Evusheld: Government is urged to expedite covid antibody treatment for vulnerable patients

With covid-19 cases rising and winter approaching, immunocompromised patients are frustrated at the government’s inaction on rolling out the preventive drug, reports Gareth Iacobucci

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The UK government has been urged to re-examine its decision not to purchase a new covid-19 antibody drug for clinically extremely vulnerable people, amid warnings that these patients face renewed risk from the disease this winter.

Evusheld, manufactured by AstraZeneca, is a combination of two long acting antibodies, tixagevimab and cilgavimab. It is given as two separate, sequential intramuscular injections and can be administered in the community, unlike some other monoclonal antibodies, which are given by intravenous infusion in hospital.

Evusheld was approved for use in the UK in March 2022 by the Medicines and Healthcare Products Regulatory Agency after trial results showed that it reduced the risk of developing symptomatic covid-19 by 77%, with protection lasting at least six months after a single dose. But in August the government said it will not purchase the treatment yet because of “insufficient data” on the duration of protection it provides against omicron and its subvariants. This remains its position.

Evusheld is currently being submitted for approval by the National Institute of Health and Care Excellence. But, because this process is not due to conclude until well into 2023, clinicians and patients have warned that people who could potentially benefit from the drug will miss out this winter.

Additional vaccine doses “not sufficient”

In a letter sent to the health and social care secretary for England, Thérèse Coffey, on 26 September, Saad Shakir, director of the independent Drug Safety Research Unit, urged the government to make Evusheld available for the most vulnerable patients, alongside robust real time monitoring of any adverse side effects.

Shakir argued that such an approach was taken with other covid-19 treatments and vaccines and that the 500 000 immunosuppressed people in the UK, including organ donor recipients and patients with cancer or leukaemia, deserved the same expedient approach. He wrote, “With the winter months approaching it is becoming increasingly important to provide immunocompromised and vulnerable individuals with protection against covid-19, for these people, providing additional vaccine doses is not sufficient.

“Indeed, there have been covid-19 deaths among this patient subgroup since Evusheld was approved by the MRHA, which perhaps could have been prevented with use of this drug. There will be numerous covid-19 related hospitalisations among clinically extremely vulnerable people if they remain unprotected.”

Policy inconsistencies

The Drug Safety Research Unit argued that the “post-authorisation” approach that was used to roll out covid-19 vaccines and treatments straight after clinical trials, through observational studies and monitoring of adverse reactions through the UK’s yellow card scheme, should also be used for Evusheld.

Lennard Lee, an academic medical oncologist from Oxford University and a member of the National Clinical Expert Group for Immunocompromised Patients, told The BMJ, “We are isolated in this: 32 countries have rolled it out. France, Israel, and America all have data showing ongoing effectiveness against omicron.”

Lee said there was inconsistency between the government’s policy on covid vaccines and its approach to antibody treatments, and he warned that the window for protecting very vulnerable patients this winter was rapidly closing.

“We’ve already seen that the fourth wave of covid is coming now [in the UK], so I’m calling for a pilot—if not an implementation—this winter,” he said. “Other countries are reporting on their outcomes because they rolled this out this for the immunocompromised patients in spring and summer [2022]. We’re very much one of the last to do so.”

Department cites lack of evidence

In a statement sent to The BMJ a Department of Health and Social Care spokesperson said, “We are keeping the evidence under close review, and NICE have begun their appraisal of Evusheld. If they consider the treatment to be clinically and cost effective, it will be made available on the NHS in the usual way.”

The spokesperson added, “To increase the evidence base upon which Evusheld can be assessed, we are urgently exploring commissioning a clinical trial.”

On 6 October the department published a response to two letters from a coalition of charities that had urged the government to shift its stance on Evusheld.
In response, Steve Barclay, Coffey’s predecessor as health secretary, said that the view of the expert panel that advises the government, RAPID C-19, was that there were limitations in sample sizes, methodologies, and overall robustness of the available data on Evusheld. He said that “there remained uncertainty that Evusheld would prevent symptomatic covid-19 caused by current omicron variants in the vulnerable population who would potentially be eligible.”

**Patients exposed to risk**

But Martin Eve, an immunocompromised patient with rheumatoid arthritis and vasculitis who leads the Evusheld for the UK patient campaigning group, told *The BMJ* that the government was “out of line with international consensus.”

“We remain concerned that the UK’s clinical advisers appear to have looked at the same data as the rest of the world but come to the opposite conclusions,” he said.

Eve said that he was still shielding from covid-19 almost completely because of the risk to his health and that he and others felt let down by the government, arguing that Evusheld was “being held to a higher standard than other covid drugs.”

He told *The BMJ*, “The DHSC says that the ‘duration’ of protection is the problem. Yet the rapidly authorised Moderna vaccine specifically states that ‘it is not known [for] how long you will be protected.’ The calls for further randomised trials on this vulnerable group at this point are also unethical. You don’t test parachutes that have been shown to work 80% of the time in the real world by giving them to only 50% of people jumping out of a plane.

“The immunocompromised are told, time and time again by the DHSC and JVCI, that although the vaccines will not provide them with full protection, ‘something is better than nothing.’ The DHSC takes the opposite view on Evusheld, telling us that unless it does everything the department will give us nothing. As a result, a significant patient population in the UK will now continue to live in isolation and at extreme risk over a third winter of covid.

“We’re not naive that this gives us 100% protection. We’re just asking for additional partial protection right now as an urgent measure that is needed this winter.”

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