriate instead
  + Suggestion that a consultation should only be required for optimised or negative recommendations

**NICE response:** NICE agrees that a consultation will normally only be required if the recommendation is optimised (i.e. for a narrower population than the marketing authorisation) or negative. In order to give stakeholders a fair chance of submitting evidence to address the uncertainties that led to these recommendations, a consultation period of 4 weeks will be retained.

* Support for public committee meetings but concerns about why this would take longer to arrange.

**NICE response:** If NICE holds meetings in public, these should (as far as possible) not clash with other NICE meetings in public, require sufficient staff available to support public observers, patient and clinical experts and ensure the smooth running of the committee in line with their terms of reference. This is important to make sure that only authorised attendees receive confidential documents/ are present for confidential discussions. However, because the additional submission and review steps have lengthened the process, this preparatory work can be done alongside those steps, so does not itself add time to the revised process.

* Support for stakeholder nomination of clinical experts, but concern that this could slow down the process. Suggestion that a pool of experts could be brought together to be called on as needed to address this.

**NICE response:** Because the additional submission and review steps have lengthened the process,nominating and selecting experts for each review can be done in parallel with the other steps and will not itself slow down the process. Stakeholders for individual reviews may be different (although there will be some overlap) and it is important that all stakeholders are given the chance to nominate the experts they consider most appropriate for a particular review.

* Concerns raised that the original model may be inappropriate if there have been changes (e.g. from CMDU to primary care pathways)

**NICE response:** A change such as that described above would affect some of the parameter value in the model, rather than the underlying structure. Changes to parameter values may be put forward (with appropriate supporting evidence) within this process. If however, the company that makes the medicine thinks that a different model structure is needed to assess the value of their medicine, then they can opt for this. However, this will need to be a full STA review.

* Some stakeholders raised concerns that the cost-recovery charge remains too high

**NICE response:** The cost-recovery charge has been set in line with the rapid review charge. The current rapid review process only allows consideration of new PAS or other commercial arrangement proposals. The resources required for the process of updating COVID-19 technology appraisal recommendations are at least equivalent to those required for rapid reviews triggered by new commercial arrangements.

# Final process for updating technology appraisal recommendations for COVID-19 medicines

## 2.1 Surveillance

* + 1. Surveillance of clinical evidence will continue. If the surveillance activity highlights new information that may trigger an update of the TA recommendations, this will be passed to the TA team to consider
    2. Stakeholders may also submit new information to NICE, and should send information to [nice@nice.org.uk](mailto:nice@nice.org.uk), stating the guidance topic it relates to.
    3. The decision-making about whether to review the recommendation will then follow section 8 of the [Health Technology Evaluation Manual](https://www.nice.org.uk/process/pmg36/chapter/guidance-surveillance). Section 8.4 of the Manual describes that NICE considers the surveillance review and determines if it should have a public consultation. A consultation will only take place when the review has identified significant uncertainty in the appropriate decision option. NICE expects that consultations will not be needed routinely. A consultation would be appropriate if there is a difference of opinion between NICE and the stakeholder(s) submitting evidence. Review decisions will be published on the NICE website.

## Update Process

* + 1. When finalising the decision to review the guidance, NICE will have a call with the company to explore whether the rapid update process can be used or whether a full STA review is needed.
    2. To use the rapid update process the company must agree:
* to use the same model structure as in the original appraisal (some parameter values may be updated)
* to a maximum of 4 weeks to develop an evidence submission
* to pay the cost-recovery charge.
  + 1. The review will continue under the same scope as the original appraisal and it will be reissued with the invitation to participate. There will not be a formal decision-problem meeting.
    2. If the company that makes the medicine considers a different model structure need to be used, then an STA review will be initiated.
    3. An update will be initiated when an invitation to participate is sent to stakeholders. This will clearly set out the process that is to be followed and the associated timelines. NICE will aim to minimise the time between a review decision and starting the update process.

### Submissions and evidence review

* + 1. NICE will give stakeholders 4 weeks to make a submission from invitation to participate. Company submissions should be focussed on the new evidence identified during the guidance surveillance, and include the revised cost-effectiveness results. The company should also provide a budget impact submission.
    2. The external assessment group (EAG) will have 4 weeks to review the submissions. This includes a 1 week period for the company to respond to EAG requests for clarification. Following receipt of the EAG report, the company will have the opportunity to highlight any factual inaccuracies and check the confidential marking is correct.

### Patient, clinical and commissioning experts

* + 1. Stakeholders will be invited to nominate patient, clinical and commissioning experts when a review of the recommendation is initiated, in line with the usual STA process. Selected experts will be invited to submit a statement and attend the committee meeting.

### Decision-making committee

* + 1. Topics will be considered at public meetings of the full standing technology appraisal committee.

### Consultation on draft guidance

* + 1. When draft guidance is issued, there will be a 4 week consultation period. Draft guidance will usually only be issued when the recommendation is optimised to a subgroup of the population in the marketing authorisation or negative.

### Appeals and publication

* + 1. The appeal process and timelines will follow [NICE’s technology appraisal appeals process guide](https://www.nice.org.uk/process/pmg18/chapter/foreword). Following resolution of any appeals, NICE publishes the final guidance. At this point, the 90 ‑day funding implementation period applies for commissioners. Requests to vary the funding requirement to take account of net budget impact will be considered in line with [section 5.9 of the health technology evaluation manual](https://www.nice.org.uk/process/pmg36/chapter/developing-the-guidance#varying-the-funding-requirement-to-take-account-of-net-budget-impact-technology-appraisals-and).

## Overall summary and timelines

* + 1. In most respects, reviews will follow the [health technology evaluation manual](https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation), with the exceptions of the shorter submission period and shorter evidence review stage (as outlined in paragraphs 2.2.6 and 2.2.7 above) and no technical engagement option. There will also be less time allocated to NICE internal teams to prepare materials for the committee and to draft the guidance documents.
    2. These changes will be clearly documented in the invitation to participate letter issued to stakeholders and must be accepted by the company to proceed. This will result in the following timeline, if a positive recommendation is made at the first committee meeting:

**Table 1: Timelines for straight to draft final guidance decisions**

|  |  |
| --- | --- |
| **Week** |  |
| Week -4 | Surveillance trigger identified |
| Week -3 | Surveillance review done |
| Week -2 | Decision to update communicated |
| Week -1 | Planning update into programme |
| **Week 0** | **Issue Invitation to Participate** |
| Week 1 |  |
| Week 2 |  |
| Week 3 |  |
| Week 4 | **Stakeholder submissions** |
| Week 5 | Clarification step |
| Week 6 |  |
| Week 7 |  |
| Week 8 | **EAG critique due** |
| Week 9 | Company factual accuracy check |
| Week 10 | EAG response to factual accuracy check |
| Week 11 |  |
| Week 12 | **Committee meeting** |
| week 13 | Preparation of guidance document |
| Week 14 |  |
| week 15 | Positive recommendation: guidance issued for appeal (3 weeks) |
| Week 16 |  |
| Week 17 |  |
| Week 18 | Appeal period ends |
| week 19 |  |
| week 20 | **No appeals, final guidance** |

* + 1. In addition, a company may propose to further expedite the timelines if it is happy for the review to proceed without a company submission (and the need for consequent external academic review) or needs less than 4 weeks to make a submission. Timelines are subject to NICE and EAG resource availability and capacity.

