

Resource

Information about Coronavirus (COVID-19)

Print

Frequently asked questions

Why should I get vaccinated?

The vaccination programme against COVID-19 has been successful in reducing the mortality rate posed by the virus in all its forms and allowed many to return to living without much in the way of restrictions to their freedoms.

Now as we head into the winter months viruses such as COVID-19 are spread much more easily, for the simple reason that we do more socialising indoors without windows open for airflow. The autumn boosters are important to help bolster the protection against the strains of Coronavirus and are being offered to all those aged 50 and over, as well as, those who are increased risk from the virus strains.

This is due to this increased risk of contracting a respiratory infection but also because over time the immunity offered by the vaccinations to date can wane over time, and so it is necessary to give it a "top up".

Booster vaccines also act to "top up" immunity facilitated by contracting COVID-19 ("natural immunity"). Best way to think of it is that more protection is always best! All vaccines approved for use in the autumn booster programme are proven to be safe and highly effective. If you're eligible, the NHS will offer the most appropriate vaccine for you.

The darker and colder winter months tend to put an increased strain on the NHS too which as many of you will know is already under a lot of pressure. By getting your booster vaccinations and seasonal flu vaccine, you can help to reduce this pressure. Not only this, but the more eligible individuals who take up their boosters the more of a protective barrier is put around at risk communities.

Vaccination efficacy

The relationship between contracting COVID-19 and hospitalisation and death has been weakened with over 93% of eligible UK individuals over the age of 12 receiving at lease one dose of the

Coronavirus vaccine.

Moreover, despite the protection against infection reducing over time, the vaccines still provide a high level of protection against serious disease outcomes, requirement for treatment in hospital and risk of death. This is especially true when booster doses are also taken up with the added bonus of these sort of "resetting" the timer for decay of the vaccines protective quality versus infection.

How do we know this and that the vaccines are safe?

The UK Health Security Agency publishes weekly reports looking at vaccine effectiveness and the impact of vaccination on the population.

COVID-19 vaccines approved for use in the UK have met strict standards of safety, quality and effectiveness set by the UK's independent medicines regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

At every stage of the development of a new vaccine extensive checks and balances are conducted as required by law. The data looked at includes all the results from laboratory studies, clinical trials, manufacturing and quality controls and testing of the product. By doing so this ensures that the benefits of a vaccine far outweigh any possible risks and that risks are reduced to manageable levels as is considered safe.

The nitty gritty numbers:

According to COVID-19 vaccine surveillance report: week 35 (publishing.service.gov.uk) dated 1 September 2022, two to 4 weeks after a booster dose of either the Pfizer or Moderna vaccine following an AstraZeneca or Pfizer primary course, effectiveness against symptomatic infection ranges from around 60 to 75%, dropping to almost no effect from 20+ weeks after the booster.

Two to 4 weeks after a booster dose of either the Pfizer or Moderna vaccine following an AstraZeneca or Pfizer primary course, effectiveness against hospitalisation for the Omicron variants is about 90%, dropping to 60% after 6 months.

For those aged 75 and over who received a spring booster risk of infection more than halved in the first few weeks afterwards compared to those not boosted.

What was the effectiveness of the vaccines against previous strains?

Prior to Omicron, primary vaccination was shown to have high effectiveness against symptomatic infection (over 70%), hospitalisation (over 90%) and death (over 90%) for the alpha and delta strains.

Booster doses in the autumn of 2021, showed very high effectiveness against hospitalisation and death for the delta variant (over 95%). Clinical trials also showed similarly high efficacy against the strains circulating in 2020.

Where can I get more information about the vaccines, coronavirus and my condition?

NHS website:

- Coronavirus (COVID-19) vaccination | NHS
- How to look after yourself at home if you have coronavirus (COVID-19) or symptoms of COVID-19 | NHS
- Coronavirus (COVID-19) vaccine for people with a severely weakened immune system | NHS
- Health conditions and coronavirus (COVID-19) vaccination

The Arthritis and Musculoskeletal Alliance (ARMA) website:

COVID-19 vaccination and MSK

British Society for Rheumatology (guidance for clinicians):

COVID-19 guidance

Government website:

- Coronavirus (COVID-19): guidance and support
- Access community-based treatments for coronavirus (COVID-19)

Should people with RA be vaccinated/receive the booster vaccines, even if they are on immunosuppressant medication?

All people with RA?should be encouraged to take up any and all vaccines/boosters against coronavirus when they are offered, irrespective of the medications that are being treated with. The benefits of the COVID-19 vaccination outweigh the risks and by having the vaccine, this will reduce the risk of developing severe complications due to COVID-19.?Moreover, as protection wanes with time and may have begun at a lower level than that of the general population, it is all the more important to bolster it with the boosters where they are on offer.

The guidance?for those in doubt?is to?seek advice from the relevant health care practitioner.

Treatments for COVID-19

What are "Therapeutics"?

Effective alternative treatments for COVID-19 will continue to be vital to save lives, prevent hospitalisations and reduce the full spectrum of health and economic harm from COVID-19. Additionally, scientific advice supports the use of a range of treatments with different methods of

action.

UKHSA is continuing its efforts to understand the effect of the Omicron variant on transmissibility, severe disease, mortality, antibody response, and vaccine and treatment efficacy. The Therapeutics Taskforce will continue to work with UKHSA to understand any implications for treatments.

The monoclonal antibody treatment, sotrovimab, received MHRA approval on the 2nd of December 2021. This treatment is now available to treat some non-hospitalised individuals at highest risk of developing severe disease via COVID Medicines Delivery Units. It can also be used to treat patients with hospital onset COVID-19 where genotyping shows the patient has an Omicron variant. The RECOVERY trial is assessing sotrovimab's potential as a treatment for some hospitalised patients.

