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.’*