

Patient organisation submission

Therapeutics for people with COVID-19 [ID4038]

Thank you for agreeing to give us your organisation's views on these technologies and their possible use in the NHS. You can provide a unique perspective on conditions and their treatment that is not typically available from other sources. To help you give your views, please use this questionnaire with our guide for patient submissions. You do not have to answer every question – they are prompts to guide you. The text boxes will expand as you type.

Information on completing this submission

- Please do not embed documents (such as a PDF) in a submission because this may lead to the information being mislaid or make the submission unreadable
- We are committed to meeting the requirements of copyright legislation. If you intend to include **journal articles** in your submission you must have copyright clearance for these articles. We can accept journal articles in NICE Docs.
- Your response should not be longer than 10 pages.

About you	
1. Your name	Susan Walsh
2. Name of organisation	Immunodeficiency UK
3. Job title or position	CEO
4a. Brief description of the organisation (including who funds it). How many members does it have?	Immunodeficiency UK (previously known as PID UK) supports people affected by primary and secondary immunodeficiency (PID and SID). We help give advice on managing their condition, their treatment; promote awareness and understanding of PID and SID within the general public and medical profession to promote better understanding of these conditions and their impact. We provide a helpline service, events and practical help and advice and advocate for improved healthcare. Our funding comes from public donations, events, legacies, pharmaceutical companies and trusts and foundations (Immunodeficiency UK - Sponsors). We currently have over 1000 members.

4b.	No funding has been received from any of the companies listed.
4c tobacco funding?	No
5. How did you gather information about the experiences of patients and carers to include in your submission?	<p>Immunodeficiency UK carried out a survey of its members with questions addressing the issues of this consultation. The survey was a mixture of quantitative and qualitative (free text) questions. Access to the survey was via a link sent by a membership mailing. We received 516 responses: 254 from people directly affected by PID; 194 affected by SID and 68 responses from carers of those affected. Responses were collected from 11 - 27 August 2022.</p> <p>Numbers of people testing positive: Of 254 PID respondees 101 (39.76%) had tested positive for COVID. For 194 SID patients 62 (32%) had tested positive for COVID.</p>
Living with COVID-19	
6. Please tell us what is it like for patients you support who have tested positive for COVID-19?	<p>It is important to understand the context of the situation of people with PID and SID living with COVID for the MTA. Published data, of which NICE will be aware, has shown that there are subgroups of patients with PID and SID that have poor COVID-19 vaccination responses. Consequently, there remains considerable fear, distress about the consequences of having a COVID-19 infection and profound fear within the community of contracting the virus, as shown by the survey data below of the number of people who are still shielding, with the subsequent severe impact on mental health and quality of life. This remains the case even for a large proportion of people who have benefitted from the safety net of accessing COVID therapies.</p> <p>Overall confidence in living with COVID: Of 439 respondents in our survey affected with either SID or PID, 30% were not going out at all, 43% had little confidence in going out; 16% (71) were moderately confident; 6% were mostly confident and 5% very confident. There was no statistical difference when analysing the results for the PID and SID groups separately. These results indicate that a significantly high proportion of our community are effectively continuing to shield so there are lots of individuals who have yet to be exposed to COVID for the first time.</p> <p>Confidence of living with COVID who have tested positive and had accessed therapy: Of 105 respondents (affected by PID or SID) 20% were not going out at all, 38% had little confidence in going out; 21% were moderately confident; 13% were mostly confident and 8% very confident. Indicating that even having had the experience of a 'safety-net' there remains considerable concern about getting COVID again. Average confidence in accessing healthcare in a hospital setting was 50 (scale 0 - 100; no confidence to full confidence).</p> <p>Quality of life (QoL) survey data reporting on a scale of 1 -100 (poor to excellent). Average ratings are quoted.</p> <p>All PID patients: pre-pandemic QoL rating 78 (248 responses). QoL now rated as 28 (246 responses).</p> <p>PID patients testing positive: pre-pandemic QoL rating 76 (100 responses). QoL now rated as 42 (100 responses).</p>