The novel monoclonal antibody combination Ronapreve from Roche, is available to treat the most vulnerable hospital patients in the UK, including those with severe COVID-19 and without antibodies, and high-risk patients who acquire infection whilst in hospital, but only when genotyping shows the patient does not have an Omicron variant.

What is the purpose of anti-viral and prophylactic treatments if we have working vaccines?

Vaccines remain the first line of defence against COVID-19. Antivirals and other treatments provide a necessary additional line of defence by playing a crucial role in protecting patients who become infected with COVID-19, particularly those who for whom the vaccine may be less effective such as the immunocompromised.

Antivirals could also play a key part, alongside other therapeutics, in protecting the population, especially if a variant of concern reduces vaccine efficacy.

Are treatments effective on the Omicron variant / other variants of concern?

It is crucial that the UK has many effective treatments to control the impact of the Omicron variant and protect against any future variants of concern.

It is not anticipated that there will be a reduction in effectiveness of nirmatrelvir + ritonavir or molnupiravir against the Omicron variant, as they do not attach to the spike protein on the Covid-19 virus, and as such should not be affected by mutations observed in the Omicron strain of the virus.

What are the government doing to protect the immunosuppressed?

Immunosuppressed individuals have been prioritised for research into therapeutic and prophylaxis treatments such as monoclonal antibody therapies, novel antivirals, and repurposed compounds.

Individuals whose immune system means they are at higher risk from COVID-19, including those immunosuppressed, who test positive for the virus, can directly access COVID-19 treatments. These patients will receive either the novel monoclonal antibody sotrovimab or nirmatrelvir + ritonavir. If patients are not able to receive these treatments they will be offered Remdesivir and then molnupiravir. A clinician will advise patients on the most suitable treatment for them.

Additionally, oral antiviral treatments are available through a new national study called PANORAMIC, run by the University of Oxford. This study is open to clinically eligible individuals living anywhere in the UK. Further details about eligibility can be found on the PANORAMIC website (www.panoramictrial.org).

Patients hospitalised for COVID-19 or those with hospital onset COVID may be eligible to receive nirmatrelvir + ritonavir, Remdesivir or sotrovimab.

More information on Government plans for therapeutics and antivirals research can be found here:

https://www.gov.uk/government/groups/the-Covid-19-therapeutics-taskforce

What about differences for children or young people?

Since the beginning of the pandemic children have been associated with having a better resistance to COVID-19, with most who contract the virus fighting it off quickly and efficiently. They are also noted to experience milder virus symptoms than adults. There has even now been some research to suggest that even children on immunosuppressant medications seem to have a milder clinical course than adults (Marlais et. al 2020). It is however noted that there is a need for larger sample sizes and a more systematic approach to reviewing data on children and young people's outcomes to COVID when on immunosuppressant treatment paths.

With the rollout of the autumn booster there are no real differences in eligibility criteria for children on immunosuppressants (see segment on autumn boosters for more detail). However, only those who are 12 years old and up are eligible for some of the antiviral treatments.

Further reading and references:

Marlais, M., Wlodkowski, T., Vivarelli, M., Pape, L., Tönshoff, B., Schaefer, F., & Tullus, K. (2020). The severity of COVID-19 in children on immunosuppressive medication. The Lancet. Child & Adolescent Health. Vol. 4(7), e17.

If I have had COVID-19 already, do I still need to have the vaccine?/ Why do I need a booster?

As it is still unclear how long both natural (from having the virus) and vaccine mediated immunity last, it is still necessary to have the vaccine/boosters even if you've previously had the virus.

Moreover, due to the immunosuppressant effect of the medications used in managing RA, individuals on such treatments may not mount the same immune response as those in the general population. To combat this the booster programmes have been rolled out to optimise the protection offered to these

vulnerable populations.

Visit the following link to read the <u>JCVI advice on COVID-19 vaccines for autumn booster programme</u> for more information about the autumn booster programme.

Can I get information on the coronavirus vaccines in languages other than English?

NHS England has vaccine in a number of different languages. You can access this information by clicking here.

Vaccine side effects

Dr June Raine, MHRA Chief Executive says:?"We ask anyone who suspects they have experienced a side effect linked with their COVID-19 vaccine to report it to the?Coronavirus Yellow Card website."

On the 4th of August 2022 the Government released a s summary of the Yellow card reports in relation to the COVID-19 vaccines, a document which is updated once a month.

This report reiterates that vaccination is still proving to be "the single most effective way to reduce deaths and severe illness from COVID-19". All three of the vaccines on offer within the UK (Pfizer/BioNTech; AstraZeneca; Moderna) have been through a thorough process of testing by the MHRA to ensure safety, quality and effectiveness. All three were also approved for use as boosters.

All medications carry a risk of side effects and these vaccines are no different, but the possible risks should be balanced against the potential benefits versus illness, and in the case of the vaccines against COVID-19 the benefits are still considered to outweigh the risks.

Read the following article by Healio Rheumatology for more information.

When reporting side effect please provide as much information as possible, including;

- Information about medical history;
- Any other medications;
- Onset timing of side effects:
- Treatment dates:
- and for vaccines, the product brand name and batch number.

You may be contacted following submission of a Yellow Card report so that the MHRA can gather additional relevant information for the assessment of the report.

These contributions form an important part of understanding suspected side effects and ensuring the safety of products.

Pfizer/BioNTech

This vaccine was tested on more than 44,000 individuals and in these clinical trials these were the side effects that were most regularly reported by participants:

- Pain at the injection site.
- Fatigue.
- Headache.
- Myalgia (muscle pains).
- Chills.
- Arthralgia (joint pains).
- Fever.

Each of the above side effects were reported by more than 1 in every 10 individuals but were generally mild or moderate in intensity and short lived. Younger individuals (under the age of 55) were more likely to report adverse reactions to this vaccine.

