Department of Health & Social Care

From Will Quince MP
Minister of State for Health and Secondary Care

39 Victoria Street
London
SW1H 0EU

13 March 2023

Dear Patient Groups and Charities,

The Secretary of State for Health and Social Care wrote to you on 15 December to update you on decisions around Evusheld, access to treatments over Winter, and plans to launch an antibody testing study. This letter is intended to provide an update on these issues before the Department's Antivirals and Therapeutics Taskforce closes on the 31 March.

Evusheld

In that letter in December, we reiterated our decision not to procure Evusheld through emergency routes, and we have published the clinical advice that underpinned the decision as well as details on the decision-making process and governance around it. NICE has been able to expedite its appraisal of Evusheld, and as I'm sure you are aware, NICE has now published its draft guidance[1] which does not recommend Evusheld to protect against COVID-19, citing the lack of clinical efficacy against current variants and those likely to be circulating in the near future. In developing its recommendations NICE has considered evidence from clinical trials and laboratory testing, as well as the experiences of people who are at increased risk from COVID-19.

The draft guidance is open for public consultation until 9 March, after which NICE's independent Appraisal Committee will consider the comments received, ahead of publishing final guidance. Final guidance on the use of a drug is only issued after a very careful consideration of the evidence and engagement with stakeholders.

NICE has recently announced that it is developing a new rapid review process through which it can update its existing recommendations on the clinical and cost-effectiveness of COVID-19 medicines, so they can be made available more quickly to patients if they show promise against new variants. NICE will be launching a public consultation on proposals for the new rapid update process from 3 April.

COVID-19 therapeutics and access to treatments

NICE has separately evaluated the therapeutics currently licensed for the treatment of patients with COVID-19 to establish whether they can be recommended for routine NHS use based on an assessment of clinical and cost effectiveness. Some of these treatments have been made available through the interim clinical commissioning policies that were put in place during the pandemic. NICE's evaluation supports the transition to routine commissioning arrangements as we move out of the pandemic response.

[1] Project information | Tixagevimab plus cilgavimab for preventing COVID-19 [ID6136] | Guidance | NICE

Following a consultation on initial draft guidance in November, NICE published its final draft guidance on 21st February. An overview of NICE's recommendations is shown in the table below. Sotrovimab was not recommended in NICE's draft guidance for consultation, but it has now been able to recommend it following consideration of more clinical evidence and discussions with the company. This is welcome news, particularly for those patients that cannot receive Paxlovid due to contra-indications. Once NICE publishes its final guidance, the treatments that NICE recommends will move into routine NHS commissioning.

Setting	Recommended	Not recommended
Mild COVID-19 (in people who have high risk of progression to severe disease, this setting also includes hospital-onset COVID-19)	• Nirmatrelvir plus ritonavir • Sotrovimab (only if nirmatrelvir plus ritonavir is contraindicated or unsuitable)	• Casirivimab plus imdevimab • Molnupiravir • Remdesivir • Tixagevimab plus cilgavimab
Severe COVID-19 (without supplemental oxygen)	• No technologies recommended	• Casirivimab plus imdevimab
Severe COVID-19 (with supplemental oxygen)	• Tocilizumab	• Casirivimab plus imdevimab • Remdesivir

Antibody testing

The government remains absolutely committed to protecting the most vulnerable, including through prioritised access to vaccines, treatments and free lateral flow testing and tailored advice. I am delighted to confirm that last week, an antibody testing study has been funded by the National Institute for Health and Care Research (NIHR) to establish if antibody testing can identify which immunosuppressed individuals remain at greatest risk of severe COVID-19 infection after vaccinations.

The Stratification of Clinically Vulnerable People for COVID-19 Risk Using Antibody Testing (STRAVINSKY) study will receive £2.8 million and involve 3000 immunocompromised participants over 2 years. 2600 participants will receive a finger-prick antibody test, with 400 receiving more detailed immune analyses. The study will include the analysis of pooled existing antibody testing evidence (>15,000 immunosuppressed patients) from several studies (for example, OCTAVE, MELODY, PROSECO, and other studies) to develop an understanding of how each patient group responds to the programme of COVID-19 vaccinations.

It is hoped the findings will provide clinicians, policymakers, and members of the public with up-to-date information on the incremental impact of the programme of booster vaccinations and inform future advice and targeted medicines for people who are immunosuppressed. We will work closely with NIHR and the research team for interim updates on the study progression.

The researchers will work with the British Society for Immunology to engage with patient groups about the study and their potential involvement. Further information will be available from the researchers when details are confirmed. We have also invited the researchers to present at the Enhanced Protection Programme (EPP) stakeholder forum on 20 March, which we hope you can attend.

I hope you find this update helpful, and my officials look forward to discussing these issues with you further and answering any questions you may have at the forum. I would like to thank you for all of your engagement on these important issues, and want to take the opportunity to reassure you that the patients your organisations represent will remain a priority for us going forward.

Yours sincerely,

WILL QUINCE MP
MINISTER OF STATE