## Cost recovery

* + 1. The applicable charge will be £106,200 for 2023/24 in line with the charge for a rapid review, if companies agree to use the existing model from the original appraisal. If companies instead wish to submit new modelling the standard STA charge will apply - £151,700 for 2023/24.
    2. Because of the speed of potential reviews, it may not be possible to issue the charging invoice and receive payment before starting the rapid update. However, as part of the charging process the company will still need to provide NICE with a Unique Reference Number (URN) as their commitment to pay for the update. NICE reserves the right to not publish final guidance until payment in full has been received.

## Review

2.5.1 This process will be reviewed annually and updated or stood down as necessary. Next review: October 2024.

# Appendix 1 – consultation comments

|  |  |
| --- | --- |
| **Organisation** | **Comment** |
| ABPI | The first part of the consultation on the proposed COVID-19 rapid review process has led to changes which more closely align it to the standard STA process, but still provide a shorter timeframe from ITP to guidance publication (20 weeks versus 38 weeks). These changes respond to some of our previous feedback to ensure the process allows adequate time for company evidence submission and appropriate stakeholder consultation to inform NICE’s decision-making on COVID-19 therapies.   ABPI recognises and appreciates the need for a standardised process that incorporates sufficient steps to allow for evidence to be scrutinised and welcomes the changes that have been made. The unique nature of COVID-19 may create a greater sense of urgency in certain circumstances and, whilst a bespoke approach for each treatment is not feasible, NICE does appropriately recognise that there should be scope for flexibilities and “a company may propose to further expedite the timelines”. It would be helpful to formalise this step and update the process to include a conversation between NICE and the company at the point that a surveillance trigger is identified. This would allow an assessment of factors such as the evidence available and the resource required to assess the evidence, for example, and for the process to be shortened if appropriate, to ensure that it is proportionate to the level of decision-making risk. It would also help clarify the scope of the update at the earliest stage possible, to support evidence submission preparation.  ABPI understands from the consultation document that if an existing model evaluated by NICE cannot be used, the full STA fee will be charged, and the rapid review timelines cannot be utilised. It would be helpful to recognise there may be some amends made to the model to incorporate the updated evidence. Given the potentially urgent need for guidance for novel COVID-19 therapies due to emergence of new variants, the process should allow for rapid review of therapies that have not had a prior NICE evaluation if the need arises.   The consultation document states a separate process statement will not be published and the timeline changes will be confirmed in the ITP letter. ABPI does not consider this to be transparent, and requests that an addendum to the HTE manual or an additional short process statement is finalised and published following this consultation, so that it is clear to all stakeholders what the process steps and timelines are for updating guidance for COVID-19 therapies. |
| ABPI | With the reduction in surveillance activity and the likelihood that triggers for review will be lower, it is wholly appropriate that there is a more flexible arrangement in place for stakeholders to submit new information to NICE and we welcome this addition to the process. Stakeholder contributions would be optimised if there was clearer guidance from NICE on the criteria that will be used to inform whether a recommendation will be reviewed using this process. It would be helpful if NICE could publish the criteria that will be used to make review decisions.  Companies should be notified at the earliest possible timepoint if their medicine(s) is (are) being considered for review due to new information having been identified during surveillance. Data/information related to the trigger should be shared with the company so that they are aware of the nature of the consideration.   As proposed in the general comments above, an additional formal process step should be included at the point of trigger identification to allow for consultation between the company and NICE to ensure that a proportionate approach is being taken, to balance the level of risk and the evidence and resource requirements. This dialogue should also help clarify the scope of the update.  In the Surveillance section, NICE specifies that "A consultation will only take place when the review has identified significant uncertainty in the appropriate decision option. NICE expects that consultations will not be needed routinely." A consultation would be appropriate, and increase transparency and fairness, if there is any dispute between NICE, the surveillance evidence submitter, and any other relevant stakeholder (including the manufacturer of the COVID-19 medicinal product subject to review) over the decision taken by NICE to review a recommendation. |
| ABPI | ABPI welcomes the inclusion of stakeholder submissions in the process as these form an important component of an overall review and help to inform decision-making. Four weeks is appropriate in most circumstances, but should there be an urgent need for a therapy to be assessed, this window could be reduced further. In these scenarios, two weeks is probably the shortest time period possible that will still allow for sufficient stakeholder input.   It is helpful that the requirement to use existing economic modelling in this process has been clarified, for medicines which have already been evaluated by NICE. However, the updated information/data may require updates to be made to the model and submitted with the evidence package. As per the STA process, there should be a factual accuracy check following the EAG critique, ahead of the materials being developed for the committee meeting. It is critical that the model can fully support the evaluation of the treatment under consideration, in line with the defined decision problem. Companies should be able to make suitable changes to the existing model if required to effectively model the new/updated data.   Given the important role of real world evidence (RWE) in relation to COVID-19 therapies, as evidenced in TA 878, and upheld in the appeal review process (“the appeal panel were persuaded that NICE had failed to take adequate steps to identify relevant evidence and treated RWE inconsistently” ), it would be helpful to provide greater clarity on what types of RWE, such as observational studies or ongoing assessments, would be permissible to rapid updates and in what circumstances. It is important that a consistent approach it taken to the use of RWE and the document should link to the NICE Real World Evidence Framework. NICE should ensure that the principles set out within the framework are adhered to in the rapid update process. A shared understanding of how RWE will be applied will support more effective use of resources by companies and NICE.  As per our previous comment, ABPI asks NICE to consider the utility of this rapid process for medicines that have not already been evaluated if an urgent need for guidance arises. |
| ABPI | ABPI welcomes that the approach has been updated to incorporate stakeholder nominations for clinical, patient and commissioning experts. |
| ABPI | ABPI acknowledges that NICE has introduced a public committee meeting to increase transparency. Should there be an urgent need for COVID-19 therapy guidance or if the decision-risk is deemed low, ABPI suggests NICE’s streamlined approach to committee decision making should be utilised for efficiency and speed of guidance.   The ongoing role of the In Vitro Advisory Group needs to be clarified. Given the multi-faceted nature of decision-making about COVID-19 therapies, NICE committees should be able to access appropriate expertise from a pool of suitably qualified experts across a range of specialist areas from epidemiology to the management of infectious diseases in adult and paediatric populations. This will support appropriate and informed decision-making. ABPI would also welcome clarification on how NICE will review, seek feedback on and utilise the In Vitro framework for supporting the evaluation of in vitro data. |
| ABPI | A four week consultation period is helpful to include in the standard process, but should not be required if a positive, non-optimised, decision has been made. To best utilise NICE’s resource, ABPI suggests the consultation period is put in place only for optimised or negative recommendations. This will support NICE’s aim to publish guidance as rapidly as possible. |