	<p>All SID patients: pre-pandemic QoL rating 76 (191 responses). QoL now rated as 27 (189 responses). SID patients testing positive: QoL rating 77 (60 responses). QoL now 37 (60 responses).</p> <p>These findings underline the significant impact of the threat of COVID has on the lives of people affected by PID and SID.</p> <p>The impact on health of having a COVID-19 infection was variable and person specific ranging from mild illness to serious illness, including the need for hospitalisation – 4 patients said they needed admittance to ICU. Those who were badly affected described the experience as frightening, terrifying, scary, distressing. Some people described the quick deterioration of their health and the anxiety of accessing COVID medicines.</p> <p>Experiences: ‘I thought I was going to die, I was alone and terrified. It was incredibly difficult to access treatment and help. How I drove myself to be tested and eventually to receive sotrovimab I'll never know, I'm surprised I didn't crash the car and of course no-one wanted to take me. I have never been that sick and I never want to feel like that again’. ‘Horrific and the most frightening time of my life’. ‘Very, very frightening. I don't want to go through it again’.</p> <p>‘Fairly mild in comparison to what I was told would happen’; ‘Like a bad cold but it cleared in a few days. I was scared that I would become very unwell though.’</p> <p>Data from CO-VAD study (antibody deficient patients) indicates that inpatient mortality has remained high (19% for PID, 42.8% for SID) suggesting if you are sick enough to end up in hospital then that is a poor prognostic sign. CO-VAD (patients with antibody deficiency) data is available on 155 individuals with SARS-CoV-2 infection since the deployment of vaccination (January 2021). This comes from a mix of CO-VAD and UKPIN data. Hospitalisation rate with Omicron was 9.9% vs 2.2% for the general population and mortality was 2.7% vs 0.2% for the general population. As of August 2022 (publication under review), the cumulative incidence of infection in the longitudinal cohort is 28.6% which is much, much lower than the ONS cumulative incidence of infection in the general population which was 70% back in February 2022. The COVAD patients were infected later in the pandemic, mainly during the latest Omicron wave. Survey data results concerning experiences in access, attitude to accessing healthcare are given below.</p>
<p>7. What do carers experience when caring for someone with COVID-19?</p>	<p>Carers experience stress, anxiety, feeling inadequate, worry and anger and frustration about the access to medicines process and access to good information, the lack of knowledge about the conditions that their loved ones have when accessing COVID medications and having to educate the CMDU and other medical professionals about their needs. It is important to state that many carers are still shielding and leading very restrictive lives, in order to protect their relatives. We received 68 free text experiences from carers – here are some response:</p> <p>‘It was really scary. There was significant breathlessness and she had to go into hospital alone for treatment. She was breathless for</p>

	<p>weeks and we were significantly worried she might die. This is continuing as she is extremely worried about getting it again.’ ‘Scary, long hours on the phone trying to get antivirals. Very worried about how it would effect condition and coping alone. Monitoring breathing, fluids and blood pressure without support.’ ‘Very scary particularly the way their breathing was affected. They still have a terrible cough and tire easily. I used vaporizers and lots of pillows to help them to breathe. Fortunately they were never so ill as to require hospitalisation. They were unable to have the vaccines due to allergies. I sat up every night cupping my bands and massaging to bring up the mucus when they had Covid.’ ‘Terrifying at first!!!! But my son’s COVID infection turned out to be no worse than other viral infections he has had in the past.’ ‘My daughter was extremely sick at home. Terrible opinion from 111, she should at least she been assessed by paramedics. I’m a doctor and I was worried about her. She now has many health problems as a result, (Long Covid is such a benign sounding term for how ill she is). She is mostly bed bound and has PTSD from being in fear for her life at the beginning.’ ‘My dad had CLL, when he tested positive for covid he was declined anti virals as he felt OK. He died of covid several months later’. ‘Awful, worrying and unknown. We dread him getting it again.’ ‘Which way would it go....frustrating as they thought I was over anxious. Anger as they not only had not come across di George before but then failed to actually look it up.’</p> <p>‘Despite all of our best efforts, our immunosuppressed daughter contracted Covid because she had to go into work one day, and despite her wearing high quality masks, because there are no longer any mitigations in place, she was infected. It was absolutely terrifying, our worst nightmare. Fortunately her specialist team accessed Sotrovimab for her really quickly, but it didn't seem to neutralise anything. She was very poorly, dropping SATs which we constantly monitored, isolated her at home and double masking in the house. She tested positive for 15 days, had to come off all of her other disease modifying medications to give her immune system a chance to recover, and has now had to go on a high dose of steroids to help get her back on track before resuming her usual treatments. All because of the position this government is taking that despite all of the real world wide data there is regarding effectiveness, it will not procure Evusheld. She leads a virtually non-existent life, she is a young woman whose life has shrunk to nothing. I have seen her change form a strong person who dealt with her underlying condition (Lupus) as best she could and led as full a life as possible to a shadow of her former self, frightened of contact with people and who I now not only fear for physically, but mentally as well. She used to have a life, she used to socialise, travel, do normal things all of which meant putting money into the economy. She doesn't do any of that now so if we dispassionately take out the physical and mental effects of not being able to live with Covid, the economical impact is significant. Because this doesn't only affect her, it affects us as her carers as well. Our lives have shrunk too, we are in our 60s and cannot enjoy a full life because we have to weigh up everything in the context of what risk might we bring home to her. We only socialise now in a limited way, we have only travelled once and I am reluctant to do so again. So we too aren't putting money into the economy.’</p>
<p>Interaction with underlying conditions</p> <p>8. For people with underlying</p>	<p>The survey results showed that COVID-19 has adversely affected confidence in accessing healthcare in a hospital setting. 169 of 437 respondents (38%) were < 20% confident; only 86 of 437 respondents (20%) had > 60% confidence. Some responses indicated that people were willing not to access any healthcare in hospital due to the risk of getting Covid, especially as restrictions have been</p>

