

## Single Technology Appraisal: Tixagevimab–cilgavimab for preventing COVID-19 Kidney Care UK Patient Organisation Submission

### Kidney Care UK - Key messages

<p><b>In up to 5 bullet points, please summarise the key messages of your submission.</b></p>	<ul style="list-style-type: none"><li>• Shielding and other restrictions are severely affecting the quality of life, mental and physical health, financial security, social connections and achievement of personal goals of people who remain at much higher risk from Covid and are less protected by the Covid vaccine. Impacts are felt also by family members.</li><li>• As well as the impact of shielding/behavioural restrictions the anxiety and constant vigilance engendered by immunosuppressed people’s ongoing risk from Covid is having a grave impact on mental health and quality of life.</li><li>• The extra layer of protection provided by a prophylactic treatment would enable people to start to resume a normal life. Even if individuals choose to retain some restrictions, small steps towards normality would be life changing for many.</li><li>• A prophylactic treatment is an opportunity to move towards equality for what’s become a marginalised group in society.</li><li>• The lack of effective protection that does not have the huge mental, physical, economic health impact of shielding or restricting behaviour is a clear unmet need.</li></ul>
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<p><b>How did you gather information about the experiences of patients and carers to include in your submission?</b></p>	<p>The information and views represented in this submission has been gathered through a range of sources:</p> <p>Kidney Care UK advocacy services and Facebook support group, the views of Kidney Care Staff who are kidney patients, our Patient Advisory Group. We have also run regular surveys throughout the Covid pandemic to capture the experience and challenges faced by people with kidney disease. These have collected over 2,500 responses in total. Our series of 10 Covid Question Time webinar has also provided a significant insight into people’s experiences and concerns. Throughout the pandemic people with kidney disease have turned to the charity for advice, information and guidance and to share their experiences. This has provided a very deep and broad understanding of the experience of this group.</p> <p>We also ran a survey to inform this submission, asking about the impact of living with Covid when immunosuppressed and views on the advantages and disadvantages of the technology. We invited responses via our e-newsletter, social media channels and website and gathered responses from 181 people who are severely immunosuppressed or carers/family members.</p>
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<p><b>Living with the condition -</b> <b>How has shielding from COVID-19 affected vulnerable people?</b></p>	<p>Covid continues to have a major impact on the lives of people who remain at higher risk and are likely to be less well protected by the vaccine:</p> <ul style="list-style-type: none"> <li>• <b>93% of survey respondents said Covid had affected their day-to-day activities in the past month. 93% said it had affected their family or social life.</b></li> <li>• <b>59% of respondents said they were extremely worried about their risk from Covid, 31% very worried, 6% moderately, 1% slightly and 1% not at all.</b></li> <li>• <b>When asked how their risk from Covid had increased their levels of stress and anxiety over the past month, 40% said it had extremely, 36% very much, 14% moderately, 7% slightly and 2% not at all.</b></li> </ul> <p>Many people at higher risk who may not describe themselves as shielding are carefully following current Government guidance on how to reduce their risk. These behaviours can have very similar negative affects to shielding but people feel they have no choice but to follow them in order to keep safe.</p> <p>Shielding and other restrictions are severely affecting the quality of life, mental and physical health, financial security, ability to maintain social connections and achieve personal goals of many immunocompromised people. Impacts are felt also by family members. We have grouped impacts into themes, with illustrative quotes from respondents to the survey run to inform this response:</p> <p><b>Impact on mental health</b></p> <p>Many people reported struggling with feelings of anxiety and low mood, following an extended period of shielding and living with heightened risk of Covid. Our survey of kidney patients (343 responses received) carried out in Feb/Mar 2021 when restrictions were starting to ease found 68% of respondents would like continued mental health support to help them cope as restrictions ease (Kidney Care UK, 2021). The survey to inform this response found impact on mental health continues, quotes include:</p> <p><i>Simple tasks such as going to the dentist, hospital, hairdressers are all filled with fear</i></p> <p><i>Constantly risk assessing situations that healthy people take for granted is exhausting and stressful. You never know your own level of exposure to Covid, and it leaves you doubting, fretting and regretful if you go somewhere that felt too busy. It basically saps all the fun and ease from life</i></p>
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*These restrictions have definitely affected my mental health, and I am much more anxious. I also see myself differently; before 2020 I had an active life, now I feel unable to do most things I used to enjoy outside the home.*