| ABPI | It is disappointing that the 90 day funding requirement has not been updated to support rapid patient access to COVID-19 therapies. A 30 day funding requirement has historically been permitted for fast track appraisals and it is expected (although NICE has not confirmed this) that this has now been applied to cost comparison appraisals. There should be an ability to shorten the mandatory funding period of priority COVID-19 medicines given the significant impact speed of access will have should the pandemic enter a renewed period of intensity, not just on patient outcomes but for the NHS and society more broadly. ABPI seeks further discussion on this. |
| ABPI | The process timeline has extended due to additional elements being added, as per feedback from the first consultation. ABPI supports this given the importance of appropriate and sufficient stakeholder input. However, as commented previously, the process must also be as proportionate as possible to the decision that is going to be made. If, for example, a small amount of additional data or change to the data needs to be reviewed, this may not require such a lengthy process to be followed. Given the pandemic nature of COVID-19, there should be some flexibility permitted to support a faster timeline if needed. It is important that this is agreed between NICE and companies at the outset of the review, in advance of the invitation to participate. For example, the stakeholder evidence submission timeline could be shortened, the EAG review may not be required and the committee preparation time could potentially be shortened. This could allow a very rapid process in such circumstances where it is considered appropriate.  It would be helpful if NICE could specify which stakeholder submission template(s) would be used to submit evidence and to ensure these are made available on the NICE website.   To reduce the process timeline we note there are no scoping or decision-problem meeting steps built in. It would be helpful to understand how NICE intends to confirm and communicate the guidance update scope and decision problem? Communicating this to stakeholders as early as possible will be needed to support their evidence submissions. |
| ABPI | NICE’s consideration of the fee for companies and its subsequent reduction is welcome, however this still feels disproportionately high for conducting a review of medicines which have already been through an STA or MTA. NICE is permitted to charge fees only on the basis of actual cost recovery, as per the Treasury guidelines on Spending Public Money. It is hard to see how the proposed process justifies such a high fee. It would be helpful to provide further evidence for the justification of the fee.  A full STA fee for a submission with a new economic model would not be needed if NICE still utilised a rapid process. ABPI suggests this process flexibility is incorporated and the fee for this would then sit in between that which is confirmed for review of previously evaluated COVID-19 therapies and the full STA fee. |
| Kidney Research UK | The onus should not be on stakeholders, such as patient organisations, to alert NICE to potential triggers from the UKHSA data. If NICE do not put enough significant resource to understand future Covid-19 surveillance plans, this will inevitably become the case. |
| Kidney Research UK | We felt that a rapid process must not be solely designed to cut the time allowed for stakeholder input, and so we welcome patient organisations having longer than one week to reply. However, we would have like to have seen some innovative thinking to create a process that is not just simply a process with shortened consultation windows. |
| Kidney Research UK | Selecting patient and clinical experts should not need to slow down the process. A pool of potential experts could be brought together now for this purpose, who can be called upon quickly once a process has started, rather than doing it anew for each appraisal. |
| Kidney Research UK | We do not recognise the rationale provided for extending the length of time of the process to enable a public meeting. A short period of notice would be understood by public attendees, given the need for a rapid process, and it remains unclear why facilitation of a public meeting would require extra weeks to prepare for. |
| Kidney Research UK | "In addition, given the changes to expert involvement outlined above, topics will be considered at public meetings of the full standing technology appraisal committees, rather than by a subset of the committee – p. 4"  We understand this change. |
| Kidney Research UK | We are concerned about how the rapid update process will be distinguished from the full technology appraisal review process without a separate process statement. This is a specific rapid review process for a particular purpose and is worth setting out separately. As acknowledged, the new steps as outlined are much more akin to the standard process, and as such we are disappointed by the ambition to find genuine solutions to the challenges facing the approval process by Covid treatments. |
| Lupus UK | It may not be suitable to use the existing economic model because of changes to treatment pathways. These models have been developed based on a national COVID Medicines Delivery Units (CMDU) model, which is no longer in use as the pathways are now the responsibility of each Integrated Care Board (ICB).  In addition, the greatest burden of COVID-19 has shifted from secondary care to primary care as fewer people are hospitalised with severe disease. We are now seeing greater pressure on GP services from patients experiencing longer-term symptoms, secondary infections, chronic disease flares and general deterioration in health following COVID-19. The role of COVID-19 therapeutics in reducing pressure on primary care services is an important consideration for the economic model as we continue to move into this next stage. |
| Lupus UK | This could create unnecessary duplicated work and waste time. Our concern with the original draft of the process was the lack of specificity about the number of clinical experts who could be called upon for a Committee meeting. Could there be a pool of experts available to select from? If there are concerns about having standing experts, perhaps a process for withdrawing or vetoing experts could then be introduced? |
| Lupus UK | It is disappointing to hear that making these committee meetings public will slow the process and prevent a subset committee from being used to expedite matters.  Could there be a compromise where the meeting is not open to the full public, but may be observed by representatives from registered stakeholder organisations? Could this reduce the time needed to arrange and facilitate by eliminating public registration? |
| Lupus UK | I do not think the reasons why the full standing technology appraisal committees will be needed instead has been made adequately clear. Could this be explained please? |
| Lupus UK | I agree that a proposed consultation period of 1 week would be insufficient to enable many organisations to adequately consider and submit a response. We may need to find a compromise between this and the standard 4 week period to avoid delays to treatment being made available. Could 2 weeks work? |
| Lupus UK | Can we have reassurance that, if a Multiple Technology Appraisal is being conducted and any appeals relate to only one of the treatments, that the final guidance for the other is not also delayed by the appeal process. |
| Lupus UK | This revised process has increased in duration significantly - from around 8 weeks to 20-38 weeks. This can no longer be considered "rapid", as originally suggested.  The opportunity for stakeholders to have greater participation is welcome, but a middle-ground may need to be found. Patient organisations will require at least a couple of weeks for a fair chance at providing some form of submission. |
| Blood Cancer UK | We are concerned that without triggers from UKHSA data that the onus will be on stakeholders to alert NICE to potential triggers. NICE should meet with UKHSA to understand what its future COVID-19 surveillance plans are and if they can be incorporated into this process. |
| Blood Cancer UK | Existing economic models may no longer be appropriate due to changes in COVID-19 medicine delivery in England, following the transition of responsibility to Integrated Care Boards. This has also shifted the balance of the burden, such as increasing the burden for primary care providers. NICE should explore ways for new economic models to be submitted without a move to a full review and extended timeline. For example, companies could make amendments or updates to existing economic models. |
| Blood Cancer UK | While we raised concerns in the consultation about if, when and how the pool of existing patient and clinical experts would be reviewed and expanded, we believe the suggested alternative of nominating experts for each review will add too much time to the process. Instead, a review of the pool of experts should take place now with stakeholders given the opportunity to put people forward or raise concerns about existing members of the pool. Once the pool of experts is reviewed, experts could be called upon when a review of a recommendation is initiated. |