<p>conditions (for example cancers, autoimmune disorders):</p> <ul style="list-style-type: none"> • If applicable, how has living with COVID-19 affected their condition? • If applicable, how has the normal treatment pathway for their condition been affected? (For example, cancer treatment options, regularity of assessments, accessibility issues related to treatments) 	<p>lifted.</p> <p>The regularity of appointments and face-to-face appointments has decreased for people with PID and SID. 56% reported a decrease in appointments with 6% reporting an increase. 87% of respondents reported a decrease in face-to-face appointments with 5% reporting an increase. These findings have important consequences as there is a need for regular monitoring. PID and SID are chronic conditions affecting multi-organ systems. Routine care should involve regular blood tests, scans, lung function tests etc. Many people reported a complete lack of confidence in attending in hospital appointments, having dental, eye, breast screening checks, smear tests, etc due to the fear of mixing with other people who were not wearing masks. Some people welcomed the shift from face to face to phone or video consultations to mitigate the risk of getting COVID through travel and in hospital settings but recognised the need that physical examination and hospital-based tests are required to fully assess their health.</p> <p>Patient quotes: ‘Since freedom day in 2021 I have not been able to safely visit NHS sites. Worried about catching covid whilst travelling to the appointment or in the NHS venue’. Attending hospital environment is so traumatic and stressful’. ‘Many safeguards have been removed that would help protect me.’ ‘Scans and checks missed so many areas I have got far worse. Was meant to have a bone density scan but this was missed for 18 months and it dropped 25%!’ ‘Haven’t had any maintenance x-rays, Ct-scans etc for over 2yrs now’. ‘I have not had my usual yearly scan for 3 years.’ ‘Since the advent of COVID-19 I have had more regular clinic appointments but no scans or tests since 2019 to assess the health of my organs and my body overall.’ ‘As an insulin-dependent diabetic I no longer get diabetic reviews, either in the community or at hospital.’ ‘Supply of my medicine [immunoglobulin] has been affected’. ‘I did not get my treatment with Rituximab for 16 months and this led to a flare up.’ ‘I was referred to a cardiologist, had one appointment and my 2nd appt is nearly 2.5years later! I am terrified to go to face to face appointments’. ‘Failure to have face to face examination has led to an undiagnosed incisional hernia as a result of the transplant’.</p>
<p>Short term versus long term</p> <p>9. For the people you represent who have tested positive for COVID-19, on average, how long did their symptoms last for?</p> <p>a) Did anyone have any long-term effects from COVID-19? Approximately what proportion does this</p>	<p>Short term. Symptoms were reported to last for a few days to many weeks and were person specific. 32/157 (20%) respondents reported symptoms lasting < 10 days, with 63/157 (40%) respondents reported symptoms lasting several weeks. It is noteworthy that 37% of respondents reported that receiving COVID-19 medications did not clear their infection, resulting in COVID rebound, recurrence of symptoms and in some cases, people required 2nd courses of treatment. This inability to clear infection resulted in time off from work and in some cases long periods of illness and hospitalisation.</p> <p>‘It [Paxlovid] definitely improved my condition and I believe I would have ended up in hospital very poorly without it. However I was still positive on day 18, ended up in A&E on day 20, was very poorly for weeks to come and still suffering after effects now’; ‘tested positive for ten weeks after taking paxlovid’; ‘I continued to develop different symptoms and remained very unwell signed off work for 3 weeks. I tested positive continually for 17 days’; ‘I was still testing positive at 21 days but had to return to work on day 19 whilst still feeling terrible.’; ‘Admitted to hospital with a very high viral load 10 days after finishing outpatient treatment’.</p> <p>‘Molnupiravir did not clear the infection needed to have Sotromivab as a follow-up treatment’. ‘The first course of Paxlovid failed to clear the virus and so I got COVID rebound, recurrence of symptoms and I needed a 2nd course of Paxlovid before I was consistently</p>

