

NATIONAL CLINICAL EXPERT CONSENSUS STATEMENT

Coronavirus monoclonal antibodies as a prophylactic therapy against COVID-19 for immunocompromised groups

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Abstract

- Novel long-acting coronavirus prophylactic monoclonal antibody therapies have been shown to be effective in preventing COVID-19 in immunocompromised individuals who are at increased risk from SARS-CoV-2.
- Prophylactic antibody therapies should be made available in a timely manner to give an antibody immunity boost to vulnerable patients.
- Real world evaluations should be co-implemented to provide confidence of ongoing effectiveness.
- Successful delivery of a coronavirus prophylactic antibody therapy programme would deliver significant benefits to healthcare systems, communities and immunocompromised individuals.

Background

The United Kingdom's clinical response through the coronavirus pandemic has been to protect the lives and livelihoods of individuals. Some individuals have immune systems that are weakened because of their underlying health conditions, or medical treatment, and are immunocompromised.

Individuals who are immunocompromised are at increased risk of severe sequelae from coronavirus such as hospitalisation, intensive care unit admission and death. Vaccination is currently the most effective mechanisms of protection from future SARS-CoV-2 infection reducing disease severity. However, there is evidence that immunocompromised individuals do not mount a full immune response to vaccination, and work from the OCTAVE trial has shown that 40% of patients have low or absent levels of SARS-CoV-2 antibody reactivity compared to healthy subjects after coronavirus vaccination.¹ Furthermore recent work from the UK Coronavirus Cancer Programme has shown that immunocompromised individuals with cancer have much more rapid waning of vaccine effectiveness.² Analyses by the QCOVID consortium has provided confirmation that the use of immunosuppressive drugs or having an immunosuppressive condition is associated with increased hazard ratio for COVID-19 death or hospitalisation.³ Work by ICNARC has shown that 14.0-27.7% of vaccinated critically ill patients admitted to intensive care units in the UK were immunocompromised patients.⁴

Antibody replacement therapy is an effective form of prophylactic treatment that is already part of standard care for patients with primary and secondary immunodeficiencies. Recently, new long-acting prophylactic antibody therapies against SARS-CoV-2 have

been developed and shown to be effective in immunocompromised patients. This treatment could be used in the United Kingdom as a vaccine adjunct to deliver a long-lasting monoclonal antibody booster that could prevent severe coronavirus outcomes in immunocompromised individuals who have not responded to vaccination. If implemented, this would form a new long-term strategy to safeguard and protect immunocompromised patients.

This clinical consensus statement pulls together the expertise from the four nations of the United Kingdom, from 17 clinical specialities responsible for treating immunocompromised groups and provides clinical-based consensus recommendations for the use of prophylactic antibody therapy as a vaccine adjunct in immunocompromised patients.

Rationale and objectives

Access to monoclonal antibodies as a prophylactic treatment against coronavirus, for immunocompromised patients, must deliver additional significant clinical benefit to current standard of care. Seven areas of clinical benefits may be observed for healthcare systems as well as the individuals receiving the treatment.

From an individual patient perspective, the rationale for accessing prophylactic antibody treatments is to prevent direct adverse coronavirus events. This includes, coronavirus infections (1), COVID-19 hospitalisation (2) and coronavirus deaths (3). Indirect patient benefits include improved mental health and confidence to reduce shielding and increase social contact and amelioration of psychological impacts of perceived withholding of treatment (4),⁵ and minimised interruption of existing healthcare programmes (5) (e.g. delays in accessing chemotherapy due to COVID-19).

Additionally, for the broader healthcare system, access to monoclonal antibodies may be beneficial in reducing clinical demand on primary care, emergency services and intensive care (6). This might arise as a result of a reduction in serious sequelae from COVID-19 in immunocompromised individuals. Any reduction in health care demand would reduce the pressures on healthcare systems, especially over the winter months.

Finally, the prevention of coronavirus infections in immunocompromised individuals may prevent the development of new pathogenic variants (7). This might be expected as immunocompromised individuals are more likely to experience chronic coronavirus infections, characterised by persistent shedding of the virus and viral evolution.^{6,7} Ineffectual and prolonged

coronavirus virus eradication increases the potential for SARS-CoV-2 variant immune escape.

Scientific and clinical evidence

The scientific rationale for SARS-CoV-2 prophylactic antibody treatments in immunocompromised groups was established by the PROVENT clinical study.⁸ This study was performed at 87 sites in the United States, United Kingdom and Europe and consists of a study of 5,197 patients. It included adult patients, who were at higher risk of adverse outcome from SARS-CoV-2 infection and included individuals predicted to be poor responders to vaccines, or who had intolerance to vaccines. They were randomised in a 2:1 ratio to receive a single intramuscular dose of Evusheld or a saline placebo.

Evusheld is a combination of two long acting monoclonal antibodies, tixagevimab (AZD8895) and cilgavimab (AZD1061) which bind to distinct sites on the SARS-CoV-2 spike protein. These monoclonal antibodies were engineered to increase longevity of action.