| Blood Cancer UK | We are disappointed to hear that making committee meetings public will slow the process. Online meetings and their various formats have become much quicker to organise since the pandemic began, and we feel that this delay is not necessary. Stakeholders will be willing to attend these meetings at short notice given the urgency of their subject matter. |
| Blood Cancer UK | The reasons behind the decision for a full standing technology appraisal committee meeting rather than a subset of the committee have not been made clear. |
| Blood Cancer UK | We agree that the proposed consultation period of 1 week would be too short to allow organisations to adequately respond. However, we think the extension to 4 weeks goes too far in the other direction. We recommend that the consultation period be adjusted to 2 weeks as a compromise between these two proposals. |
| Blood Cancer UK | We request reassurance that if a Multiple Technology Appraisal appeal concerns only one of its treatments, that the final guidance for the other treatment(s) is not delayed by the appeal process. |
| Blood Cancer UK | How will the rapid update process be distinguished from the full technology appraisal review process without a separate process statement? |
| Blood Cancer UK | Does this mean that, in contradiction to the original rapid update process statement, NICE did not/does not intend to build a new surveillance function and that this fee would have only covered monitoring of UKHSA, In Vitro and OpenSAFELY surveillance data? |
| Blood Cancer UK | We recommend a window of 2 weeks for submissions from invitation to allow more time for stakeholders to respond while also reflecting the urgency of a review. |
| GSK | In both the original process document and the new revised document, NICE states that the continuous surveillance programme will be based on three core sources of data being available: 1. UK Health Security Agency (UKHSA) HSA Technical Briefings 2. Published in vitro studies 3. OpenSAFELY NICE note in the revised process document that each source of data is now more limited in both detail and availability, and this is expected to reduce the likelihood of a trigger occurring. On this basis, are NICE considering any anticipated changes to the surveillance process in general?  In our initial response, GSK requested that the process should ensure that the totality of relevant evidence is considered for sotrovimab. Given there will now be greater challenges in generating data, we propose the following:  - As soon as a decision has been made that a trigger will result in a review of published guidance, that the relevant company is informed to enable them to begin generation of evidence (currently week -2) - Ensure that any new in vitro neutralisation data is considered against the Framework proposed by the In Vitro Advisory Group (IVAG) in the ID4038 Committee Papers, including the use of the adapted Toxicological data reliability assessment tool (TOXRTOOL) - Agree to build in sufficient time to enable a company to report the outcomes of its own pseudo/live virus testing (e.g. for pseudovirus testing, four to six weeks from decision to test to the reporting of results) - Consider standing up the IVAG committee (or a similar group of experts) to review all available evidence (including any RWE that can be generated by OpenSAFELY or similar) so that a thorough evaluation can be conducted by experts in the field  In addition, it is not clear regarding the threshold level of the data that will result in a trigger, given there will be uncertainty regarding the variant prevalence, the numerical change in in vitro activity, and potentially being other mitigating or conflicting factors or pieces of evidence (e.g. RWE, in vivo and effector function data) |
| GSK | GSK welcome the opportunity to respond to this second public consultation on the revised approach to updating technology appraisal recommendations for COVID-19 medicines. We note the careful consideration by NICE to the extensive feedback provided by a large number of stakeholders. In general, GSK welcome the revisions that have been made by NICE and we believe that this revised process is more closely aligned with the general principles that NICE works towards for Health Technology Assessment. The revised process appears to follow a typical NICE appraisal process and we believe this is an improvement on the earlier draft process.  Based on the recently published appeal decision for the NICE COVID-19 MTA, we request that NICE considers the outcome of this appeal before finalising its rapid review process. In particular, the feedback from the Appeal Panel regarding ensuring the totality of relevant evidence being considered, and the fact that multiple appeal points relating to process were upheld.  We continue to note that all stakeholders (including companies) should be active participants in the guidance update process, and that the process includes careful consideration of all relevant evidence by the full Committee. We have some remaining concerns relating to: 1. The continuous surveillance programme 2. The timelines continuing to be optimistic for the generation of relevant evidence in light of a surveillance trigger.  We provide detailed feedback relating to these points below, as well as additional comments, and hope that NICE will consider our constructive recommendations to ensure that the process is appropriate, in particular for treatments currently recommended by NICE. |
| GSK | Page 2, Section 2 Why does the surveillance process not refer to or consider in vivo data or RWE studies? |
| GSK | Page 3, Section 3 This states that ‘a consultation will only take place when the review has identified significant uncertainty in the appropriate decision option. NICE expects that consultations will not be needed routinely.’ If there was some compelling in vitro data from a reliable source suggesting a complete loss of neutralisation for a treatment, and therefore the NICE Committee reached a unanimous decision, would NICE go straight to a decision and bypass a consultation? At GSK we believe strongly that consultations are an important part of the NICE process and that they should not be bypassed just because the NICE Technical Team do not believe that they will be important. This is especially important in the situation where a significant number of patients at the highest risk of progression to severe COVID-19 could be left without any treatment option available to them. |
| GSK | Page 4, Submissions: We believe that there should be some flexibility to extend the submission timelines to enable informative data to be generated and shared by the company. There may be instances where it may take 1-2 months for pseudo/live virus testing to be conducted for a very emergent variant of interest, and therefore we request that this is taken into consideration via an early discussion with the company before setting a submission deadline. In addition, we believe that 1 week for the EAG to seek clarification may be unrealistic and this may take a longer time if they need to engage with their own clinical experts.  In addition, GSK believes that it is important that any EAG critique or additional analysis has a factual accuracy check stage, before committee meeting materials are developed. |
| GSK | Page 5, Decision-making committee Will the same EAG and NICE Committee be used for the rapid reviews as were used for the original NICE COVID-19 appraisals? Given the challenges faced during the original COVID-19 treatment MTA, at GSK we recommend that the same EAG and Committee are used for COVID-19 reviews given they will now have good familiarity with the evidence base and existing economic model. Alternatively, if this is not feasible then we suggest that the relevant Committee (and/or EAG) should be appropriately briefed with the previous materials, and the existing economic model.  What will happen to the process if there is a variant of concern which causes a trigger, but before the end of the review process the variant is no longer of a concern? Will the review process be terminated at that point, or will it continue until completion (even if it results in no subsequent change in the guidance)? Will the decision at the end of the process be implemented in the NHS even if the variant that caused the trigger has been phased out or is at very low circulating prevalence? |
| Vertex | It is reasonable that the process for COVID-19 medicines should follow a similar process to that for standard technology appraisals. We ask, however, that the option for technical engagement remains, and that the decision whether or not to include technical engagement is taken only after consultation with the company. |
| Individual | Whilst I fully appreciate this is NOT is NICE`s job specification the lack of data availability is putting not only the immuno compromised but the country at large in a weakened position. This will not assist the NHS next winter. |
| Individual | 2 weeks is an appropriate timescale for stakeholders to remit the required information to NICE. 4 weeks would be unnecessary. |