AstraZeneca

Clinical trials of this vaccine were conducted using over 23,000 individuals and among this population more than 1 in 10 reported the following side effects:

- Tenderness at the site of injection.
- Pain at the injection site.
- Headache.
- Fatigue.
- Myalgia (muscle pains).
- Malaise (general feeling of sick/fatigue/unwell).
- Pyrexia (fever).
- Chills.
- Arthralgia (joint pains).
- Nausea.

Most of the reported cases of side effects were considered to be mild to moderate severity and tended to clear in a few days following the jab. Less individuals in the over 65 years old bracket reported side effects and when they did, they tended to be milder than those reported by younger populations.

Moderna

Over 30,000 individuals took part in the clinical trials for the Moderna vaccine and among these more than 1 in 10 individuals reported:

- Pain at the site of the injection.
- Fatique.
- · Headache.

- Myalgia (muscle pains).
- Arthralgia (joint pains).
- Chills.
- Nausea/Vomiting.
- Axillary swelling/tenderness (swelling or tenderness of the armpit glands).
- Fever.
- Injection site swelling and redness.

Third/Booster Vaccine side effects

Once again, side effects tended to be mild to moderate severity and generally passed within a few days following their vaccine being administered. Side effects were again more common among younger individuals (compared to over 65s).

2 to 5 reports of side effects were made on average about the 3 types of vaccine per 1,000 administered doses according to the data collected by the Yellow card scheme.

"It is important to note that Yellow Card data cannot be used to derive side-effect rates or compare the safety profile of COVID-19 vaccines as many factors can influence ADR reporting. Additionally, it is important to consider that a Yellow Card report can include reference to more than one vaccine associated with a suspected reaction where different vaccines have been used as third or booster doses."

Overall the three vaccines show common side effects which are typical of many vaccines such as soreness at the injection site and generalised flu-like symptoms, aligning with the body's normal immune response. Typically, these were short-lived and did not become serious in their intensity. The types of side effects which were reported seemed to be fairly consistent across different age groups but they were more commonly reported by younger individuals.

"As we receive more reports of these types of reactions with more exposure to the COVID-19 vaccines, we have built a picture of how individuals are experiencing them and the different ways that side effects may present in people. Some people have reported a sudden feeling of cold with shivering/shaking accompanied by a rise in temperature, often with sweating, headache (including migraine-like headaches), nausea, muscle aches and feeling unwell, starting within a day of having the vaccine. Similar to the flu like illness reported in clinical trials, these effects may last a day or two."

More information:

- Coronavirus (COVID-19) vaccines adverse reactions | GOV.UK
- Article on?Rheumatology?on?COVID-19 vaccination and anti-rheumatic therapies via the Oxford University | Oxford Academic
- Reporting side effects to your RA medications | NRAS
- Making medicines and medical devices safer | YellowCard

I have had an anaphylactic reaction in the past, what should I do?

Following close surveillance of the initial vaccine roll-out, the Medicines and Healthcare products Regulatory Agency (MHRA) has advised that individuals with a history of anaphylaxis (to food, an identified drug or vaccine, or an insect sting etc.) CAN receive a COVID-19 vaccine provided they are not known to be allergic to any component of the vaccine.

If you have a known anaphylactic reaction to any of the components of the vaccine, please discuss this with you GP and notify the centre where you receive the vaccine. Generally, you should not be given the vaccine if you have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- A previous dose of the same COVID-19 vaccine.
- Any component contained within the COVID-19 vaccine.

You can find further information if you are worried about anaphylaxis at the sites below:

- Homepage | Anaphylaxis UK
- COVID-19 vaccination and MSK | ARMA
- Anaphylaxis | NHS

Boosters

Who is eligible for the autumn booster jab?

Guidance as to who is eligible for the autumn boosters can be found here:

Over 50s to be offered COVID-19 booster and flu jab this autumn | GOV.UK

Below is a summarised list of eligible groups and the categories that apply to those with rheumatoid or juvenile idiopathic arthritis and those who come into close contact with these groups such as carers are shown in bold.

- Residents in a care home for older adults and staff working in care homes for older adults.
- Frontline health and social care workers.
- All adults aged 50 years and over.
- Persons aged 5 to 49 years in a clinical risk group, as set out in the Green Book.
- Persons aged 5 to 49 years who are household contacts of people with immunosuppression.
- Persons aged 16 to 49 years who are carers, as set out in the Green Book.

Find out more about the autumn booster programme here: <u>Autumn COVID-19 booster and flu vaccine</u> programme | NHS

When should I have the spring (2nd) booster jab?

The JCVI advised on <u>21 February 2022</u> that a spring booster (a second booster) should be offered, around six months after the last vaccine dose, to individuals aged 12 years and over who are immunosuppressed.

What vaccines are being used for the autumn boosters?

After reviewing data on booster responses from different combinations of COVID-19 vaccines, the UK, following JCVI advice, will introduce bivalent vaccines targeted at both Omicron and the original strain of COVID-19 to the deployment programme.

JCVI has advised the following vaccines for eligible adults aged 18 and above:

- Moderna bivalent vaccine.
- Pfizer bivalent vaccine.
- Moderna wild-type vaccine.
- Pfizer wild-type vaccine.
- Novavax vaccine, when no alternative clinically suitable UK-approved COVID-19 vaccine is available.

For eligible people aged 12 to 17 years:

Pfizer wild-type vaccine

For eligible children aged 5 to 11 years:

Pfizer wild-type paediatric formulation.

How long does booster vaccine protection last against COVID-19?

Recent data (from lab and real world) from the UK Health Security Agency indicate that booster vaccine effectiveness against severe outcomes of COVID-19, such as hospitalisation requiring oxygen or ventilation and admission to intensive care, remain high (about 80%) to over 6 months after a booster vaccine. However, this number will be an average of all data collected and so does not reflect individual differences in vaccine effects.