*I've been shielding for 30 months. I only go to clinic appointments. I fight depression everyday, everyday feels wasted as my life is on hold. Have lost fitness, am lonely, despairing. The thought of the winter and increased risk through having to close windows really frightens me - in addition to kidney transplant I have asthma. I think I'm clinically depressed due to 30 months of essentially lockdown.*

*I am shielding still and don't leave the house, my husband has to turn down face to face work and shields with me. My mental health is very poor and I often think about suicide*

### **Physical health**

Respondents reported problems with maintaining physical health. Reasons include being fearful of attending in-person medical appointments, unable to continue with physical activity due to shielding/avoiding crowds, difficulty sleeping due to reduced levels of activity as well as heightened anxiety, challenges to following a healthy and varied diet when shopping online only:

*Not able to go swimming which was my main form of exercise before Covid.*

*We had a good social life going to ballroom dances which is physically and mentally important but have not been able to do this for the past 2.5 years. We are existing rather than living.*

*My sleep pattern has been altered due to anxiety and the need for constant hypervigilance.*

*Before the pandemic I never missed a health appointment - now far too risky to go to the opticians, dentist, GP's and hospital because the rules have been relaxed.*

*I have to have everything delivered, unable to access all the deals in store (making it more expensive during a time when money is getting tighter) reliant on what is in stock on the day (which often leads to key ingredients missing making healthy food prep difficult)*

### **Financial health/employment**

Throughout the pandemic we have heard from vulnerable people who have missed out on opportunities because of having to work from home or had to give up their jobs entirely. Survey responses included:

*I had to stop my wedding photography business as the risk of mixing with large groups is very high. I have lost a lot of income. Trying to build a new business so I can work from home - it is very difficult to get new business up and running as I can't meet people in person.*

*I continue to work at home so am missing interaction with work colleagues and missing opportunities I don't socialise anymore. I am unable to perform my job (self-employed cafe owner) as I feel uncomfortable/ at risk being in close proximity to attend who may or may not have Covid*

### **Impact on daily activities**

Respondents to our survey reported that shielding and trying to reduce their risk from Covid meant they had had to give up activities that had brought fulfilment and richness to their lives pre-Covid, including hobbies and interests, attending church, voluntary activities, helping in children's school activities:

*I am a scout leader but have not attended scouts since February 2020 except for online events. I have missed many social and family events because of the need to minimise risk*

*Our lives have been affected by: No working, normal family visits, going out socialising eg restaurants, pubs, concerts, theatre, football & NO holidays. Everything in our lives as been destroyed. Life is now about survival.*

*I'm still anxious about travelling on buses and being around people in general. I go to a few shops at quiet times, but I have barely left my hometown since 2020, and have missed many many events and chances to catch up with friends. I don't drive and have to rely on others for getting anywhere including hospital appointments. I am back at my volunteering but only a couple of hours a week because I can get a lift and Sunday mornings are quiet.*

**As a number of these quotes have shown, the impact of shielding and anxiety caused by being at higher risk of Covid often extends beyond the person with kidney disease to their carers and family.** They may be shielding or restricting their activities to reduce the risk of passing on Covid, and the anxiety they feel about their loved one being at high risk can be difficult to deal with:

*My family's lives circumscribed along with mine, to keep me safe. At first lockdown husband decided to shield with me, had no idea we would still be effectively doing so this long. Mentally, living with 'living with Covid' takes its toll on such a sociable and outgoing person. And I mind for him, as well as for me. He follows the guidance, as do all the rest of the family to protect him, but it curtails all normal social activities and isolates not only himself, but his wife who is his carer too.*

