NICE National Institute for Health and Care Excellence

Therapeutics for people with COVID-19

ID4038

Stakeholder information meeting

14 April 2022

Agenda

09:30 – 09:35	**Welcome and introductions**
09:35 – 10:15	**Process discussion** Supporting documents: • Process statement
10:15 – 10:20	**Break**
10:20 – 10:50	**Protocol discussion** Supporting documents: • Pre-invitation scope • External Assessment Group protocol
10:50 – 11:00	**Any other business and close**

Background

- NICE issued a draft scope for consultation in January 2022
- We held a scoping workshop with company, patient and clinical representatives on 25th January 2022
- Comments from a broad range of stakeholders were received during the consultation
- In March we communicated a top-level summary on the outcome
- **Today** is an opportunity to provide more detail on the process that NICE will follow and the approach to the evidence review

Outcome of the scoping workshop

Stakeholder comments on timing

- Broad support for NICE to carry out an evaluation of the clinical and cost-effectiveness of these treatments
  - "As the acute situation is appearing to ease, subject to further variants emerging, we feel that it is important to consider these interventions at an individual and a public health level, taking into account both clinical and cost-effectiveness to guide future commissioning / funding decisions."

- Timing is crucial, but right now is perhaps not the right time to start a multiple technology appraisal
  - "COVID-19 presents a rapidly changing landscape with emergence of different variants."
  - "appropriate for NICE to progress this appraisal once the NHS has moved out of a pandemic situation to treating COVID-19 as part of its usual work-flow."

Outcome of the scoping workshop

NICE's consideration of comments

- Acknowledge the concerns around timing, but as some stakeholders highlighted, a multiple technology appraisal (MTA) can take more than 11 months to reach recommendations.
- NICE would not be able to respond quickly using its standard MTA approach if it becomes clear that guidance is required.
- Taking this all into account, we will be resequencing the steps of an MTA in order to start the academic work to assess the clinical evidence and develop an economic model now, without formally starting an evaluation.
- Developing and validating an economic model first will enable us to be much more responsive and undertake the evaluation stage and produce recommendations in a shorter time frame.

Evaluation process

2 phases:

- **Phase 1 - Academic evidence synthesis and modelling work**
  - NICE commissions the modelling work from an academic group, without formally starting the evaluation
- **Phase 2 - Evaluation and decision-making**
  - using the model developed in Phase 1
- This means that NICE could move much more rapidly to produce recommendations when the timing is right.

Phase 1 timelines are confirmed

	Phase 1
March 2022	External Assessment Group starts work
April 2022	SIM 14 April
May 2022	
June 2022	Deadline for External Assessment Report: 30 June
July 2022	4-week consultation on External Assessment Report (4-29 July)

Evaluation process

NICE will assess the best time to start Phase 2

- Phase 2 will start when NICE issues an invitation for stakeholders to submit evidence
- We will be seeking evidence that is not included in the external assessment report
- Stakeholders will have 28 days to provide any submissions
- Nominations for clinical experts, patient experts and commissioning experts will also be invited and selected at this time

If it is appropriate to move straight from Phase 1 to Phase 2, the earliest it would be possible to hold a committee meeting is October/ November 2022

Governance

- The standard MTA process is detailed in the NICE health technology evaluations guidance development manual.
- This MTA will follow all the steps in this process, but re-sequenced and with shortened timelines because of the exceptional nature of the disease area
- Process statement clearly links the proposed approach to the steps in the guidance development manual
- Changes only relate to process, not methods or committee structured decision-making
- The recommendations will be subject to the usual appeals process

Updated scope

Changes to the scope after the scoping workshop

	Final scope (pre-invite)	Draft scope
Population	• People with mild COVID-19 at high risk of progressing to severe COVID-19 • People with severe COVID-19	• People with COVID-19 who have not been hospitalised • People with COVID-19 who have been hospitalised
Comparators	• Established clinical management with or without corticosteroids and appropriate respiratory support • The interventions will be compared to each other	For people who have not been hospitalised: • Established clinical management For people who have been hospitalised: • Established clinical management with or without corticosteroids and appropriate respiratory support
Outcomes	As per draft scope, except for: • Hospitalisation (requirement and duration).	
Background	As per draft scope, except for addition of: • Distinction between neutralising mABs and immunomodulatory mAbs. • Detail about treatments for people who are non-hospitalised with COVID-19 but thought to be at high-risk of progression to severe COVID-19.	
Other considerations	As per draft scope, except for addition of: • Impact of vaccination status or SARS-Cov-2 seropositivity on the clinical evidence base, generalisability and interaction with other risk factors. • Impact of different variants of concern of COVID-19 on clinical evidence base.	

And, changes to related national policies and updates to scope in line with the 2022 process and methods guide.