| Individual | As a member of the public - ie not knowing the processes involved it is hard to understand why making the meetings public should further extend the timescales. |
| Gilead | While having the option to submit new evidence to NICE is appreciated, it seems unclear what criteria will be applied by NICE to determine whether or not this new evidence will be sufficient to warrant an update to the existing NICE recommendation |
| Gilead | Currently the guideline suggests that only NICE may trigger an update to the recommendation based on its surveillance activities. However, it would be equally important for companies to be given the opportunity to alert NICE to new evidence becoming available, so that the TA team can consider the new evidence, thus enabling companies to trigger a guidance update |
| Gilead | If the company agrees to do so, there should be an opportunity for the company to interact with the EAG to discuss the adaptation of the EAG cost-effectiveness model if deemed necessary to fit a change in patient population or for any other structural reason |
| Gilead | Applying the standard STA cost doesn't seem reasonable, as the proposed COVID process is - as explained in this document - a cut-down version of a standard STA process (24 weeks vs. 42 weeks); Taking into account the reduced time of this proposed process (approx. 60% time effort compared to standard STA), the costs should not be higher than £85,000 |
| Anthony Nolan | We welcome the opportunity for stakeholders to submit new information to NICE however we are concerned that with the scaleback of community surveillance by UKHSA, patient organisations such as Anthony Nolan will struggle to access the necessary data to trigger a review. What's more, the burden should not be on patient organisations to supply the necessary information. |
| Anthony Nolan | We welcome the opportunity for stakeholders to make submissions however we are concerned that 4 weeks for stakeholders to submit and a further 4 weeks for the EAG review means that the total process may take up to 38 weeks if there is an appeal. If possible, we would recommend a shortening of these two stages. |
| Anthony Nolan | We welcome the consultation period to revert to 4 weeks. This stage is the most time-intensive for stakeholders to complete so 4 weeks is appropriate (while the other stages can be shorter). |
| Anthony Nolan | Overall, we welcome the opportunity for increased stakeholder input but are concerned the process is no longer 'rapid'. If possible, we would favour a process that in length is a balance between the initial proposal and this new proposal. |
| Forgotten Lives UK | We are concerned that the surveillance process still does not set or even mention a threshold or limit which will trigger the rapid update process. What rise in efficacy will be sufficient to trigger this? How many variants will there need to be a change seen in to start this process? What type of evidence would be sufficient to demonstrate such a change in efficacy? It is clear from the discussions during the review panels that one of the main stumbling blocks has been establishing the acceptable limit of efficacy, which has led to circular discussions. Therefore, we believe that the parameters that are or will be set in order to start the assessment should be specified. |
| Forgotten Lives UK | Whilst we take on the concerns raise by other stakeholders about timescales for stakeholder submissions and the EAG review we think that 4 weeks is too long, and a compromise of 2 weeks should be implemented. |
| Forgotten Lives UK | We think it's critical that patient, clinical and commissioning experts are allowed to be involved in the committee meetings. We think a pool of nominated lay members/clinical experts would allow decisions to be assessed rapidly/feedback given. |
| Forgotten Lives UK | We think that there must be as much transparency as possible to allow confidence in the decision made. If a public meeting cannot be arranged then the stakeholders/clinical experts at least should be able to attend this. |
| Forgotten Lives UK | We think a 4 week timescale for the consultation period is too long. This should be reduced to 2 weeks as a compromise. |
| Forgotten Lives UK | Whilst we welcome the efficiencies suggested in the revised approach, they are not enough, and we must reduce timescales further. There is still a significant section of the population that has no effective drug in place to protect them from severe infection and are currently still reliant on a small number of treatments if they contract Coronavirus (COVID-19). Many of these people who are affected are now in their fourth year of living a restricted life, with consequences for both them and in many cases their families and households, too. The effects on their mental health are also well documented and the subject of a current study at the universities of Bath and Liverpool.  We appreciate that it is essential that NICE retains its worldwide reputation for transparency, independence, and integrity with regards to healthcare technology appraisals. It is, however, absolutely vital that fast progress is made in the establishment of new assessment pathways tailored to COVID-19 drugs. This needs to be in place as soon as possible, ready to accept newly developed drugs. The call for this faster system is wide ranging with pharmaceuticals, patient groups, professional bodies, clinicians, and NHS England all in support. |
| Pfizer | Companies should be informed at the earliest opportunity that their medicine is being considered for review. Companies should also be given sufficient time to review the surveillance data that has triggered the review. |
| Pfizer | Four weeks will provide stakeholders with enough time to develop a robust evidence submission in most cases. However, there should be flexibility to reduce or extend this window, depending on the complexity of the review and its relative urgency, and in agreed by the Company. |
| Pfizer | We are pleased that NICE have introduced greater opportunities for stakeholder involvement in this process and acknowledge the impact this has had on proposed timelines. However, there will be cases where a more rapid decision is needed and therefore flexibility is needed to allow for more accelerated timelines. |
| Pfizer | We suggest the draft guidance consultation period of four weeks should only apply to negative recommendations or those that will restrict the eligible patient population. A consultation period of four weeks following a draft positive recommendation would introduce unnecessary delays to access (when there is an urgent public need for the treatment) or given the urgency interim funding from FDG could be put in place. |
| Cardiothoracic Transplant Patient Group | The Cardiothoracic Transplant Patient Group (CTPG) appreciates the opportunity to be consulted and comment on the revised approach to Covid 19 medicines.   The transparency of the process has enabled the CTPG to view the comments and opinions from other stakeholders and review your response to these comments.   The CTPG has no further comments to make at this time but wishes to remain as a stakeholder in all future appraisals relating to Covid 19 processes, therapies and preventative treatments. |
| NHSE | Can NICE clarify what constitutes ‘significant uncertainty’ thereby triggering a consultation and the process NICE will use to determine whether this threshold has been reached? There are significant concerns that the process needs to ensure that NICE can take account of all critical information available, including implementation considerations, which could have significant implications for review of recommendations. |
| NHSE | It would be helpful to confirm that there is scope to extend this 4 week period for the external assessment group’s review to ensure that all pertinent evidence is considered. For example, should further clarification be required or if significant uncertainty remains which requires further consideration the process should accommodate this. |
| NHSE | There is significant concern that use of an existing economic model from an original appraisal may not be the most appropriate model to use for updating technology appraisal. For instance, if a new service delivery model or extended associated costs are required. In addition, with the changing healthcare landscape such as COVID testing provisions, it is crucial that these changes are reflected in the underpinning assumptions which inform an economic model.  This could have significant implications on the cost-effectiveness of the technology.  It would be helpful for NICE to confirm the process by which it will evaluate if the parameter assumptions within existing the economic model are appropriate before it is used and confirm that underpinning assumptions will be tested with appropriate stakeholder before proceeding with a review. |
| NHSE | NHSE supports the nomination of all appropriate clinical and commissioning experts to ensure the committee has a rounded view of the issues under review. For example, it is essential that input from commissioners is available to understand the ability to implement updated guidance. |