<p>represent?</p> <p>b) If yes,</p> <ul style="list-style-type: none"> • What were they? (for example physical and mental impacts, impact on ability to work) • On average, how long did the effects last for? • What treatments did they need for the long-term effects of COVID-19? 	<p>COVID-free.’</p> <p>Long term effects. 59% (93/157) of PID + SID respondents who had tested positive for COVID reported long-term effects of having had COVID. 70% (64 of 92 respondents) reported effects lasting several months. Physical impacts reported included: reduced breathing capacity for several months, lung pain, constant coughing, exacerbation of previous health problems, increased susceptibility to infection, mobility issues, fatigue and exhaustion, anosmia, gastrointestinal problems; joint pain, cognitive difficulties with memory/attention /concentration/word finding difficulties (brain fog), dizziness, fainting, headaches & migraines, post exertion symptom exacerbation (PESE/PEM), diarrhoea, neurological symptoms such as vertigo, spells of deafness in one or both ears, spells of agonising headaches, vision problems, heart problems. The mental health impact, in this group, was mentioned in 21% (20/93) of responses. Anxiety, worry, fear, depression, isolation, panic attacks, PTSD, frustration at losing previous relatively fit lifestyles were reported. Impact on ability to work was mentioned in 13% (12/93) responses and included loss of employment, bedbound/unable to work – on disability benefits, need to take several months off work, taking reduced hours/ inability to work full-time, phased returns to work, occupational health support and reasonable adjustments at work, need to take early retirement and expectation to lose jobs due to continuing health problems. These problems have led to people losing income with resulting financial instability. There was also mention of the on-going need to depend on other people for care and support.</p> <p>Treatments offered: Montelukast, Stemetil, Amantadine (recommended by consultant neurologist/access refused by GP), home oxygen, inhalers, steroids, carbocisteine, ivabradine, antibiotics, pain medications. Other treatments included breathing exercises, physiotherapy, CBT referral, referral to other specialities. 5 people reported being referred to long-COVID clinics but reported long waits for referral and triage. Many people still waiting for referrals. 33 people reported no interventions have been offered.</p>
<p>Current treatment for COVID-19 in the NHS</p>	
<p>10. What do patients or carers think of current treatments and care available in the NHS?</p> <p>- for preventing severe COVID-19 in people with high risk of hospitalisation</p> <p>- for treating people in</p>	<p>We had 430 survey responses to this question and received a mixed response. Here are some examples of responses:</p> <p>‘The vaccine roll out was chaotic. The treatment - infusion of antibodies was very efficient’. ‘Excellent’. ‘Prevention would be better than treatment’; ‘Completely inadequate and patchy.’; ‘Helpful to me if I test positive for covid in time and get access quickly enough to care required, but I don’t feel safe ‘in between’ with all preventions lifted’; ‘To date, I've have been very happy with treatments offered.’ ‘It's slowly got better with the introduction of new treatments such as antivirals’; ‘It is comforting that there are treatments available, but the path to accessing them seems quite complicated.’; ‘Appreciate access to antivirals which made a difference to recovery after Covid although process could have been speedier, not available at weekend.’; ‘I feel abandoned’; ‘There are good drugs available for covid for people already on treatment. But these are post infection and not preventative.’ ‘There are very good options but they are challenging to access’; ‘In a word, mystifying. I am baffled by the UK’s approach to protecting the clinically vulnerable. The rest of the developed world has adopted a multi-pronged strategy for the vulnerable, but for some unknown reason, the UK government seems to be stubbornly sticking to a narrow plan of Paxlovid only. At least that was my</p>

