Citizen Participation and Public Petitions Committee

2nd Meeting, 2023 (Session 6), Wednesday 8 February 2023

PE1950: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Lodged on	9 August 2022
Petitioner	Alex Marshall
Petition summary	Calling on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld prophylactic treatment for people who have zero or weak response to the COVID-19 vaccines
Webpage	https://petitions.parliament.scot/petitions/PE1950

Introduction

1. The Committee last considered this petition at its meeting on 9 November 2022. At that meeting, the Committee agreed to write to the COVID-19 Therapeutics Clinical Review Panel, Blood Cancer UK, Immunodeficiency UK, Kidney Research UK, the Scottish Medical Council and the Medicines and Healthcare products Regulatory Agency. It also agreed to invite the petitioner and/or the patient campaign group, Evusheld for the UK, to give evidence at a future meeting.

2. The petition summary is included in **Annexe A** and the Official Report of the Committee's last consideration of this petition is at **Annexe B**.

3. The Committee has received new responses from the Scottish Medicines Consortium, Immunodeficiency UK, Blood Cancer UK, Kidney Research UK, and the Petitioner, which are set out in **Annexe C.**

4. Members may wish to note that the petitioner has declined to participate in the evidence session on the basis that they consider the emergence of new COVID-19 variants to have rendered the Evusheld treatment ineffective.

5. Written submissions received prior to the Committee's last consideration can be found on the petition's webpage.

6. Further background information about this petition can be found in the SPICe briefing for this petition.

7. The Scottish Government's initial position on this petition can be found on the petition's webpage.

Action

The Committee is invited to consider what action it wishes to take.
Clerk to the Committee

Annexe A

PE1950 : Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Petitioner

Alex Marshall

Date lodged

9 August 2022

Petition summary

Calling on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld prophylactic treatment for people who have zero or weak response to the COVID-19 vaccines.

Previous action

Written to MSP and MP

Background information

Immunosuppressed people are at high risk of serious illness or death.

In a similar petition to the UK Parliament, the petitioner notes:

- Lockdown and shielding has not ended for many people with blood cancer, organ transplants, and other forms of immune compromise
- Treatments like Evusheld may offer protection for immunosuppressed people, similar to the way COVID-19 vaccines protect much of the wider population.

The clinical trials for Evusheld, showed positive results and was found to reduce the risk of developing symptomatic COVID-19 by 77%. As a result Evusheld has been authorised by the Medicines and Healthcare products Regulatory Agency (MHRA).

This treatment has also been recommended for authorisation by the European Medicines Agency, with further information on the clinical trial and decision to approve Evusheld in the UK available in the BMJ.

Annexe B

Extract from Official Report of last consideration of PE1950 on 9 November 2022

The Convener: PE1950, on ensuring that immunosuppressed people in Scotland can access the Evusheld antibody treatment, was lodged by Alex Marshall. It calls on the Scottish Parliament to urge the Scottish Government to enable access, via the NHS, to Evusheld prophylactic treatment for people who have had a weak or zero response to Covid-19 vaccines.

In raising the petition, Alex highlights that lockdown and shielding has not ended for many people who are immunocompromised, such as those with blood cancer and organ transplants. He suggests that treatments such as Evusheld could offer protection to immunosuppressed people who have so far shown a weak or zero response to existing Covid-19 vaccines. Alex tells us that clinical trials have shown positive results and were found to reduce the risk of developing symptomatic Covid-19 by as much as 77 per cent. As a result, Evusheld was granted a conditional marketing authorisation by the UK Medicines and Healthcare products Regulatory Agency.

In response to the petition, the Scottish Government noted that Evusheld was developed and tested before the emergence of the omicron variant and that further testing is required to establish whether the treatment is effective against omicron variants. I note that omicron was identified some time ago. As such, there no established UK supply arrangement for Evusheld currently.

The Government states that it will closely monitor the outcome of further research and that it will write to update the committee in the event that there is a decision to make Evusheld available to patients in Scotland.

The committee has also received a submission from Blanche Hampton. She has shared her experience as an immunocompromised person who has had zero response to six vaccinations and who is now shielding again. Blanche has highlighted the fact that Evusheld is provided in other countries and that no negative effects have been reported.