| NHSE | NHSE is supportive of holding committee meetings in public with a full standing technology appraisal committee. It is of paramount importance that appropriate representation is present. |
| NHSE | NHSE is supportive for a 4-week consultation period. |
| NHSE | NHSE is supportive of the usual process with respect to request to vary the funding requirement. However, NHSE has significant concern that there is a gap in the process which does not enable a revised budget impact assessment to take place at the appropriate stage in the process. It is essential this takes place as early in the process as possible to support decision-making and any requests for varying funding requirements to be appropriately managed. |
| MSD | MSD welcomes the opportunity to participate in the second consultation round pertaining to NICE’s updated proposals outlining a revised approach for the rapid updating of technology appraisal recommendations of COVID-19 therapeutics.   In May 2023, as part of the original consultation, MSD raised significant concerns which were broadly similar with those raised from other stakeholders.  The original rapid review process did not form a good basis for the committee to review decisions due to lack of transparency, the extremely limited stakeholder engagement and the condensed timelines. We were also concerned that it focused on identifying in-vitro mAb studies and thus only the mAbs would be subject to ongoing assessment of clinical effectiveness, leaving other COVID-19 therapeutics without a clear route for reassessment. Additionally, the proposed approach failed to provide a clear framework for the submission of real world evidence (RWE). Whilst mAbs are potentially subject to increased COVID-19 selective evolutionary pressures and the need to have a framework for ongoing surveillance for new variants and in-vitro data is justified, equally so, we do consider that the clinical evidence for AVs may also become less certain as changes in population immunity and COVID-19 variants continue to take place.   It is of paramount importance to set up a transparent framework for any future rapid updates that is both consistent and compliant with the current health technology evaluation manual. This will ensure that any future updates follow methodologically robust processes and are unlikely to be subject to the same level of critique or criticism as was the recent MTA, which was subject to Appeal and with many appeal grounds being upheld by the Appeal Panel in the recent decision.  Whilst we recognise the revised approach represents a change from standard STA processes, we also appreciate that it aims to strike a balance between rapidity and quality by delivering faster updated guidance and also ensuring that stakeholders are better engaged via the ability to make submissions, nominate experts, and actively contribute at consultation stage. All these factors, alongside changes on how committee meetings are held and review decisions are communicated, increase the transparency of the proposed process.   Overall, we welcome most of the changes proposed as they partly address issues flagged in the first round of consultation. However, we still consider that the current proposals lack clarity in places to understand the full extent to which this route can be used in the future by manufacturers. Most importantly, we are cognisant of the exceptionality of COVID-19 guidance and recognise that generation of guidance may require a framework such as the new proposed process, but we consider this is not necessary for other conditions under NICE’s remit. As such it should be explicitly stated in the updated proposal that this review framework is not intended to be rolled out in the future to the standard TAG programme (STA, MTA or HSTs) but is a specialised process for updating the COVID-19 medicines guidance.  We also consider that some uncertainties remain around the new process, which we outline below: • Whilst the revised process now resembles more closely that of the single technology appraisal route, it should be made clear that this is the case from a timeline perspective only when a draft negative decision is issued that requires consultation.  • We welcome the aspiration expressed aiming to conduct the assessment process with the criteria and rigour outlined in the standard health technology evaluation manual, which we consider moves the process in the right direction to avoid the shortcomings of the original COVID-19 therapeutics assessment. • We do ask that the EAG do prioritise these reviews regardless of the type of model the stakeholders select to support their submission and that their review should be as short as possible if the original MTA model is to be repurposed to support a submission (update with clear documentation and justification)  • We do ask that the EAG and NICE are aware that in some instance if any bespoke data analyses are likely to be needed and these are flagged by the EAG at the 1 week clarification station stage, it may not be possible for these to be addressed from Stakeholders on time to inform the Committee meetings • We understand COVID-19’s exceptionality within the HTA evaluation framework and with that in mind MSD consider it paramount that data flow to and quality of OpenSAFELY is not impacted during the transition to ICBs to ensure robust future updates. MSD suggests NICE work with NHS-E to ensure mitigation plans are in place for this situation. • It should be made clear that in the updated proposal this review framework is not intended to be rolled out in the future to the standard TAG programme (STA, MTA or HSTs) other than updating the COVID-19 medicines guidance. |
| MSD | The proposal still appears to be focused on in-vitro clinical data. RWE is emerging and is of paramount importance to understand the real world usage of AVs. The finalised proposal should explicitly state that RWE other than in-vitro studies is in scope for rapid updates and that companies can submit such evidence for consideration. We also consider the implications that limited surveillance may have in the likely number of in-vitro studies being published and this needs to be addressed by widening the scope of RWE under assessment. |
| MSD | OpenSAFELY was discussed extensively in the COVID-19 therapeutics assessment Committee meeting but also by the Appeal Panel. Safeguards should be put in place that enable the robust data flows to the OpenSAFELY platform to continue uninterrupted following the switch from primary care commissioning of COVID-19 therapies to ICBs. As we move into ICB commissioning, costs associated with the delivery of these technologies is expected to change and as such it is important for data flows to adequately capture these changes to aid future guidance updates, particularly given the large impact these assumptions had on the cost-effectiveness of some technologies. |
| MSD | We are concerned that without more detail around this step (including explicit statement that evidence can go beyond in-vitro studies) the whole process will be even less fit for purpose given the reduced data generated from surveillance gathering from the UKHSA.  Given the now necessary reliability on RWE, necessitated by the evolution of COVID-19 and the limitations associated with evidence derived from RCTs in this setting, it is important that such evidence is adequately considered.  Please elaborate on the process of new evidence submission and the type of evidence that stakeholders may submit to trigger an update. What level of information will be required from the companies (ie simple description of the study alongside what elements on the original guidance it may affect)?  Please explain what constitutes significant uncertainty that could trigger a consultation on the update itself. We cannot be certain how often a consultation could be required but if disagreements persist, then the only valuable way forward for resolution is a robust consultation. Therefore consultations should not be treated as exception but rather as the norm in this case. |
| MSD | Please clarify that this constitutes a formal submission of evidence – and that manufacturers have 4 weeks to do so.  Please clarify the logistics around making these types of submissions, such as the template that will be used?  It is important to note that some EAG clarification questions may require additional analyses that may not be possible for manufacturers to generate within the 1 week period.  Please clarify at which stage in the process the company can notify NICE if it intends to submit a new model. Please also clarify whether there is scope for a company to base its re-submission on the original MTA model with any additional optimisations (and a clear list of updates conducted for transparency) if necessary to reflect the requirements of the new submission. If that is the case, we do not envisage that the EAG would necessarily always require extended timelines for the purposes of model review, especially when updates have been agreed. |
| MSD | We welcome the inclusion of this crucial step in the updated process – it is important stakeholders can nominate patient, clinical and commissioning experts when a review of the recommendation is initiated. |