The study demonstrated that Evusheld reduced the risk of developing symptomatic COVID-19 by 76.7% (95% CI 46-90, p<0.001). Symptomatic COVID-19 occurred in 3 of 3441 (0.2%) of the Evusheld group and 17 of the 1731 participants (1.0%) in the placebo group. At extended follow up of 6 months, a relative risk reduction of 82.8% (95% CI 65.8-91.4) was observed. Further efficacy metrics beyond 6 months have not been published.

Following the publication of the trial, a real world evaluation from the United States (the US Department of Veterans Affairs healthcare system) published data from 1,848 immunocompromised patients receiving Evusheld over 7 months during the first Omicron wave.⁹ Outcomes were compared to matched controls using propensity score matching. Similar to results from the PROVENT study, Evusheld patients had a lower incidence of SARS-CoV-2 infection (HR 0.34, 95% CI 0.13-0.87), COVID-19 hospitalisation (HR 0.13, 95% CI 0.02-0.99) and all-cause mortality (HR 0.36, 95% CI 0.18-0.73).

Prophylactic antibody therapy implementation

1. When should prophylactic therapies be given

Prophylactic antibody therapies must deliver benefit to individuals at a period when they are at greatest level of risk from SARS-CoV-2.

Similar to vaccination, protection levels are likely to wane, and this reduction in protection of monoclonal antibody is due to natural monoclonal antibody degradation. Evusheld has been designed with a YTE mutation to triple the duration of response and could afford over 6 months of protection.

This duration of protection must be balanced by the lead-time required to establish the operational structures to implement the clinical programme. Additionally, prophylactic antibody therapies should be delivered when the drug is effective, as it is impossible to predict the future potential emergence of resistant variants.

The SARS-CoV-2 pandemic has been characterised globally by repeated surges in cases. In the United Kingdom, this occurs with new variants and especially in the Autumn/Winter period as a result of more indoor transmission of the virus. Pilot implementation of the prophylactic antibody therapy programmes should therefore occur prior to the Autumn/Winter surge. In practice, an early pilot of a prophylactic antibody therapy programme during the Summer will

ensure that effective clinical systems, processes and training are in place to ensure that the maximal benefits of the programme are achieved.

2. Patient selection

Patients who would derive meaningful benefit should be offered prophylactic antibody therapy. Eligibility should be informed by evidence from published prophylactic antibody therapy studies (e.g. from clinical trials and real-world evaluations), population-scale analyses of risk from coronavirus, and most importantly, comprehensive clinical assessment and judgement by treating clinicians.

Informed patient discussion and consent is crucial to the success of the programme. This should include an explanation that prophylactic antibody therapies should be used in conjunction with coronavirus vaccination (unless the patient is intolerant or has contraindications to vaccination). Patients should be informed that prophylactic antibody therapy will significantly reduce their risk from coronavirus, however, it is not possible to eliminate risk in its entirety. Furthermore, that the use of more than one coronavirus prevention measure, when community rates are high, will deliver greater levels of protection (e.g. combination approaches with handwashing, self- and contact testing, personal protective measures, social distancing, vaccines etc). Finally, significant potential adverse events should be discussed.

To optimise resource allocation, access should be made initially available to those who are most vulnerable to severe sequelae from COVID-19 with expansion in eligibility over time. Selection of individuals at the highest level of risk could encompass known risk features, and this may include

1. Patient diagnosis and or treatments.
2. Laboratory ascertained absent (or low) SARS-CoV-2 spike protein antibody response following vaccination.
3. Patient demographics
4. Vaccination history (intolerance or contraindication of coronavirus vaccination)

The recently published Independent report guideline from the United Kingdom's Department of Health and Social Care (DHSC) outlines identifies 10 of the highest risk clinical subgroups (Table 1).

Table 1. Department of Health and Social Care independent report of highest risk clinical subgroups (May 2022).

1. Down's Syndrome
2. Solid Organ Cancer
3. Haematological diseases and recipients of haematological stem cell transplant/CAR-T therapy
4. Renal disease
5. Liver diseases (e.g. advanced chronic liver disease)
6. Solid organ transplant recipients
7. Immune-mediated inflammatory disorders
8. Immune deficiencies
9. HIV/AIDS
10. Rare neurological and severe complex life-limiting neuro-disability conditions

<https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies>

3. Which prophylactic antibody therapies should be implemented

At the time of publication, only one prophylactic antibody therapy been approved by the United Kingdom's Medicines and Health products Regulatory Agency (MHRA).

Evusheld consists of an administration of tixagevimab and cilgavimab, given as a one-off intramuscular injection. Administration is delivered at different injection sites in two different muscles, preferably in the gluteal muscle. Monitoring is required to identify rare hypersensitivity reactions including anaphylaxis, clinically significant bleeding and cardiovascular and thromboembolic events. Evusheld may be used during pregnancy where the expected benefit to the mother justifies the potential risk to the fetus. There is no data on the treatment benefit or risk to newborn or infants via breast feeding. Evusheld should be delivered as described in the Summary of Product Characteristics (SPC).¹⁰

4. How should clinical care be delivered

Clinical care should be designed to maximise uptake of Evusheld amongst eligible immunocompromised individuals whilst simultaneously making effective use of healthcare resources. This will maximise patient mental health, allow a return to normal working environments and improve quality of life.