	<p><i>I'm distant from my children when they're back at school, ..., strain on my relationship due to my not wanting to 'live with Covid', my adopted children have missed out on opportunities because I can longer provide the opportunities I once could.</i></p> <p><i>It affects every single day. I cannot do anything without thinking of the risk of catching it or bringing it to my twin sister who already had her kidney transplant.</i></p>
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<p><b>Is there an unmet need for patients with this condition?</b></p>	<p><b>Yes, effective protection from Covid that does not have the profound impact of shielding or restrictions is an unmet need for patients less likely to be protected by Covid vaccines.</b></p> <p>People who are immunocompromised are arguably in a worse situation now than during wave 1 of the pandemic. Although Covid is still circulating, shielding is no longer an option for most. There are currently no alternative methods of protection.</p> <ul style="list-style-type: none"> <li>• There are no vaccines that work for many who are immunocompromised – a study of kidney transplant recipients without prior natural infection found 24% and 19% do not have any detectable spike protein antibody in response to 3rd and 4th doses of vaccine respectively. T cell responses are poor following fourth dose vaccination regardless of prior infection status. (<a href="https://doi.org/10.1016/j.eclinm.2022.101642">https://doi.org/10.1016/j.eclinm.2022.101642</a>)</li> <li>• Many immunosuppressed people have a reduced response. We do not yet know what level of antibody response confers adequate protection against Covid and there is no policy for the clinical testing of vaccine response.</li> <li>• Many Covid antiviral treatments are not suitable for people with CKD, and they have proved impossible to access in the 5-day window for many people. The short window also deters people from going abroad on holiday or for work.</li> <li>• Shielding can reduce the risk of catching Covid, but there are important practical and ethical reasons why this is not an appropriate alternative to prophylactic treatment for people at highest risk:             <ul style="list-style-type: none"> <li>○ There is no longer income support for immunocompromised people who are shielding, so shielding is not an option for people who cannot work from home:                 <ul style="list-style-type: none"> <li>▪ Almost half (47%) of kidney patients are in the two most deprived quintiles of the <a href="#">population</a> and cannot afford to quit their jobs. Many won't be trained in jobs that cannot be done from home, and can't afford training to change career</li> <li>▪ The cost of living crisis exacerbates this. Kidney patients risk worsening health if they turn off their heating to save money so giving up their jobs to shield at home is now even less affordable.</li> </ul> </li> <li>○ Kidney patients who receive in-centre dialysis cannot shield – they travel to hospital 3 times per week, putting themselves at risk. The cost-of-living crisis makes at home dialysis</li> </ul> </li> </ul>
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	<p>unaffordable, since many trusts are not reimbursing patients for the additional utility costs of running dialysis machines at home.</p> <ul style="list-style-type: none"><li>○ There is no mental health support for people who need to shield, and the mental health impact is considerable.<ul style="list-style-type: none"><li>▪ Kidney patients with poor mental health are more likely to suffer disease progression and death (Tsai, Y., Chiu, Y., Hung, C., Hwang, S., Tsai, J., Wang, S., Lin, M., &amp; Chen, H. (2012). Association of symptoms of depression with progression of CKD. <i>American Journal of Kidney Diseases</i>, 60(1), 54-61. <a href="https://doi.org/10.1053/j.ajkd.2012.02.325">https://doi.org/10.1053/j.ajkd.2012.02.325</a>)</li><li>▪ The heavy burden on shielders' mental health has been underscored by recent <a href="#">research</a> from the University of Bath.</li></ul></li></ul>
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<p><b>What do patients or carers think are the advantages of the technology?</b></p> <ul style="list-style-type: none"> <li>• How would having a prophylactic treatment available impact the day-to-day lives of vulnerable people? (for example, how would it change the activities people do, or how they feel?)</li> <li>• How would having a prophylactic treatment available impact carers?</li> </ul>	<ul style="list-style-type: none"> <li>• Having a prophylactic treatment available would be life changing for many people who remain at higher risk of Covid. A very common phrase in response to this question is '<i>I would get my life back</i>'.</li> <li>• Advantages described by kidney patients include; significantly reducing the constant anxiety and hypervigilance created by the ongoing risk from Covid; resuming activities that give life meaning and purpose with resulting improvements in mental and physical health; financial benefits through enabling a fuller return to employment; feeling a sense of greater equality with the rest of society.</li> <li>• Kidney patients report to us that even if prophylactic treatments may not be a magic bullet, a safe and effective protective drug offers another layer of protection. This may reduce anxiety enough to enable a more normal life. Compared to how many have been living, even small adjustments could be life changing.</li> </ul> <p><b>Patient quotes:</b></p> <p><i>It would build my confidence to go out more, reduce anxiety and improve my mental health. Without this I do not see an end to my continuing to shield myself due to the risks</i></p> <p><i>Life changing. Less anxiety, more life living with my precious gift that was supposed to give me my life back!!</i></p> <p><i>Feeling more protected would encourage me to try buses again, which would change my life, to be honest - no more relying on my elderly mother for lifts, and I'd be able to visit friends again. Also I'd feel confident enough to volunteer more hours which definitely improves my mental well-being.</i></p> <p><i>Evusheld represents a "safety net" that gives confidence to all immunosuppressed individuals to try to get back to "normal". To shop, eat out, go to work, have a drink with friends without fearing grave illness or even death. It's as much preventing a mental health crisis in this group of people as it is potentially reducing the medical crisis</i></p> <p><i>It's not a magic bullet, but would reduce the overall risk from infection (of death, hospitalisation and/or serious illness leading to reduced quantity of life) to a level where moderate activity could be resumed. I would not run around the world yet or meet up in an enclosed space when rates were high, but when rates are moderate to low I would be able to commute to work with only my mitigations in place in relative safety, and could regain a small social life. I would also be less concerned about visiting a</i></p>
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	<p><i>medical setting when needed but not essential, ensuring my overall health was maintained and would feel less of a potential drain for the NHS</i></p> <p><i>It would give me freedom to do more things, even if I still wore a mask, I'd feel more able to participate in society</i></p> <p><i>Life changing. It would rescue me, and help my physical, emotional and severely worsening mental health. Hosp appts would be safer. I could see people, make a cautious return to living, go home. The list is endless.</i></p>
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<p><b>What do patients or carers think are the disadvantages of the technology?</b></p>	<p>Respondents to our survey were not aware of potential disadvantages. As highlighted in the previous answer, many respondents reflected that it may not removal all risk from Covid, the additional protection it did offer would change the balance of risks and benefits when considering how they lived their daily lives. <i>It's not a silver bullet but it would provide a better quality of life and protect against most variants. At the moment I have no protection and most antivirals clash with meds.</i></p>
<p><b>Are there any groups of patients who might benefit more or less from the technology than others? If so, please describe them and explain why.</b></p>	<p>People who are immunosuppressed and do not respond well to the Covid vaccines may benefit from the technology more than people who do respond to the vaccines. However, as we understand it research has not yet been able to ascertain what level of response is needed for protection, making it difficult to clearly define this group. Within our survey respondents:</p> <p>68% of people had had an antibody test (this will include privately bought tests as well as NHS provided)</p> <p>28% had not had a test, 4% were not sure if they had.</p> <p>Of the people who had had an antibody test:</p> <ul style="list-style-type: none"> <li>• 49% reported no antibodies detected</li> <li>• 39% had some antibodies (this included low positives and uncertainty whether any protection provided)</li> <li>• 11% were not sure of result (some people had had multiple tests with varying results depending on timeframe)</li> </ul>