Can the seasonal flu vaccine and COVID-19 vaccine/booster be administered at the same time?

The ComFluCOV trial indicates that co-administration of the influenza and COVID-19 vaccines is generally well tolerated with no reduction in immune response to either vaccine. Therefore, the two vaccines may be co-administered where operationally practical.

Therefore those eligible to have both a COVID-19 autumn booster and a flu jab, will have these co administered of the COVID-19 and flu vaccinations where possible and clinically advised, especially where this improves patient experience and uptake.

How do I book my autumn booster?

Once invited you will need to book your booster online Book or manage a coronavirus (COVID-19) vaccination or by calling 119.

Government advice

Vaccines and travel

The NHS COVID Pass is used to show an individual's COVID-19 status for travel purposes, including both proof of vaccination and prior infection. It also contains a record of all the COVID-19 vaccines registered with the NHS an individual has received and NHS COVID-19 tests taken.

It is available through the NHS App, nhs.uk or in letter form.

All children aged 5 and over can get an NHS COVID Pass for international travel including a digital and letter version. ?Since the 21st of July, children aged 5 and over can now access a digital NHS COVID Pass for international travel.

Since Friday the 18th of March, there have been no COVID-19 related travel rules in place for anyone entering the UK. The NHS COVID Pass for travel continues to be available as proof of COVID status for outbound travel to other countries where COVID-19 travel rules are still in place.

Does every country accept NHS COVID Pass as confirmation of vaccination status?

Members of the public are advised to check their destination country entry requirements before travel.

See: https://www.gov.uk/foreign-travel-advice.

Do I need a booster to be considered "fully vaccinated" and be able to travel abroad?

Each country sets their own requirements for entry, therefore border health measures of other countries fall outside the jurisdiction of the UK government. This means that some countries may require booster doses to enter.

We advise all members of the public to check destination country entry requirements before travel.

See https://www.gov.uk/foreign-travel-advice

Will fourth doses be added to the COVID Pass?

Individuals who have received four or more doses, to "top up" their vaccines will see these additional doses appear in the NHS COVID Pass.?Any vaccination is registered with the NHS and which is recognised by the NHS will appear in the NHS COVID Pass.

What measures are being taken by the JCVI and government to ensure immunosuppressed individuals are able to access the coronavirus vaccinations?

COVID-19 vaccination appointments are available to book via the <u>NHS booking system</u> or via calling NHS 119 (calls to this number are free and translators are available on request).

On the 26th of May 2022, an open letter (from the NHS, charities and community leaders) was circulated to encourage those who are immunocompromised to book their vaccination via these procedures or by visiting a walk-in vaccination centre.

What advice is being offered by the JCVI and government to reduce your risk of COVID-19 infection?

UK government has been offering a few different forms of guidance for those who are immunocompromised and at greater risk from COVID-19, providing advice around vaccinations, testing for the virus, treatments for those infected with coronavirus and behaviours to reduce infection risk.

Further information on reducing your risk of infection can be found on the links below:

- COVID-19: guidance for people whose immune system means they are at higher risk | GOV.UK
- People with symptoms of a respiratory infection including COVID-19 | GOV.UK
 - Reducing the spread of respiratory infections, including COVID-19, in the workplace | GOV.UK
- The British medical journal also wrote a piece suggesting 7 main points which need to be addressed in order to adequately reduce infection rates and reduce the subsequent disruption caused by them. A seven point plan to suppress covid infections and reduce disruptions | The BMJ

This guidance combined with the successes of the vaccine rollout and ongoing booster programmes is thought to mean that those who fall under the clinically extremely vulnerable (CEV) category, no longer need to 'shield' and can begin taking steps towards re-entering society.

Of course, it is understandable that many people will feel nervous about doing so and want to take precautions to keep themselves as safe as possible.

Here's some advice on how you can do that but please remember that these are just some ideas and you should do what feels right for you.

- Ensure that you take up any and all vaccines you are eligible for.
- Continue to follow any condition-specific advice provided by your specialist team.
- Avoiding meeting individuals who have had a positive result for the virus (or are otherwise ill, or have been in contact with someone who is). Face-to-face contact with such individuals is advised to be avoided for 10 days following a positive test.
- Meet people in well ventilated areas or where there are air filtration conditioning units.
- Ask people you are in contact with to take precautions such as being cautious ahead of
 meeting, keeping their distance and wearing a mask (them or yourself). It may also be
 appropriate to ask them to take a rapid lateral flow test but it is worth noting that these are no
 longer free for the general public.
- Speak to your employer about reasonable adjustments (see also: Reasonable adjustments for workers with disabilities or health conditions | GOV.UK) which could be rolled out in the workplace to help protect you, and if appropriate working from home.
- Reducing the spread of respiratory infections, including COVID-19, in the workplace | GOV.UK
- Maintain social distancing and reduce time spent in enclosed and/or crowded public spaces when out and about, if this feels right for you.
- Avoid touching your face when out and about, carry some hand sanitizer (at least 43% ethanol)
 and wash your hands regularly (ideally with soap and hot water but with hand sanitizer as
 necessary).
- Wear a face covering in crowded public spaces, although this measure mainly protects others it does still offer some protection for the wearer too. You can also investigate air filtration masks.

What is Evusheld and how does it work?

Evusheld (AZD7442) is a monoclonal antibody treatment designed to prevent infection with the SARS-CoV-2 virus prior to exposure to an infected individual.

It is a combination of two human monoclonal antibodies, tixagevimab (AZD8895) and cilgavimab (AZD1061). These antibodies are designed to bind the spike protein, which prevents the virus from being able to attach to and enter cells.

They are to be given as two separate intramuscular injections one after the other. You can see the patient information leaflet and further information on the drugs here:

https://www.gov.uk/government/publications/regulatory-approval-of-evusheld-tixagevimabcilgavimab

Evusheld is a made by pharmaceutical company? <u>AstraZeneca</u>.? The treatment was designed for people who are less likely to be well-protected from COVID-19 by vaccines, which can include people who are immunocompromised.