<p>hospital with severe COVID-19</p>	<p>experience when contracting COVID last month – Paxlovid was Plan A, Plan B and Plan C. In no way was the therapy tailored to my immune deficiency. Anti-virals suppress the virus, not kill or clear it. My whole life I have struggled to clear infections – a simple cold turns into something that could put me in hospital or even kill me. Surviving my infancy was a miracle that I owe to the NHS. But my clinicians have strategies for such “breakthrough” infections. My concern is that my clinicians’ hands are tied. They were not consulted about the best treatment options for me when I got COVID. And that was because there really was only one treatment option – 5 days of Paxlovid. They weren’t even allowed to modify the length of the course of Paxlovid. Previously the approach was a combination therapy of anti-virals (to suppress the virus) and mAbs (to help clear it). But this was not an option available to me.’</p> <p>‘I think having the antivirals available for the immunocompromised is fantastic. They helped me enormously when I tested positive in June 2022. ‘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’. ‘The two treatments available to people previously designated as CEV appear to be sotrovimab and Paxlovid. Sotrovimab has been withdrawn by the FDA as ineffective against Omicron variants. Paxlovid has problems with breakthroughs, and is also unsuitable for many people who take medications’. ‘When I had Covid I was given monoclonal antibodies within 2 days of testing positive. These seemed to make a difference to me. I think it is brilliant that these treatments are available otherwise I could have been much more unwell.’</p> <p>Further examination of views and unmet need are given in other sections.</p>
<p>11. How do the COVID-19 treatments being offered interact with your community’s disease area?</p> <p>Are there any contra-indications?</p>	<p>Yes, there are significant drug interactions with other antivirals and medications that are used to treat primary and secondary immunodeficiency that limit the options available to treat COVID-19. This restricts treatment options and further adds to the stress patients feel once they have tested positive. High spike antibody levels from prior vaccination for monoclonals (and this may apply also to spike antibody from immunoglobulin replacement soon).</p> <p>There is concern about the misinterpretation of antibody levels in primary and secondary immunodeficiency patients. People in our community have been rejected for monoclonal antibody therapy on the basis they've made an antibody response, but antibody binding capacity doesn't mean the antibodies work - this has been proven in patients affected by CVID.</p>
<p>12. What impact does having these drugs available in the NHS have on your community?</p>	<p>COVID-19 treatments offer a vital safety net for those people with PID and SID who are eligible for treatment and test positive and can access the therapies in the prescribing therapeutic window. They have proved life-saving for some patients and have significantly reduced patient mortality since the start of the pandemic. They are welcomed and valued. However, there are issues concerning the ease of accessibility to the therapies, the ability to meet demand for those requiring treatment, with more transparency needed for patients about the decision-making process, and a requirement for better communication of the availability of these therapies, the need for widening of eligibility and better training of GPs, 111 and 119 services to ensure smooth access pathways.</p>

