Department of Health & Social Care

39 Victoria Street
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15 December 2022

Dear patient groups and charities,

Thank you for your continued engagement and for attending the Enhanced Protection Programme stakeholder meetings, where my officials provide regular updates on COVID-19 issues impacting the immunosuppressed population. I hope this letter provides a further update on the treatment options available to the immunosuppressed population this winter.

Prophylaxis

In September, the Secretary of State for Health and Social Care wrote to stakeholders confirming that the Government would not procure Evusheld through emergency routes in 2022, because it does not have clear efficacy against Omicron variants. The Department also published the clinical advice that underpins this decision. Since then, we have received a number of questions on the process that led to this decision. As such we have created a GOV.uk page that outlines all of the information publicly available: Evaluation of medicines to prevent COVID-19 - GOV.UK (www.gov.uk).

It remains our position that we should not procure Evusheld at this time, as there has been no significant new evidence to suggest it is effective against Omicron variants, and moreover recent research suggests its effectiveness is compromised against the newer variants that will be prevalent this winter.

We are now aware of preliminary data that suggest Evusheld may have further reduced efficacy at neutralising BQ.1, which represents greater than 40% of all sequenced UK COVID-19 samples[1] according to the latest available data published 25 November, compared to other SARS-CoV-2 variants. The EMA has recently published advice that highlights the reduced efficacy of monoclonal antibodies, including Evusheld, with the current variants in circulation[2]. Evusheld works by providing an initial dose of antibodies that will decline as the body metabolises them. If the level of antibodies falls below a level where it cannot neutralise the virus, or if the variant evades the mechanism of the Evusheld antibodies, it will result in infection and may also drive mutations to create new variants, putting individuals at increased risk.

[1] SARS-CoV-2 variants of concern and variants under investigation: technical briefing 48 (publishing.service.gov.uk)
[2] ETF warns that monoclonal antibodies may not be effective against emerging strains of SARS-CoV-2 | European Medicines Agency (europa.eu)

Due to this changing COVID-19 landscape, with variants that further evade neutralisation by Evusheld growing rapidly in the UK, it is no longer viable to conduct a randomised-controlled clinical trial on Evusheld as originally considered. It has also not been possible to agree terms with the company to enable an Evusheld clinical trial as proposed. We recognise that this is disappointing news, and we will keep this under review as new variants emerge. We would like to reassure you and your members that we continue to closely monitor the market for new prophylactic options and there are other prophylaxis candidates currently being studied in the PROTECT-V trial.

You will be aware that AstraZeneca has made Evusheld available privately in the UK. This is a matter for individual patients and their healthcare providers and is separate to any government consideration of its use within the NHS. Our clinical experts continue to advise there is currently insufficient data on the duration of protection offered by Evusheld in relation to the current variants and any new variants that may emerge.

In the Health Secretary's previous communications with stakeholder groups, we noted that Evusheld is being evaluated by NICE regarding its clinical and cost-effectiveness in preventing COVID-19. This work is underway as a priority and, following agreement with the manufacturer, NICE has already expedited its appraisal of Evusheld for the prevention of COVID-19 by two months. The current timeline would see the draft guidance published in February 2023. NICE will conduct the appraisal as swiftly as possible while maintaining rigorous and impartial appraisal standards.

Access to Treatments

The Government have made available treatment options within the community and in hospital for NHS patients at greater risk from COVID-19. This includes oral antivirals as well as monoclonal antibody and intravenous antiviral treatments. Since December 2021 these treatments have been available from COVID Medicine Delivery Units (CMDUs) and their equivalents in the Devolved Administrations, which provide direct access to community based COVID-19 treatments. During the week commencing 28th November around 1,010 non-hospitalised patients in the UK received COVID-19 treatments, bringing the total patients who have received these treatments to around 111,370.

NICE are conducting a Multiple Technology Appraisal (MTA) to evaluate these treatments for continued use in the NHS. The draft recommendations have now been published and recommend that some, though not all, of these treatments appear to be clinically effective and cost-effective[3] but these may change following the consultation period. The NICE appraisal will influence which treatments the NHS uses over the longer-term i.e. in 2023 and beyond.

[3] NICE recommends 3 treatments for COVID-19 in draft guidance | News | News | NICE

We want to reassure patients that the antiviral treatments currently in use will remain available as treatment this winter. Following a careful review of current data by NHS England experts and recent guidance from the WHO[4], the existing clinical policy access policy for sotrovimab has been amended[5]. It may still be considered as a treatment option where the other available antiviral treatments are not suitable. Other antiviral treatment options this winter remain unchanged, namely Paxlovid as a first line treatment, remdesivir as a second line treatment or molnupiravir as a third line treatment.

Antibody Testing

The primary aim of the autumn COVID-19 vaccine booster programme is to increase immunity in those at higher risk of severe COVID-19 during winter 2022/23. This campaign, alongside the annual flu vaccination programme, will help provide additional protection and help reduce pressure on the NHS. Anyone invited for either a seasonal flu or COVID-19 vaccine is strongly encouraged to take up their offer of vaccination as soon as possible to maximise their protection ahead of winter.

NHS England continues to invite people who are immunosuppressed for all COVID-19 vaccine doses they are eligible to receive, including their COVID-19 autumn booster doses. GPs or hospital specialists invite those with severe immunosuppression based on clinical judgement of optimal timing for the individual concerned. Local COVID-19 vaccination sites have been advised by the NHS to allow people with immunosuppression to self-declare their eligibility for a COVID-19 autumn booster vaccination, and they can also attend walk-in sites to make getting their booster vaccination as easy as possible.

As previously mentioned, we are planning to launch an antibody testing study this winter to investigate the level of protection in immunosuppressed groups following the programme of vaccination boosters. Some early studies[6][7] on antibody and T-cell responses have shown that for some immunosuppressed groups there is an incremental increased response following two or three doses.

We are working with COVID-19 antibody testing experts to develop this study, building on existing data and research infrastructure to enable more informed decisions for interventions, such as additional vaccinations or a future pre-exposure prophylactic and the level of protective behaviours, based on an individual patient's risk.

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[4] https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.5

[5] CAS-ViewAlert (mhra.gov.uk)

[6] Response to additional COVID-19 vaccine doses in people who are immunocompromised: a rapid review - The Lancet Global Health

[7] One-month humoral response following two or three doses of messenger RNA coronavirus disease 2019 vaccines as primary vaccination in specific populations in France: first results from the Agence Nationale Recherche contre le Sida (ANRS)0001S COV-POPART cohort - Clinical Microbiology and Infection

The study aims to start sampling shortly to assess the impact of the autumn booster vaccinations, including the use of bivalent vaccines. It is hoped that results of the research would inform additional guidance for patients and the strategy for a future wider testing programme in 2023. We will provide more information on the study when the details are finalised.

We recognise the impact that COVID-19 continues to have on immunosuppressed groups, and we appreciate your continued interest. We look forward to future engagement with you and other patient groups over the coming months.

Yours sincerely,

WILL QUINCE MP
MINISTER OF STATE