Before I ask members for comments or suggestions, I see that we are again dependent on our old friends the MHRA, with which the committee has had dealings in the past. Those dealings have not always been terribly satisfactorily. Therefore, given that the conditional marketing authorisations were granted prior to the omicron variants and that no UK supply arrangement exists for Evusheld, I wonder whether, among any other recommendations that we might have, we should contact the MHRA to ask about the status of any evaluation that it might undertake. The omicron

variants became apparent some time ago and I would have thought that there might be more urgency about assessing the implications of Evusheld.

As the submission from Blanche Hampton says, Evusheld is provided in other countries and no negative effects have been reported. I wonder whether we can establish any practice in relation to that and, if there is, we could draw that to the attention of the MHRA and the Scottish Government.

It has been reported in the media and elsewhere that people who are immunocompromised face a hugely debilitating sense of continuing exclusion and isolation, when the rest of the world has largely moved on. It seems unreasonable that we are not expediting every opportunity to make life more acceptable for them. Do committee members have any other suggestions or comments?

Alexander Stewart: I suggest that we write to the UK Covid-19 therapeutics advisory panel, to seek information on the considerations that it has given to making Evusheld available as an antibody treatment to patients. We should also write to Blood Cancer UK and Kidney Research UK, to seek their views on the issues that have been raised by the petitioner. In addition, we should write to the Scottish Medicines Consortium to request the review of its decision to wait for the National Institute for Health and Care Excellence report to provide access, via the NHS, to the Evusheld treatment for people who have zero or limited response to Covid-19 vaccinations. Finally, we should invite the petitioner and patient groups that campaign on the need for access to Evusheld to give evidence.

The Convener: I am not sure whether I heard you, Mr Stewart. Did you include Blood Cancer UK, Immunodeficiency UK and Kidney Research UK as organisations that we might write to? Are you content that the committee approaches them?

Alexander Stewart: Yes, absolutely.

The Convener: There any no other comments or suggestions from the committee.

We have the Scottish Government's response. Could we slip in an extra question when the Cabinet Secretary for Health and Social Care is next with the committee? As the topic is fresh in our minds, if the cabinet secretary is with us next week, we could do that, just to get an understanding of what the Government could do to accelerate access. It is a matter of considerable public concern. The cabinet secretary might prefer to wait until a later date, but let us see whether that is a possibility.

Are members content with that approach?

Members *indicated agreement.*

Annexe C
Scottish Medicines Consortium submission of 9 December 2022

PE1950/C: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Thank you for your letter dated 14 November 2022, in relation to PE1950 and “the request for a review of the SMC decision to wait for the NICE report, and provide access, via the NHS, to Evusheld® prophylactic treatment for people who have zero or limited response to the COVID-19 vaccines”.

The remit of the Scottish Medicines Consortium (SMC) is to provide advice to NHS Boards and their Area Drug and Therapeutics Committees across Scotland about the status of newly licensed medicines and new indications for established products.

Throughout the COVID-19 pandemic, SMC and NICE have collaborated with other UK partners to ensure rapid access to effective treatments for COVID-19 through the Research to access pathway for investigational drugs for COVID-19 (RAPID C-19) initiative. This collaboration has ensured early patient access to effective COVID-19 therapies in a clinical area with rapidly changing evidence.

SMC and NICE have agreed to extend their partnership working, through alignment of guidance on the NICE technology appraisal of tixagevimab–cilgavimab (Evusheld®) for preventing COVID-19 (Joint statement: NICE and SMC/HIS collaboration (scottishmedicines.org.uk)). SMC will be part of the appraisal and decision making process and will input directly to the technology appraisal through co-opting of an SMC member to the NICE committee. In addition, an SMC nominated clinical expert practising in NHS Scotland will be present as an additional clinical expert for the committee meeting. The committee is meeting on 24th January 2023, with final guidance expected to be published on 4th April

2023. NICE and SMC will produce separate guidance and advice documents, based on the shared assessment process. In Scotland, the advice will have the same status for health board consideration as other SMC advice on new medicines.