	<p>Most importantly, our survey shows there is a huge unmet patient need (survey data below) for the availability of prophylactic preventative therapies to improve the quality of life, mental health of people, to increase the participation of immunodeficient patients in society, including economic benefits, not withstanding significantly reduced clinical risk and less hospital bed use.</p>
<p>13. Is there an unmet need for patients with this condition in relation to therapies for treating COVID-19?</p> <p>Are there any key subgroups of patients we should consider?</p>	<p>COVID continues to pose a significant risk to patients with PID and SID and there remains an unmet need to understand the correlates of protection against severe disease and optimise mitigation, prophylactic and therapeutic strategies to minimise the ongoing burden of the pandemic to these vulnerable groups. Key groups that require prioritisation are given in section 16. It is noteworthy that the APPG on Vulnerable Groups to Pandemics has produced a ‘National Clinical Expert Consensus Statement ‘Coronavirus monoclonal antibodies as a prophylactic therapy against COVID-19 for immunocompromised groups’. This was produced and endorsed by over 120 clinicians indicating that the medical profession is also of the opinion that there is an unmet need. https://bit.ly/3bpE6oO.</p> <p>Survey data on unmet need: 79.67% (341/428 responses) from people affected by SID or PID indicated an unmet need. <u>Of those responses</u> 40% (139/341) specifically mentioned the need for Evusheld and 12% (41/341) stated the need for prophylaxis/prevent infection therapies, indicating that people recognise ‘fall-back’ treatments are available but desperately want a protective strategy. Only 3.5% (15/428) of respondents said there was no unmet need; 4.4% (19/428) stated they didn’t know.</p> <p>‘I do not generate memory antibodies – so DoH banging on repeatedly about the success of the vaccine program is very frustrating. Vaccines might be good enough for some vulnerable patients, but vaccination alone is not enough for my needs.’</p> <p>Other responses concerning the question of unmet need included communication and access issues - confusion about who is eligible, access - especially for people who live alone and are feeling ill and don’t know how to chase for access; concerns about who makes the decisions on access with many responses indicating that access should be under the control of speciality consultants; eligibility too tight; concerns about demand not being met; concerns about no access to CMDU at weekends; the need for longer doses of anti-virals to clear COVID-19 infections; delays in access; the anxiety of not knowing if you will get access to the medicines on offer (people are very frightened and this is causing mental health issues and distress); need for a clearer strategy/message given so people know what is available and the criteria needed; concerns about the over dependence on one anti-viral – Paxlovid and underuse of Sotrovimab; the need for combination therapies; unmet need in relation to antibody testing to see if a protective response has been made by vaccination..</p> <p>‘I am very concerned about the lack of transparency about who is eligible for covid treatments (antibody or anti-virals). I have not been contacted and when I spoke to my GP they could not say with certainty that I would receive them, only that it would be evaluated based on the rules and criteria at the time I caught covid. If I knew for certain I could receive them that would make a</p>

	<p>difference in my assessment of my risk from Covid.'</p> <p>'Yes, there is prophylactic options available such as Evusheld which is being used in other countries. This has not been made available so consequently life is still anything but normal for me and I am having to be incredibly careful still. If I keep contracting covid and needing months off work then I will lose my job. I still cannot go to the shops or a restaurant or meet friends and family in their homes because I do not want to experience the terrifying experience I have already had once with covid. I think much, much more needs to be done to support the immune compromised in getting back to normal life and being able to function in society and prophylactic medicines would facilitate us being able to take steps to do this.'</p> <p>'Yes, absolutely. There are many thousands of primary and secondary immune deficient people still living their lives under shielding conditions - removed from society and from 'normal' life, unable to go into public contact situations without fear - people with children, jobs, family, dependents, etc - who still cannot participate in everyday activities because of the lack of protection available. There is an enormous unmet need. None of the therapeutic options currently on offer give any protection for these vulnerable people, and Evusheld is the only option available for these people to be able to return to some kind of 'normal' life.'</p>
<p>Hospital and community treatment settings</p> <p>14. For those people that you represent who were <u>hospitalised</u> due to COVID-19</p> <ul style="list-style-type: none"> • At what point after being diagnosed with COVID-19 did they receive any form of treatment? • What did their treatment pathway look like? • How long did they 	<p>Hospital setting -These are hard questions to answer comprehensively because the treatment pathways keep changing. There are the known knowns and unknowns. CO-VAD study data (under review for publication; Shields et al.,) indicates that 63.2% (n=98/155) of individuals in this cohort received specific treatment for COVID-19 (73 treated as outpatient, 25 as inpatient).</p> <p>Access in community settings survey data – we received 154 responses who had tested positive for COVID -19. Results on the timing on access to COVID medicines results showed that: 30.46% (46) of these patients were not offered any form of treatment – see comments below; 4.64% (7) received treatment on day 1; 17.22% (26) received treatment on day 2; 19.87% (30) received treatment on day 3; 9.27% (14) received treatment on day 4; 14.57% (22) received treatment on day 5; 1.99% (3) received treatment on day 6; 0.66% (1) received treatment on day 7 and 1.32% (2) received treatment after 7 days.</p> <p>Treatments were offered to 105 patients in our survey. Breakdown: Paxlovid 39%; Remdesivir 5.71%; Molnupirivir 6.67%; Sotrovimab 37.14%. 11.4% of respondents couldn't remember the medication given.</p> <p>COVAD data - Since the deployment of CMDUs, 61.4% (n=70/114) of treatment eligible patients actually got treatment from a CMDU. We found significantly lower rates of hospitalisation (4.3% vs 15.9%, p=0.03) amongst individuals treated by CMDU but overall mortality was not affected (2.8% vs 4.5%, p=0.63).</p> <p>Reasons given for not being offered medication were refusal without giving an explanation was a common occurrence; not ill</p>