Will the UK Government procure Evulsheld for pre-exposure prophylaxis?

On the 5th of September 2022 the government published their current decision around Evusheld's use in the UK.

"Based on the evidence that is currently available and after careful analysis and consideration, the UK Government has decided not to procure Evusheld for prevention through emergency routes at this time.

However, the UK Government has referred Evusheld to the National Institute for Health and Care Excellence (NICE) for evaluation, which provides evidence-based, rigorous evaluation of the clinical and cost effectiveness of medicines for use in the NHS.

This is a decision based on independent clinical advice by RAPID C-19 (a multi-agency group) and a UK National Expert Policy Working Group and reflect the epidemiological context and wider policies in our pandemic response and recovery.

The Chief Medical Officer is content that the correct process for providing clinical advice has been followed and agrees that Evusheld should now be assessed by NICE.

While we recognise that this is disappointing for those patients who were hoping to have access to Evusheld at this time, it is essential that the UK Government is fully informed and has sufficient evidence of likely benefit when making procurement decisions. The NICE assessment process provides a robust evidence-based evaluation that underpins the procurement and use of the vast majority of drugs in the NHS."

Evusheld – AstraZeneca's new prophylactic treatment: a new hope?

AstraZeneca's new prophylactic treatment "Evusheld" has become a spotlight issue for patients and stakeholders but as yet little is known about its proposed rollout following its approval in the UK.

Clinicians agree: Evusheld should be delivered as soon as possible

Over 120 leading clinicians representing 17 different clinical specialities, across all 4 nations, have released a clinical consensus statement saying that there is sufficient evidence that the COVID-19 preventative? Evusheld? would have clinical benefit to people who are immunocompromised, and a protective? antibody treatment? program should be delivered as soon as possible.

This is the largest known coronavirus clinical expert statement that has been published to date in the United Kingdom.

The statement sets out: the scientific evidence showing the benefits of this treatment; when these treatments should be given; who should be given them and how a rollout should happen – laying a clear roadmap for implementation.

On Evusheld, the UK lags behind 32 other countries

Evusheld is a drug made by pharmaceutical company? AstraZeneca? that is made up of two monoclonal antibodies: cilgavimab and tixagevimab. The treatment was designed for people who are less likely to be well-protected from COVID-19 by vaccines, which can include people who are immunocompromised. Evusheld is a treatment given by injection and gives people antibodies that can destroy COVID-19 for up to six months. 32 other countries including Israel and the US have already bought the drug and are giving it to many people who are immunocompromised.

<img src="https://nras.org.uk/wp-content/uploads/sites/2/2022/08/Coalition_Of_Charities.width-700.png"

18 charities write to Secretary of State for Health and Social Care

For many immunocompromised people, the first lockdown in 2020 never ended, which is why in addition to the clinical consensus statement, on the 1st of August 2022, 18 charities including ourselves, signed an open letter to Steve Barclay MP, urging the government to buy Evusheld to protect the people they represent who remain vulnerable to COVID-19.

You can see the?letter here.

What can I do to help?

We would like to request your help with this – we've written a template letter below that you can use to send to your MP asking them to write to the Secretary of State. You can find out who your local MP is and their contact details using the? find your MP website.

Click here?to see our template letter to MPs.

It's just a template, so feel free to personalise it and make any changes you wish so that it reflects your opinions and concerns. If you send a letter to your MP about Evusheld, we'd love to hear about it.

You can let Victoria (our Covid-19 Policy Officer) know at?<u>vtecca@bloodcancer.org.uk</u>?with the subject line?I wrote to my MP.

While the Government so far has refused to give us the information our community needs, we hope that these letters will show them how important this issue is to immunocompromised people.

The Government at present have made the decision to wait further evidence following the NICE review of the drug, this is scheduled to begin autumn 2022 but will conclude early in 2023. Further campaigning efforts are likely.

Ongoing testing efforts

Following a continued reduction in COVID case numbers, the government has moved to cease routine testing of asymptomatic cases across further settings. This means that only individuals showing symptoms in hospitals and care homes will continue to be tested, alongside immunocompromised individuals being admitted into care in either of these settings. In essence, symptomatic testing in high-risk settings will continue.

"Testing will remain in place for admissions into care homes and hospices from both hospitals and the community, and for transfers for immunocompromised patients into and within hospital to protect those who are most vulnerable."

Testing will also be available for outbreaks in certain high-risk settings such as care homes.

Year-round symptomatic testing will continue to be provided in some settings, including:

- ?NHS patients who require testing as part of established clinical pathways or those eligible for Covid treatments.
- NHS staff and staff in NHS-funded independent healthcare provision.
- Staff in adult social care services and hospices and residents of care homes, extra care and supported living settings and hospices.
- Staff and detainees in prisons.
- Staff and service users of certain domestic abuse refuges and homelessness services.

This builds on the already ended free testing for members of the general public on the 1st of April which formed an early stage in the government's "Living with COVID" plan.

On the 24th of August when the press release announcing this change was released, COVID cases had fallen to 40,027 and data pointed to the transmission risk having also reduced. At this time data from the previous 7 days showed deaths had fallen to 744 and hospitalisations to 6,005.

This illustrates the effectiveness of the vaccination efforts which continue to form the backbone of ongoing actions to protect the most vulnerable individuals in society.

"The government continues to encourage all who are eligible to take up booster jabs. Autumn boosters will be available to book through the National Booking Service ahead of the wider rollout, due to start on the 12 September. The NHS will contact people when it is their turn".

While it is not expected to be required, the government will continue to monitor the situation and will resume testing should this be found to be needed.

Miscellaneous questions

Should I stop taking my medications before, or after, having the vaccine?