| MSD | We welcome the changes proposed on the conduct of committee meetings in the updated process – it is important for transparent and robust recommendations that committee meetings take place within the public domain, and with the full participation of standing technology appraisal committee members, rather than by a subset of the committee members as proposed originally. Stakeholders, including manufacturers, should be given adequate opportunity to contribute to the evidence discussion. |
| MSD | MSD agree with the need to provide adequate time for a robust consultation and reverting back to the standard consultation period of 4 weeks is welcomed. We anticipate this will overall increase participation from stakeholders including patients, clinical experts, and commissioning experts, as well as providing adequate time for robust participation in the process. |
| MSD | MSD noted the link of cost-recovery charge to the model received. However, we ask for clarity on whether an optimized MTA mode would incur a Rapid review or a standard STA Charge.  We do ask that NICE clarify how the current issues that resulted from following the Process statement in the original COVID-19 therapeutics assessment will be resolved, as these could impact the cost-recovery charges. |
| Kidney Care UK | Thank you for the opportunity to comment on the proposed new approach to monitoring and updating technology appraisal recommendations. We appreciate the work that has gone into NICE’s consideration of comments received and adaptation of the original proposal in response to comments about greater stakeholder participation. It is very difficult to get the balance right between speed and engagement. However, we feel a timetable closer the original described would be more appropriate given the need to provide rapid access to effective treatments.  We suggest the four-week consultation period is shortened to 2 weeks and, as raised in our original consultation response, we request that stakeholders are given adequate notice of the consultation period over which the consultation will occur so that we can plan in the time required to review and respond. In addition, it’s important to consider whether that period consists of 10 working days or the time available is reduced due to national holidays for example. The period should be extended if it is over a period such as Easter or Christmas. We are unsure whether a four-week period to make a submission plus a nomination process for experts, followed by a public meeting with the full committee, strikes the right balance between speed and involvement. It may well be difficult to draft a meaningful submission in less than four weeks, so we would suggest keeping the four-week submission period but consider doing without the nomination of experts and full public meeting (although having a larger pool of patient/clinical/commissioning experts thereby allowing the most appropriate to be selected depending on specifics of the review might be sensible). We would like to see transparency maintained by recording the appropriate sections of the discussion and making these available. We would like the system to be able to adapt to current events. With regard to the model, we are concerned that retaining the original model might be problematic if important assumptions change. For example, CMDUs have closed and the treatments are provided in primary care or via other arrangements. These changes may not trigger a review in themselves but keeping them updated will provide a more accurate assessment of the cost effectiveness of the drug treatments. |
| Immunodeficiency UK | Please can there be some joint working between UKHSA and NICE about surveillance and triggers. As it stands the process appears to be reliant on stakeholders to alert NICE to potential triggers. |
| Immunodeficiency UK | Use of existing economic model: This was based on delivery of medicines via CMDUs. This is now outdated as therapies are now being delivered by individual ICBs. Burden has shifted to primary care providers. These are major changes that need to be factored in an updated economic model. |
| Immunodeficiency UK | To save time and to be better prepared for the rapid review process we suggest that a pool of experts be convened now. Stakeholders should be contacted now about representation. |
| Immunodeficiency UK | Not sure why public meetings will slow the process as online events so much easier to set up and organisations now have much more experience at doing this. Our community values NICE instigating a rapid review process so would be understanding of a short lead in time to avoid delays. |
| Immunodeficiency UK | Please can NICE explain why a full standing TA committee is needed in this regard? |
| Immunodeficiency UK | Please can we go for a compromise of two weeks? We need to keep a so-called 'rapid review' rapid. |
| Immunodeficiency UK | How will the rapid process be distinguished from a full TA review - please explain. |
| AbbVie | Relevant stakeholders would benefit from further clarity regarding criteria used to assess and inform whether a recommendation should be reviewed.  AbbVie request that NICE make efforts to define and share this criteria, so stakeholders submitting evidence and manufacturers of recommended COVID-19 medicinal products understand the decision-making framework that informs appraisal updates. |
| AbbVie | For purposes of transparency and fairness, AbbVie believe that a consultation would be appropriate if there is any dispute between NICE, the surveillance evidence submitter, and any other relevant stakeholder (including the manufacturer of the COVID-19 medicinal product subject to review) over the decision taken by NICE to review a recommendation. |
| AbbVie | This timeline is very useful, please can a similar timeline be provided in the Health Technology Evaluation manual to map out key milestones of the novel cost comparison and Single Technology Evaluation processes. |
| AbbVie | A clarification question response period of 1-week could be challenging but feasible if the number and complexity of questions reflects that of a proportionate review process. However, in exceptional circumstances whereby clarification questions are more extensive than expected, we hope that NICE will be flexible in agreeing an extended response timeline. |
| AbbVie | Economic evaluation is designed to allow the precise understanding of the way quality of life and the costs of providing care evolve over the relevant timeframe the intervention impacts a person’s health. Economic models are more useful decision making aids when they comprehensively reflect the experiences of the patient with a given therapy.  To capture the specific details around the treatment administration, its benefits or side effect profile properly, it's important to have the flexibility to create the right economic analysis structure. However, a set structure lacks the nimbleness to capture value comprehensively.  When the standards of care shift or the evidence changes regarding the impact of disease consequences (e.g. long Covid and the breadth of its impact), a dynamic tool is needed to adapt to and properly mirror the real world understanding of clinical practice and disease background.  As clinical research occurs on a global scale within international trials, it is important to ensure that the correct approximations, assumptions and adjustments are able to be made for extrapolations to be relevant to UK patients. However, a single economic model structure cannot cover each new medicines specific circumstances adequately.  Embracing step changes in innovation by incorporating them effectively into an economic model will foster positive cycles of innovation, benefiting both patients and the NHS. The potential repercussions of taking a single model approach within any treatment line are to reduce the incentives for innovation, particularly via the channel of downgrading the value of care standards across the board. For this reason, we disagree with proposals to give companies the discretion to inform value decisions using a generic, and 'blunt' economic tool that may not fully capture the benefits and costs of any given treatment. This approach would be disproportionately unfair to companies looking to innovate and solve clinical problems for conditions with severe unmet need.  Therefore, even though the companies may have the choice to submit their own economic model, the principle of a lesser type of model being appropriate still warrants examination. We wish to provide caution in shifting towards overly simplistic modelling approaches. |
| AbbVie | In line with standard process, AbbVie believe that technical engagement should remain as an optional component to account for exceptions whereby technical engagement may help to resolve key uncertainties/issues prior to committee meeting? |
| AbbVie | It would be helpful for NICE to clarify how less time allocated for preparation of materials for the committee, and for drafting guidance documents would impact the format of these materials. AbbVie hope that efficiency would be achieved while maintaining both transparency and quality. |