<p>spend in hospital?</p> <p>If they had an underlying condition how did this impact the condition?</p> <p>15. For the people you represent that had treatments for COVID-19 in <u>community settings</u>:</p> <ul style="list-style-type: none"> • At what point after being diagnosed with COVID-19 did they receive any form of treatment from the NHS? • What did their treatment pathway look like? • Was there a preference for receiving tablets versus treatment with other administration methods (for example intravenously) • Can you tell us a bit about their experience of accessing these 	<p>enough; too young (person aged 44 years of age); no capacity to provide the medication needed ‘told there was high demand and I wasn’t considered a priority’; on the eligibility list but when needed people told they weren’t eligible. Not on the ‘NHS list’ - ‘No consideration was given whatsoever to the fact that I have a long-standing diagnosis of immunodeficiency with chronically low T cell levels. My condition was effectively not recognised by the wider NHS and my NHS immunologist did not by their own admission have power within the system to ensure that their patients were added to the list to people with rapid timely access to anti-viral medication’.</p> <p>Data from this report https://reports.opensafely.org/reports/antivirals-and-nmabs-for-non-hospitalised-covid-19-patients-coverage-report/ indicates that only a small proportion of eligible people are actually getting access to COVID medicines.</p> <p>Regional variability in prescribing is evident from government statistics: Statistics » COVID-19 Therapeutics (antivirals, neutralising monoclonal antibodies and interleukin 6 inhibitors) (england.nhs.uk)</p> <p>Difficulties reported were with access helplines – unanswered calls leading to people being outside the treatment window, lack of knowledge of helpline personnel, no contact by the CMDU sometimes in spite of chasing by GP; doctors; medicines promised were not delivered. Many people reported the need to chase constantly (‘fight for access’) the system to get treatment. In many cases specialist health teams had to get involved to gain access either by direct contact with CMDU or via providing patients with consultant letters.</p> <p>Preference: of 120 respondents, 56.67% (68) stated they were not given an option on treatment. 35.83% (43) were happy to receive the recommended treatment and 7.50% (9) stated a preference for receiving tablets.</p> <p>Access: 63 people (37%) out of 142 respondents reported having to travel to outpatient settings while positive for COVID. Of 27 respondents who stated transport used: 7 people were offered ambulance/hospital transport; 6 had to drive themselves to centre whilst feeling unwell; 10 people had to rely on family members to take them as so ill; 1 person reported having infusion at home delivered by a nurse; 1 person reported delivery of tablets (Paxlovid) at home; 1 person reported walking to the centre. 1 person stated being offered a sotrovimab infusion but elected to receive tablets as they didn’t want in infect as didn't want to infect anyone else.</p> <p>Overall experience of access was variable: Of those people who accessed COVID treatments, and rated their experience, the average rating of patient experience on access (103 responses) was 3.4 on a rating of 1 to 5, where 1 = very poor and 5 = excellent. Breakdown of rating was (%; no of respondents): Very poor/Poor – 23.53 % (24); Average – 25.49% (26); Good – 26.47% (27); Excellent 24.51% (26).</p>
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<p>treatments? (for example travelling to clinics/outpatient settings while testing positive for COVID-19)</p> <ul style="list-style-type: none"> • Were there any issues with accessing these treatments? 	<p>Comments of people who had accessed therapies: ‘They are absolute life savers for us! Being on anti CD-20 therapy for three plus years has meant that I mounted an absolute ZERO antibody response to the four covid vaccines I was given which has left me with terrible covid anxiety which is having a major impact on my life! Having caught covid for the first time in July just gone being able to have the Sotrovimab infusion helped me massively.’ ‘It was awful, I was hospitalised within 24 hours of testing positive it was then a fight and a battle to get the antibody treatment as everyone agreed I was eligible but couldn't have them due to being in hospital. I only got them in the end because we got my MP involved. I got them with 1 hour to spare!’ ‘I struggled for 5 days to get antivirals. One person was going to ring me later that day when I tested positive, she said someone else would ring me day after and they didn't. Day 3 I had to ring again said Dr would ring me he said pharmacist would ring me on day 4, he didn't, I had to contact CMDU again. Day 5 someone rang from pharmacy and said couldn't deliver till day after as it was almost 4pm I had to resort to ringing round to see if someone could pick up antivirals for me before 5 otherwise it would of been day 6 and would of been too late.’</p> <p>‘My experience was excellent. I have had 5 jabs. I had a call in less than 24hrs when I tested positive, and was offered Paxlovid straight away the following day. Within a few days I felt much better. Paxlovid definitely worked for me.’ ‘I had to wait 19 hours on hospital trolley (including one night) to get Sotrovimab and had to insist. It was a real struggle.’ ‘Excellent! Both me and my daughter were contacted promptly when we tested positive for Covid and both received Sotrovimab within 24-48 hours (one in London, one in South West).’</p> <p>Impact of contraindications on therapy offered: Of 102 people that received COVID medicines in community settings 21.57% (22) of people had a contraindication which meant they couldn't be given a certain therapy. These included blood thinners, chemotherapy/immunosuppression treatments, liver function problems, underlying nature of medical condition. Several people reported having to stop their routine medicines to be given COVID medicines, which caused health problems down the line.</p>
<p>Patient population</p>	
<p>16. Are there any groups of patients who might benefit more or less from the technologies than others? If so, please describe them and explain why.</p>	<p>Yes. Anyone who has not made a good antibody response to vaccination. It is essential for those patients with primary antibody failure who will not recover B cell function and for those patients who have had B-cell depleting agents. Possibly even more important for those who are older/have co-morbidities e.g. poor lung function. There are also PID patients that can make antibodies but who may be susceptible for different reasons and are not on the list.</p> <p>Low grade lymphomas are over-represented in SID clinics, suggesting a more profound immune system problem. Recent rituximab, CD19 CAR-T, BTK inhibitors treatment patients. Based on current epidemiology data: older patients, more lymphopenic patients and patients with more comorbidities are more likely to end up in hospital.</p>