It is vitally important to keep your RA as well controlled as possible so any decisions around whether it would be appropriate for a temporary cessation in your medications should be

discussed with your rheumatology team. Advice may vary on a case by case basis.

Depending on the level of activity of your disease you can find out more about <u>disease activity scores</u> <u>here</u>. Stopping your medication could lead to a flare up of your condition. Because of the knock on effect of the pandemic in delaying access to health services and response times from GPs and other NHS units, it may not be possible to get timely assistance to manage the flare.

The Arthritis and Musculoskeletal Alliance (ARMA) initially advised patients should not stop taking their immunosuppressant drugs for the vaccine, unless advised to do some by a member of their specialist team. Following results of the OCTAVE and OCTAVE-DUO studies which demonstrated the reduced efficacy of the vaccines in those on immunosuppressants, more research has been conducted (and is ongoing) in this area with an eye to improve the immune response mounted by individuals on these types of treatments.

The 'VROOM' study conducted by Abhisshek, A et. al (2022), has shown in their sample, that ceasing methotrexate treatment for 2 weeks following administration of the 3rd COVID-19 dose compared to continued treatment as usual, can bolster the immune response which is mounted. Most interestingly, the authors note that this increase was sustained up to 12 weeks for those who suspended methotrexate treatment and that even at this later point of examination, their antibody response was higher than that of the group who continued their methotrexate as normal 4 weeks after vaccination.

Regardless of medication or previous stops in treatment for other vaccinations, individuals are encouraged to weigh up the pros and cons with their specialist team to choose the safest and most appropriate course of action.

Do the vaccines contain animal products?

The PETA UK website says, "The vaccines made by Pfizer/BioNTech, Oxford/AstraZeneca and Moderna that were recently approved for use in the UK do not contain any animal-derived ingredients "

Read more here:

Can Vegans Get a COVID-19 Vaccine? | PETA

Vaccinations and their protection versus different strains of the virus

All vaccines which have been rolled out in the UK to date have been primarily targeted at the original strain of COVID-19. Although this might sound like they are likely to be ineffective against newer mutations ("strains") of the virus they have consistently remained effective at preventing severe disease against subsequent variants.

Therefore, any vaccine being offered as part of the autumn boosters are considered highly effective and to yield a strong booster response, and should be taken up in order to protect the most vulnerable this winter.

Should I stop my medication(s) if I am showing symptoms of COVID-19?

You may be advised to?pause?your medications?if?you are showing symptoms of COVID-19?but you should seek proper medical advice from speaking to 111 and ideally your rheumatology team.

Advice may vary on a case by case basis depending on disease activity and other individual factors.

What about treatments to fight coronavirus?

Changes to accessing antiviral treatments:

Previously, those who were eligible for the antiviral treatment were sent a confirmation letter and a priority PCR kit in the post. Since then, more anti-viral and nMAB (Neutralising monoclonal antibodies) treatments have become available to battle the virus and of course the COVID-19 landscape has changed. Now that PCR tests are no longer in use, patients will receive a lateral flow testing kit as well as a new letter. You can see the? Letter here.

The process will then be as follows:

- As soon as you develop COVID symptoms (even if these are mild), use the lateral flow test.
- Report your test result here or by calling 119.
- You will be asked for your NHS number and postcode.
- If the result is positive, wait to be contacted about treatment. If your test is negative, then you are advised to take additional tests for the next 2 days (totalling 3 tests over 3 consecutive days), these should also be reported as outlined above.
- If after 24 hours you have had no contact, call your GP or 111.

The?following letter?has been sent to healthcare professionals to make them aware of this process.

Who is eligible for treatment?

The official list of those eligible can be found?here.

Of relevance to patients with RA and JIA is the following:

- "people who have received a B-cell depleting therapy (anti-CD20 drug for example rituximab, ocrelizumab, ofatumab, obinutuzumab) in the last 12 months".
- "people who are on biologics[footnote 8] or small molecule JAK-inhibitors (except anti-CD20 depleting monoclonal antibodies) or who have received these therapies within the last 6 months

- "people who are on corticosteroids (equivalent to greater than 10mg per day of prednisolone) for at least the 28 days prior to positive PCR".
- "people who are on current treatment with mycophenolate mofetil, oral tacrolimus, azathioprine/mercaptopurine (for major organ involvement such as kidney, liver and/or interstitial lung disease), methotrexate (for interstitial lung disease) and/or ciclosporin".
- "people who exhibit at least one of: (a) uncontrolled or clinically active disease (that is required
 recent increase in dose or initiation of new immunosuppressive drug or IM steroid injection or
 course of oral steroids within the 3 months prior to positive PCR); and/or (b) major organ
 involvement such as significant kidney, liver or lung inflammation or significantly impaired renal,
 liver and/or lung function)".

The full clinical commissioning policy which will be effective from?13 June 2022?can be found?here.

How to get a lateral flow test:

Due to the government ending free access to lateral flow tests for the coronavirus, there are now only certain groups of individuals that can receive free lateral flow test kits. Check you are eligible to receive a lateral flow test on the?GOV.uk website.

If you are eligible:

Order your lateral flow tests via? the GOV.UK website. Alternatively, you can ring 119 if you have not received your lateral flow test. ? The weblink provided does not ask for proof of eligibility, just to confirm that you are.? If you want further guidance on this, please check the? following article.

Please note that the test used must be one provided by the government and privately purchased tests cannot be used.

Who do I speak to if I think I am eligible, but I have not been contacted?

If you do not receive a letter, then you may still be eligible. You can follow the same process but will have to acquire the lateral flow tests yourself. It is important that you only get the NHS/government provided lateral flow tests as privately sourced tests will not be recognised in the system. You can get the tests using the process above. If you get a positive test wait 24 hours to be contacted. After this time period you can then call either the GP, NHS 111 or your specialist clinician for an urgent referral.