I hope this helps clarify the position.

Immunodeficiency UK submission of 29 November 2022

PE1950/D: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Immunodeficiency UK strongly supports this petition. COVID-19 poses an immediate and significant risk to subgroups of people with immunodeficiency (ID). Mortality rates remain high. Evusheld would provide a protective therapy to help high risk patients with primary (PID) or secondary (SID) immunodeficiency to re-enter society and live more normal lives.

Patient: *'I do not currently feel safe with the treatments available in the UK. At the moment, if we contract Covid we are given post-exposure therapies. This then relies on us taking the risk of becoming infected and then seeking help. This feels incredibly risky and, as a result, we are still shielding with incredibly limited lives'.*

PID and SID covers a diverse range of immune conditions, and many patients may have mounted a good protective response against COVID through vaccination, however, there's no routine testing of antibody levels & T cell function to test this, leaving people in limbo concerning their COVID risk. Expert clinical judgement is needed to decide which patients would benefit most from Evusheld, based on individual vaccine response data/knowledge of underlying condition/co-morbidities. A 'National Clinical Expert Consensus Statement endorsed by 120 clinicians highlights medical profession's opinion of unmet need.

Evusheld is currently the only option for preventing COVID-19 infection. It's:

- Available in 33 other countries; UK is the only G7 country where unavailable.
- Available on private prescription (19/10/22); access costs £2,000-£2,600 leading to an inequity and survival of the wealthiest scenario. **The only solution is access via the NHS to those patients who would benefit most.**
- Being reviewed by NICE - guidance expected 23rd May 2023 - 441 days after MHRA approval - too late to give protection to high risk patients over this winter's COVID wave. Immunodeficiency UK's submission to NICE is here.

Recent evidence for effectiveness at reducing death, hospitalisation, ICU admission and preventing infection:

1. Tixagevimab/cilgavimab for prevention and treatment of COVID-19: a review

2. Pre-exposure prophylaxis with tixagevimab and cilgavimab (Evusheld) for COVID-19 among 1112 severely immunocompromised patients.

3. Covid-19: Evusheld protects the most vulnerable patients, analysis shows

New data is showing Evusheld has decreased efficacy against emerging new variants.

Benefits of Evusheld:

- Helping people re-enter their workplace/carry out normal activities of daily family life/social interaction and ensuing socio/economic benefits
- Preventing infection/reducing fear of getting infection from family members or in a work-related environment
- Reduced call on CMDU services, use of anti-virals, reduced clinical demand overall – GPs, A&E, hospitalisations, ICU costs
- Prevention of new pathogenic escape variants due to inability of some immunocompromised people to clear COVID-19, even after treatment with anti-virals. COVID infections in

immunocompromised are a possible driver of mutations (https://www.nature.com/articles/s41467-022-30163-4)
- Demonstrating that health system is **supporting all members of society** in an equitable manner.

Health risks from COVID-19

COV-AD study data https://doi.org/10.3389/fimmu.2022.984376 from Jan 2021 - April 2022:

- Vaccination programme significantly reduced hospitalisation and mortality, but mortality rates are higher than general population. In PID/SID - 10% of individuals infected with Omicron required hospitalisation and 2.7% of individual died versus 2.2% of general population requiring hospitalisation and 0.2% dying.
- Inpatient mortality remains high (19% for PID, 42.8% for SID) suggesting if people end up in hospital, then that is a poor prognostic sign.
- Since the deployment of CMDUs, 61.4% (n=70/114) of treatment eligible patients actually got treatment from a CMDU after testing COVID+. Significantly lower rates of hospitalisation (4.3% vs 15.9%, p=0.03) amongst individuals treated by CMDU but overall mortality is not affected (2.8% vs 4.5%, p=0.63).
- By April 2022, only 23% of ID individuals had suffered >1 COVID infections, compared to over 71% of general population.