<p>17. For the people you represent, what do they think about the definition of 'high risk' used to determine access to treatments for preventing severe COVID-19. Does the definition exclude any key 'high risk' patient groups?</p>	<p>Exclusions from the eligibility high risk list include:</p> <ul style="list-style-type: none"> • Combined immunodeficiencies which aren't explicitly stated • Monogenic phenocopies of CVID which aren't explicitly stated • 22q11 should be covered under the chromosomal abnormalities affecting immune function <p>Immune mediated inflammatory disease patients e.g. individuals with stable rheumatoid arthritis, but have terrible lungs with poor pulmonary function, have been turned away because their underlying disease isn't active. This needs addressing as they are at high risk.</p> <p>Equality issues concerning access: these are highlighted in the report Antivirals and nMABs for non-hospitalised COVID-19 patients: coverage report OpenSAFELY: Reports; section: Key demographic and clinical characteristics of treated patients.</p>
<p>Key messages</p>	
<p>20. In up to 5 bullet points, please summarise the key messages of your submission:</p> <ul style="list-style-type: none"> • COVID-19 is still having a high impact on PID and SID community with a large proportion of people still shielding and reporting poor quality of life and mental health issues. There remains a lack of confidence in accessing healthcare in a hospital setting with the regularity of appointments, treatment pathways and routine testing adversely affected. • Having COVID-19 medications available is highly valued but there are problems with gaining access and patchy availability. A significant proportion of people reported COVID 're-bounce' after receiving therapy and concerns about the limited number of options available given contraindications of some therapies. In those people who have had experience of access and benefitted from anti-COVID therapies there remains the fear of being re-infected, with many still living very restrictive lives. High-risk groups are missing from the eligibility list. • A significant proportion of people who had tested positive for COVID reported long term health problems lasting several months with severe impacts on physical health, mental health and ability to work. • Despite the availability of current COVID medications as a 'safety net', our community overwhelmingly reported an unmet need - the need for access to prophylaxis/prevent infection therapies. • COVID continues to pose a significant risk to PID and SID patients and there is a need to improve, speed up access pathways to the therapies available. There is a need to optimise mitigation, prophylactic and therapeutic strategies to minimise the on-going burden of COVID on PID and SID patients. 	

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