What treatments are available?

There are four treatments available in different forms – "antivirals" and "nMABs" (Neutralising monoclonal antibodies).

Treatment name	Treatment type	Administration method
"Paxlovid" – nirmatrelvir plus ritonavir*	Antiviral	Tablets
"Xevudy" – sotrovimab	nMAB	Intravenous infusion
"Veklury" – remdesivi	Anitviral	Intravenous infusion

Paxlovid OR Xevudy can be administered are first-line treatments, Veklury is a second-line treatment and Lagevrio is a third-line treatment. Combination treatment with an nMAB and an antiviral is NOT routinely recommended.

Those who receive an oral form treatment will either be asked to collect the treatment from one of the available centres or it will be delivered to their home.

Those who are having an intravenous infusion treatment will be required to attend an appropriate treatment centre where the treatment will be administered. Infusions are expected to take around half a day in total.

For more information on the treatments available for coronavirus, please see the NHS information,? found here.

See?this link?to find out about co-administration of medications with these treatments.

If I am not eligible is there another way of getting involved in the treatment?

Where patients are ineligible for treatment under this policy, recruitment to the Oxford university "PANORAMIC trial", which is building the evidence for novel oral antivirals in a broader cohort of atrisk patients, should be supported.

You can see the criteria for signing up to this study on?their website.

Further reading:

- <a href="https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies" https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies" https://www.gov.uk/government/publications/higher-risk-patients-eligible-for-covid-19-treatments-independent-advisory-group-report/defining-the-highest-risk-clinical-subgroups-upon-community-infection-with-sars-cov-2-when-considering-the-use-of-neutralising-monoclonal-antibodies
- https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2021/12/C1650-interimccp-antivirals-or-neutralising-monoclonal-antibodies-non-hospitalised-patients-with-covid19v6.pdf
- https://www.nhs.uk/conditions/coronavirus-covid-19/self-care-and-treatments-for-coronavirus/treatments-for-coronavirus/

Are people on advanced therapies (biologics/biosimilars/JAK Inhibitors) at higher risk than those on conventional DMARDs?

If you are not sure about the distinction between these types of medicines you can order, for free, our Medications in RA booklet or visit our? medication section.

The contraction and severity of coronavirus seems to be variable according to a wide range of factors and understandably people on immune mediating medications will be extra concerned about their risk from the virus.

Research has consistently demonstrated the positive effects of vaccination in protecting individuals from the worst of the virus even in populations where individuals are on immunosuppressant medications (although it can take boosters to yield a similar level of immune response compared to members of the general population).

When comorbidities (health conditions) are controlled for in statistical analyses, the increased risk of having coronavirus severely, disappeared in the majority of studies. Likewise, many studies in this area have demonstrated that aside from the use of JAK inhibitors and rituximab, other forms of DMARDs (conventional or advanced) do not seem to exacerbate the risk of severe COVID symptoms. The effect of JAK inhibitors and of rituximab worsening infection outcomes has only been shown in some studies.

Studies such as that of Mackenna et al (2022).

Further reading and references:

Mackenna, B., et al. (2022). Risk of severe COVID-19 outcomes associated with immune-mediated inflammatory diseases and immune-modifying therapies: a nationwide cohort study in the OpenSAFELY platform. Articles Lancet Rheumatology. Vol. 4, p. 490–506.

Long COVID

Long COVID describes symptoms lasting beyond or developing after the initial infection of coronavirus ("acute COVID-19") and which have no explanation with another diagnosis. "This term includes ongoing symptomatic covid-19, from four to 12 weeks post-infection, and post-covid-19 syndrome, beyond 12 weeks post-infection." (NICE). Long COVID has been noted to cover a broad range of symptoms and as occurring in a wide range of individuals, from those who had a very mild case of the virus to those who experienced it more severely.

Symptoms of long COVID:

Unlike the acute form of the infection, long COVID has much wider ranging symptomology and can impact on multiple organs and systems within the body. These can include (please note this is not an exhaustive list):

- Respiratory system (the system responsible for the exchange of carbon dioxide and oxygen in the human body).
- Cardiovascular system (powered by the heart this system is responsible for transporting oxygen, nutrients, hormones, and cellular waste products throughout the body).

- Neurological system/The Nervous system (the body's electrical wiring made up of a complex collection of nerves and specialized cells known as "neurons" which transmit signals between different parts of the body).
- Gastrointestinal system/ Digestive system (functions include?the?ingestion,?digestion,?and? absorption?of?food?or?nutritive?elements).
- Musculoskeletal systems (muscles and bone structures).

Some of the symptoms which people can experience with long COVID include:

- Fatigue2.
- Dyspnoea (difficult or laboured breathing).
- Cardiac abnormalities (structural or functional changes in the heart).
- Cognitive impairment (disordered thinking/memory or impact on other mental processes).
- Disturbances in normal sleeping.
- Symptoms typically associated with post-traumatic stress disorder.
- Muscle pain.
- Concentration problems.
- Headache.