PID/SID patient experience survey data (August 2022; 439 respondents) showed:

- 30% of respondents not going out at all, 43% had little confidence; 16% moderately confident; with only 11% mostly confident/very confident, reinforcing that people are continuing to shield.
- COVID has impacted quality of life (QoL). When rating QoL, (scale of 1 -100; poor - excellent), patients reported an average rating pre-pandemic QoL of 79 compared to QoL rating of 30, at survey date.
- Shielding having a severe adverse effect on mental health. Anxiety, fear, depression, isolation, lack of social interaction, panic attacks, and PTSD, income and ability to earn a living has led to loss of jobs/businesses. There's a constant fear from infections brought home by others; broken relationships caused by strain of shielding, people with ID living away from loved ones so that unaffected family members can get on with their lives. Many carers are shielding/leading very restrictive lives to protect relatives.

Carer: *'Despite 5 Pfizer vaccine doses my wife has no antibodies (test paid privately as told not available under NHS) she has no protection to covid and thus our lives are now so different. I've had to stop work to protect her and we have no social life merely living an existence at home and going nowhere.'*

Blood Cancer UK submission of 16 December 2022

PE1950/E: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

There are approximately 650,000 immunosuppressed people in the UK, of which over 80,000 are in Scotland. This group have medical conditions, or take certain treatments, that weaken their immune system and render them highly susceptible to infections, severe disease, and death. Due to their weakened immune systems, many also do not elicit a strong immune response from the Covid-19 vaccines, meaning they remain at very high risk from Covid, unlike most of the general population.

Evusheld

It is vital that this group has access to an effective preventative Covid treatment, because of their higher risk of severe illness and death. Evusheld is the only preventative Covid treatment approved by the MHRA (on 17 March) but it has yet to be procured. Real-world data from countries in which Evusheld is available show that immunocompromised people who took Evusheld had better outcomes. In one Israeli study, conducted during the BA.1 and BA.2 wave, patients who took Evusheld were half as likely to become infected with Covid, and 92% less likely to be hospitalised or die.[1]

[1] https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac625/6651663

Lab-based and real-world evidence show that Evusheld is effective against Omicron BA.1, BA.2, BA.4 and BA.5 (to varying degrees). However, it is uncertain whether it is effective against the currently dominant variants BQ.1 and BQ.1.1 (which are subvariants of BA.5) and other circulating variants such as CH.1.1 and XBB. In the week ending 30 November, BQ.1 and BQ.1.1 made up 52% of all sequenced Covid cases in the UK. CH.1.1 made up 12%, and XBB made up 4%.[2]

Findings from a pre-print lab-based study using pseudovirus suggest that Evusheld does not neutralise the above variants of the virus.[3] A further pre-print using live virus also suggests that Evusheld does not neutralise BQ.1 (but did not test for other of the above variants).[4] Further studies have yet to be published, but it is expected that more will be made available in the coming weeks and months. While these results suggest that Evusheld is incapable of neutralising these variants, there is a lack of consensus among clinicians and researchers as to how closely lab results translate into real-world efficacy, due to a lack of pharmacokinetic and pharmacodynamic data. For more information on these studies, Blood Cancer UK's assessment of the available evidence, and what this might mean for people living with blood cancer, see our blog post on this topic.[5]

While some variants against which Evusheld has been proven to offer protection remain in circulation, the prevalence of these variants is relatively low. It is therefore unclear how much protection Evusheld offers in the current context. In the United States, clinical guidance recommends that Evusheld be used in regions where the above variants are not prevalent, while considering individual patients' risks and circumstances.[6]

Vaccine (in)efficacy

For immunocompromised people, their risk of death from Covid is higher than those with strong immune systems, even after vaccination. One study, published on 27 September, shows that, after a third vaccine