| AbbVie | As previously noted, relevant stakeholders should have the opportunity to request public consultation of any decision to review a recommendation, if they are in disagreement with the decision on the basis of insufficient or unreliable evidence. |
| AbbVie | Please clarify the format in which a stakeholder submission would take, e.g. a full STA submission or otherwise?  It would also be helpful to detail the circumstances in which scoping and decision problem consultation would apply following a surveillance review. Neither of these milestones are listed under the 'proposed process' presented here, and it is unclear whether a re-scoping (including revision of relevant comparators) would be required once a surveillance review had been completed. Furthermore, it is unclear whether any SLR and NMA updates would need to be made prior to stakeholder submissions. These updates would be both resource intensive and time consuming, and based on the 'proposed process' presented, 6 weeks would not be sufficient time to both update relevant SLR/NMAs and generate a robust submission package. In line with NICE's proportionate approach to appraisals, AbbVie hope that NICE can apply a flexible and pragmatic view on this topic. |
| AbbVie | Please clarify when the committee meeting slides would be shared with the company and/or relevant stakeholders prior to the committee meeting? |
| AstraZeneca | AstraZeneca welcomes the opportunity to respond to the revised approach for updating TA recommendations for COVID-19 medicines. We acknowledge the progress made by NICE and appreciate the commitment to finding solutions in ensuring that guidance is reflective of the latest evidence in this evolving landscape. |
| AstraZeneca | In our response below, we have provided feedback on the changes made to the proposed rapid review process and highlighted where further information is required. We were disappointed to see that some of the comments raised by AstraZeneca in response to the previous consultation have not been taken into consideration. We note that all stakeholder comments are listed in the consultation document, however NICE’s responses do not appear to be included. AstraZeneca’s comments concerning the process associated with the use of in-vitro data and neutralising monoclonal antibodies (nMABs) are reiterated below for consideration: |
| AstraZeneca | We recommend that NICE provides further clarity on how surveillance of susceptibility of nMABs on the in-vitro neutralisation against the emergence of new variants is expected to be used to make a determination of clinical efficacy to inform conclusions based on cost-effectiveness. Specifics are needed regarding the duties of the UKHSA, genotyping, and standardisation of in-vitro testing methodology. Additional information is also needed where requirements from companies are concerned, regarding their approach with collaborators to provide evidence on in-vitro neutralisation. |
| AstraZeneca | Currently, we find the draft rapid update process to lack clarity and numerical specificity with respect to cut-off points for determining whether nMABs retain neutralisation and if so, to what degree (i.e., what are the cut-offs for determining whether nMabs retain strong neutralisation, moderate or weak neutralisation, or lose neutralisation?). |
| AstraZeneca | We recommend that until such point that alternative data becomes available, NICE should introduce a framework which concludes that an nMAB can be considered to retain clinical efficacy so long as neutralisation can be achieved (whilst a total loss of neutralisation against a particular variant is likely to mean there is a loss of clinical effect). |
| AstraZeneca | Without providing the clarity, it is not possible for NICE to reliably and routinely use in-vitro neutralisation data to updates to NICE guidance, and in particularly, it’s not possible to NICE, industry or other stakeholders to make a determination of cost-effectiveness without an agreed approach on how efficacy should be inferred on the basis of such in-vitro data |
| AstraZeneca | AstraZeneca appreciates that the extension in the process timeline presented in the consultation document is based on stakeholder comments from the prior consultation. At the same time, we recognise that a number of stakeholder comments advocated for a reduction in the process timeline. Although we share the view that consideration of stakeholder input is of high importance, we hold the opinion that at this time, NICE has not found the right degree of balance between stakeholder involvement and timeliness of the rapid review process. The process needs to be fast enough to enable patient access to treatment options that are efficacious for a condition that is subject to changing variants of concern and seasonality. The current proposal has the risk of recommendations becoming obsolete at the time of publishing. |
| AstraZeneca | NICE recently stated their commitment to find ways to produce more guidance leveraging proportional approaches (Roberts and Benger [2023]. NICE is Transforming: An update on our progress and future ambitions [Webinar]. NICE. https://www.youtube.com/watch?v=PX9RPIMwfqA ); we would expect any rapid review process to be covered within this ambition. To avoid delays in access to COVID-19 medicines, we believe there are opportunities to find efficiencies in the rapid review process without compromising the robustness of the recommendation. Akin to other rapid reviews conducted by NICE, such as rapid updates and appraisal which are evaluated via the cost comparison route, a public committee meeting should not be required, and we recommend that this update should be considered for retraction upon finalisation of the review process. In addition, we believe that the extension of the consultation period for draft decisions from 1 week to 4 weeks is excessive given the likely limited new evidence for which any updates are expected to be made. Whist AstraZeneca acknowledges the need for appropriate consultation, we propose a 2 week consultation to be sufficient. |
| AstraZeneca | AstraZeneca welcomes the reduction in the cost-recovery charge. We note that the stated fee of £106,200 is equivalent to the fee associated with a cost-comparison TA submission, however, we maintain the view expressed in our previous consultation response that this charge is disproportionate compared to the level of review required given that the scope of this consultation extends only to medicines in which final guidance has been published. Nuances of the review processes for new TA submissions and updates to existing recommendations need to be considered. For example, technologies routed through the cost comparison process initially follow the routing of the full STA process. Specifically, these technologies will progress through the full scoping process and include engagement through a decision problem meeting. If a technology is deemed to be appropriate to be considered via the cost comparison route, then the NICE medicines optimisation team are engaged, the EAG are still expected to produce a report and NICE is required to publish a recommendation for the technology. The process appears to be more extensive than what is currently being proposed for updating previous recommendations for COVID-19 medicines. Specifically, in these cases, NICE has already conducted an evaluation on the technology, a new scope will not be issued, and there will be limited new evidence to be considered which may or may not alter the original recommendation. We therefore feel that the revised cost proposed by NICE to be excessive and disproportionate to the work involved. Considering the differences in process, NICE need to provide further information on how the stated charge has been derived and justify how such a charge is in line with cost recovery. |
| AstraZeneca | Given that 30 day funding mandates are implemented for NICE fast-track appraisal timelines, AstraZeneca disagrees with the statement issued by NICE in section 1 asserting that “NICE does not have the ability to alter the legal funding timeframe. It is up to commissioners to decide whether to implement recommendations earlier than the 90 day deadline” in response to comments expressing that “the funding time-frame should be reduced from 90 days to 30 days or interim funding should be available.” The approach taken by NICE remains inconsistent with the goal of the rapid review: creating a process that can rapidly update TA recommendations for COVID-19 medicines. For the proposed process timeline, a 90 day funding mandate is equivalent to a further 64% increase in duration of a process which has been designed to rapidly update recommendations in light of new evidence. Within the context of the rapidly evolving landscape for COVID-19therapies, a 90 day funding mandate puts NICE at risk for producing guidance which immediately becomes out of date and again requires a new update to be conducted. We maintain the view that rapid reviews should qualify for 30 day funding mandates, in line with NICE fast-track appraisal timelines. |