**Are there any potential [equality issues](#) that should be taken into account when considering this condition and the technology?**

**The current unmet need for effective protection from Covid for the severely immunosuppressed should be taken into account as it places that group at significant disadvantage:**

The restrictions that people must follow to reduce their risk puts them at disadvantage compared to people who are protected from Covid by vaccination on many counts;

- access to employment opportunities
- normal participation in family and community life
- leisure and opportunities for physical activity.

Responses to our survey reflected these experiences of exclusion:

*I feel that I do not matter as much as other citizens and I cannot live my life as others do. I am not protected against Covid and feel discriminated against because the government has refused to buy Evusheld to help protect the immunosuppressed. Please help us, we are desperate to return to normal life along with the rest of the population*

*Despite living a normal life before Covid my life has completely changed and my family, relationships and well being have been compromised. We do not live with Covid in the true sense of the word. We exist on parole in a world with little empathy.*

**The current unmet need for effective protection against Covid for immunocompromised people is likely to impact differently on different groups in society:**

- CKD is more common amongst people from lower socio-economic groups. Almost half (47%) of kidney patients are in the two most deprived quintiles of the population ([UKRR data](#))
- Ability to reduce risk by working from home varies across groups - people in lower socio economic groups and of black ethnicity are less able to work from home (Blundell, R. *et al.* (2020). [COVID-19 and Inequalities\\*](#). *Fiscal Studies*, Vol 41, 291–319.)
- People from Black or South Asian communities are more likely to have CKD risk factors such as high blood pressure or diabetes – which are also risk factors for COVID-19 hospitalisation and death – and are [five times more likely to be accepted for renal replacement therapy than other groups](#)