[2] GISAID data, accessed via covSPECTRUM: https://cov-spectrum.org/explore/United%20Kingdom/AllSamples/Past6M
[3] https://www.biorxiv.org/content/10.1101/2022.09.15.507787v4
[4] https://www.biorxiv.org/content/10.1101/2022.11.17.516888v2
[5] https://bloodcancer.org.uk/news/evusheld-does-it-work-against-omicron/
[6] https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/

dose, only 22% of patients with blood cancer had generated antibodies that could help neutralise the virus, and that of those only 58% had a T cell response. Of those without neutralising antibodies, only 45% had a T cell response.[7] This level of severe immunosuppression has clear consequences: among the unvaccinated, the immunocompromised make up 2.4% of Covid ICU admissions (in England, Wales, and Northern Ireland); among those with 3 vaccine doses, this is 27.7%. Further to this, vaccine uptake among this patient cohort is relatively low. In Scotland, only 60.4% of clinically vulnerable 5 – 64 year-olds have had their autumn booster (as of 7 December, according to PHS). While severe outcomes in the general population have been mitigated by our vaccines programme, protections for the immunocompromised remain inadequate.

Post-exposure Covid treatment

While the protection mechanisms for the immunocompromised has relied upon post-exposure Covid treatments, these treatments are currently undergoing an appraisal by the National Institute for Health and Care Excellence (NICE), in collaboration with the Scottish Medicines Consortium (SMC). Their draft recommendations would withdraw all community treatments but one: Paxlovid. Paxlovid, however, has drug interactions with a significant number of cancer treatments used to treat and manage blood cancer. If these recommendations come into force in the spring, people with blood cancer for whom Paxlovid is contraindicated by their cancer treatments will either have to pause their cancer treatments to take Paxlovid (which can have long-ranging and devastating consequences), or wait until their Covid infection develops to such severity that they are hospitalised and placed on supplemental oxygen. Only at this clinical point is the next Covid treatment (tocilizumab) licensed for use.

Considering that the immunocompromised are protected only by vaccines (which, for many, do not adequately protect them) and by the post-exposure Covid treatments (which, in the spring, will become inaccessible to some of the blood cancer patients at highest risk), it is

[7] https://aacrjournals.org/bloodcancerdiscov/article/doi/10.1158/2643-3230.BCD-22-0077/709472/Anti-spike-T-cell-and-Antibody-Responses-to-SARS

vital that a safe and effective preventative Covid treatment is made available for those at the highest risk.

Kidney Research UK submission of 5 January 2023

PE1950/F: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

Kidney Research UK recognises that the Medicines and Healthcare products Regulatory Agency (MHRA) and the Scottish Medicines Consortium (SMC) are internationally respected bodies in assessing the safety and effectiveness of new medicines. However, we are deeply concerned that a return to 'business as normal' for assessing new treatments for COVID-19 is deeply unsuitable, both for patients and the health system.

COVID-19 is a rapidly evolving virus, and we recognise the significant challenge this creates for regulators and reimbursement bodies. The UK adapted to these challenges in 2020 by enabling rapid access to vaccines and treatments for Covid-19 without the need for traditional health technology assessment. We must learn from this and continue to adapt to deliver for the most vulnerable in our society.

We need a system which accepts the inevitability of additional uncertainty given ever-changing Covid-19 variants and mutations. This must also offer additional flexibility to ensure there are multiple treatment options available to patients on the NHS, including prophylactic (preventative) treatment for people who have zero or weak response to the COVID-19 vaccines.

The risk of COVID-19 to those who are immunocompromised must be a priority for policymakers, particularly as widespread evidence suggests that vaccination is less effective in transplant recipients. The importance of the vaccination and booster programme is undoubted, but we must not forget those for whom it is sadly less effective.

Prophylaxis treatments, such as Evusheld, have offered significant hope that those who have been shielding for two and a half years may have a route to exit shielding. However, opportunities to accelerate the procurement of this treatment, as taken up by 32 other countries, were not taken. Decision-makers must commit to rapidly reviewing and providing access to new prophylaxis treatments that are shown to be effective against new variants and mutations of COVID. Committing rigidly to traditional health technology assessment routes restricts the opportunity to utilise effective treatments during peak virus periods, with a prolonged period of assessment unable to keep up with rapidly evolving viruses.

Petitioner submission of 31 January 2023

PE1950/G: Ensure immunosuppressed people in Scotland can access the Evusheld antibody treatment

I regret I will not be attending the evidence session on 8th February.

Since I started the petition 6 months ago, new coronavirus variants have rendered Evusheld useless and so I cannot pursue the issues raised.