Multiple technology appraisal of therapeutics for people with COVID-19 [ID4038]

Process statement

Introduction

1. The standard multiple technology appraisal process is detailed in the NICE health technology evaluations guidance development manual. This multiple technology appraisal will follow all the steps in this process, but re-sequenced and with shortened timelines. This is described below, with cross-references to the relevant sections of the manual.

2. The reasons for resequencing the steps of this multiple technology appraisal relate to the exceptional nature of the disease area. The aim of producing guidance for the NHS on therapeutics for COVID-19 is to inform commissioning decisions on their routine use. However, only starting the evaluation at the point when treating COVID-19 is considered routine activity would not allow NICE to be responsive to the needs of the healthcare system. But there are also challenges with starting an evaluation before that point, when the healthcare system is responding to a pandemic. The aim of resequencing and shortening some of the process steps of a multiple technology appraisal is to mitigate against the challenges of both of these approaches.

3. The evaluation will be split into 2 phases:

    - Phase 1 - Academic evidence synthesis and modelling work
    - Phase 2 - Evaluation and decision-making

Phase 1 - Academic evidence synthesis and modelling work

4. The activities in phase 1 broadly correspond to section 5.6 of the guidance development manual.

5. The External Assessment Group (EAG) will develop an assessment protocol outlining what the EAG will do during the evaluation and the information it will provide in the external assessment report. This will be based on the scope that was drafted after the scoping workshop held in January 2022 (see section 5.6.1 of the guidance development manual).

6. NICE will invite stakeholders to be involved in the appraisal and attend a stakeholder information meeting (SIM) with NICE and the EAG to discuss the protocol. Stakeholders wishing to be involved in the appraisal will need to complete a confidentiality, acknowledgement and undertaking form.

7. The EAG will carry out an assessment of the clinical outcomes and cost effectiveness of the technologies (see section 5.6.15 of the guidance development manual). The assessment will be based on a synthesis of the publicly available evidence.

8. The external assessment report will be sent to stakeholders who will have 28 calendar days to provide comments (see section 5.6.20-1 of the guidance development manual).

Phase 2 – Evaluation and decision-making

9. The activities in phase 2 broadly correspond to sections 5.5, 5.7, 6 and 7 of the guidance development manual.

10. This phase will be initiated when NICE issues an invitation for stakeholders to submit evidence. NICE will be seeking evidence that is not included in the external assessment report. The deadline for receipt of evidence submission will be 28 calendar days from the invitation to participate.

11. Nominations for clinical experts, patient experts and commissioning experts will also be invited and selected at this time as per section 1.3.10 to 1.3.20 of the guidance development manual.

12. The committee's consideration of the evidence will follow the steps outlined in sections 5.7.2 to 5.7.22 of the guidance development manual.

13. Consultation on draft guidance will be as per section 5.7.41 to 5.7.53 of the guidance development manual.

14. The committee meeting to develop final draft guidance will be as per 5.7.54 to 5.7.61 of the guidance development manual.

15. Developing final draft guidance will be as per 5.7.62 to 5.7.67 of the guidance development manual.

16. Committee recommendations will be as per section 6 of the guidance development manual.

17. Finalising and publishing the guidance will be as per section 7 of the guidance development manual.

Addendum – September 2022

18. NICE and the Scottish Medicines Consortium, part of healthcare Improvement Scotland (SMC/HIS) have agreed to collaborate on this guidance so that the recommendations are relevant to the NHS in England and Scotland.

19. SMC/HIS will be involved in the development of the guidance in the following ways:

    - The SMC Chairman will be co-opted to join the NICE committee as a decision-making member
    - An SMC/HIS nominated clinical expert practising in the NHS in Scotland will be selected as an additional clinical expert for the committee meeting
    - Involvement of SMC/HIS staff in the development of the guidance documents.

20. Following resolution of any appeals, the SMC will use the final recommendations as the basis of advice to the NHS in Scotland.

21. The usual obligations for complying with technology appraisal recommendations will apply to healthcare commissioners in England. In Scotland, the MTA advice will have the same status for health board consideration as other SMC advice on new medicines.

Timelines for Phase 1

	Phase 1
March 2022	**External Assessment Group starts work**
April 2022	**Stakeholder information meeting (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)**

Anticipated timelines for Phase 2

	Phase 2
1 August 2022	**Invitation to participate**
28 August 2022	**Deadline for targeted submissions**
18 October 2022	**First appraisal committee meeting**
November 2022	**Draft final guidance issued for appeal**
Dec 2022/Jan 2023	**Final guidance published**

If draft final guidance cannot be produced following the first appraisal committee meeting, the subsequent indicative timelines are currently:

	Phase 2
18 October 2022	**First appraisal committee meeting**
November 2022	**Draft guidance consultation**
January 2023	**Second appraisal committee meeting**
February 2023	**Draft final guidance issued for appeal**
March 2023	**Final guidance published**