The prophylactic antibody therapy approved for use, Evusheld, requires storage at 2°C-8°C in a refrigerator and is delivered by intramuscular injection. These features limit potential avenues for delivery. Delivery channels could include primary care (general practitioners), specialist care (NHS hospitals, cancer treatment centres, dialysis units) or coronavirus pandemic centres (CMDU or NHS vaccination centres). Teams providing clinical care should receive adequate training, and ensure traceability of product for quality assurance.

Where delivery with coronavirus treatment centres is being considered, special precautions should be instigated to ensure that there is minimal risk of transmission of SARS-CoV-2 from individuals with a known infection, to individuals who are seeking to receive prophylactic antibody therapy. This might involve temporal as well as spatial separation between treatment centres. Consideration should be given to training and the impacts of delivery on health services such as Integrated Urgent Care and 111 services and provision made for any additional workload.

Patients should not face barriers from accessing prophylactic antibody therapy arising from digital exclusion or requirements for extensive eligibility checks. Attempts must be made to ensure the prescription process for immunocompromised individuals is optimised (e.g. through use of patient group directives).

Clinical care should continue to improve through integrated/ parallel innovation(s) or research efforts with signposting to relevant trials/opportunities.

Quality assurance

As a new form of therapy with significant potential benefits to patients, healthcare systems and the community, it is important to have a robust system of quality assurance.

Real world evaluations using patient line level data is important to provide the highest level of quality assurance of effectiveness. This data should be analysed at a national level and evaluations should

be delivered to confirm benefit across all of the clinical subgroups. Quarterly, or more frequent, quality assurance analyses should be performed to assess duration of protection as well as to understand the impact of new SARS-CoV-2 variants. Laboratory studies have shown that Evusheld retains activity against BA.4/BA.5 and BA.2.75 though effectiveness against new variants should be monitored.^{11, 12, 13 14}

Real world evaluations could be considered in conjunction with in-vitro laboratory assays, noting the relative strengths of observed human effectiveness metrics. Laboratory assessments remain important to give advance yellow-light warning of reduced prophylactic antibody therapy effectiveness, and/or the need for dose optimisations. Laboratory assessments should be validated, standardised across laboratories and utilise a variety of function assays that are not be limited to viral neutralisation assays.

Ongoing research and innovation

The potential benefits of prophylactic antibody measures and other pharmaceutical measures against coronavirus is dependent on effective, responsive and iterative drug development and pipelines.

Increased Research and Development efforts should aspire to increase competition, and potentially drive up the effectiveness of available prophylactic therapies. Efforts should also be made to signal demand to facilitate greater pharmaceutical company engagement. This will reduce the risk to immunocompromised patients, healthcare systems and communities in the eventuality that a particular prophylactic antibody therapy becomes less effective due to variant escape.

It is important that additional efforts should be made to identify duration of protection and re-dosing schedules and variant specific dosing for immunocompromised patients receiving prophylactic antibody therapy. Reports from the aforementioned studies have not reported on efficacy beyond ~6 months and there is uncertainty as to circumstances on when the 600 mg dose should be utilised.

Finally, infrastructure should be expanded for clinical evaluations. New monoclonal antibodies, human-derived polyclonal antibodies or novel therapeutics should have robust mechanisms and trials/laboratory infrastructure for evaluation in a timely and efficient manner. Similarly, there should be robust processes for timely commissioning, piloting and implementation of next generation prophylactic therapies.

Conclusion

There is strong emerging evidence that prophylactic measures using monoclonal antibodies is an effective strategy for immunocompromised individuals. Successful delivery of a coronavirus prophylactic antibody therapy requires careful consideration of issues such as patient eligibility, timing and delivery. Real-world evaluations should be initiated to ensure clinical effectiveness against potential new SARS-CoV-2 variants. Further research and innovation is important to ensure that immunocompromised patients continue to be adequately safeguarded and protected during the coronavirus pandemic.



Methodology

This expert consensus statement was delivered on behalf of the United Kingdom's All-Party Parliamentary Group for Vulnerable groups by the Clinical Leadership Team. This expert consensus statement was delivered following a national consultation on the 5th of July 2022.¹⁵ Authors consisted of clinicians from all four nations (England/Scotland/Northern Ireland/Wales). Representation was obtained from 17 medical specialities including haematology, infectious disease, immunology, medical oncology, clinical oncology, hepatology, respiratory, renal and transplant medicine, intensive care, surgery, infectious diseases, dermatology, rheumatology, gastroenterology, primary care, clinical psychology and diabetes/endocrinology. Statements were assessed by all authors and considered justified based on clinical expertise.

Disclosures

None of the authors have any conflicts of interest.

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