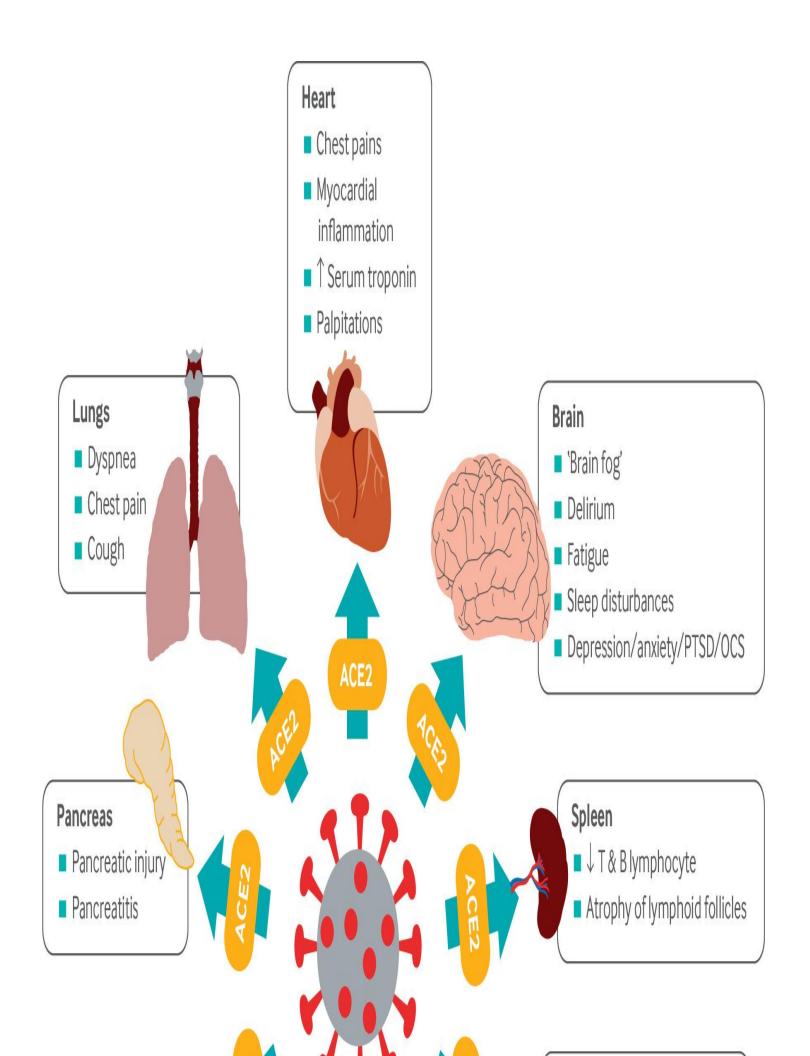


Fig 1. Taken from Crook, Raza, Nowell, Young and Edison's (2021) research paper, p2. See references and further reading for the full reference.

Symptoms of long COVID can occur regardless of infection severity, research has also demonstrated few differences in the rates of occurrence of long COVID between those treated for COVID and those who received no treatment nor in between the different treatment options.

The Office for National Statistics (ONS) in the UK is continuing to monitor the current situation, but as of the 2nd of July 2022 they estimated that in the UK's private households 1.8 million people (or 2.8% of the UK population) had long COVID symptoms (according to self-reports). Their data also suggests that the most commonly reported symptom of long COVID was fatigue (54%) followed by breathlessness (31%), anosmia (loss of smell, 23%) and aching muscles (22%).

The ONS reports that "As a proportion of the UK population, the prevalence of self-reported long COVID was greatest in people aged 35 to 69 years, females, people living in more deprived areas, those working in social care, those aged 16 years or over who were not students or retired and who were not in or looking for paid work, and those with another activity-limiting health condition or disability.

This is underpinned by data collected from round the globe which despite variations in the research methodology3 show consistently high levels of long COVID across a variety of populations studied suggesting that a substantial proportion of those infected with the virus may develop long COVID. What is unclear at this time is the changes in the frequency and severity of long COVID depending on which strain of the virus is contracted. This requires ongoing research and reactive changes to treatment strategies in order to effectively combat long term symptoms following COVID infection.

Who is at greater risk of developing long COVID?

According to Crook et al. (2021), those who are increased risk of requiring hospital treatment for COVID, of developing long COVID symptoms and of death from coronavirus include (See Crook et al. 2021, p. 9 for referenced studies):

- Older compared to younger individuals.
- Men compared to women.
- Those from non-white ethnic groups.
- Those living with a disability (of any kind).
- Those with a history of other health issues ("comorbidities") including;
 - o Obesity.
 - o Cardiovascular disease.
 - Respiratory disease.
 - Hypertension.

The role of immunosuppression in long COVID risk is still being scrutinised and up for debate. Some studies have suggested that immunosuppression may have a protective effect from long COVID symptoms however this is contentious and requires more research before it can be stated conclusively (Crook et al. 2021, p. 9-10). What is clear is that the World Health Organisation (WHO) and the Long COVID Forum Group, are placing an onus on research into providing a clearer cut clinical definition of long COVID for consistency round the world and on the development of effective

treatments to combat the health issue.

References and further reading:

- Crook, H., Raza, S., Nowell, J., Young, M., & Edison, P. (2021). Long covid Mechanisms, risk factors, and management. The British Medical Journal. Vol. 374, p. 1-18. Weblink: https://doi.org/10.1136/BMJ.N1648
- National Institute for Health and Care Excellence. COVID-19 rapid guideline: managing the long-term effects of COVID-19 NICE guideline; c2020. https://www.nice.org.uk/guidance/ng188
- Office for National Statistics (2022). Prevalence of ongoing symptoms following coronavirus (COVID-19) infection in the UK: 4 August 2022. Retrieved from: https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/bu
- ZOE Editorial Staff (5th August 2022). What's your risk of Long COVID now? Retrieved from: https://health-study.joinzoe.com/blog/covid-long-covid-risk

Can I have the COVID vaccine if I live with long COVID?

Adults can have a COVID vaccine 28 days after a positive test for COVID-19 or 28 days after symptoms started, whichever is earlier. Young people aged 16 and 17 who are not at high risk from C OVID-19 need to wait for 12 weeks. This is in line with JCVI guidance. You can check with you GP if having concerns.

Why is it so difficult to give accurate numbers about COVID and long COVID?

Back when the pandemic began it took a fair bit of time before reporting techniques were developed to allow the general public to highlight cases of symptoms. From the peak of the pandemic when most individuals were regularly reporting we have seen a dramatic drop in even those with things like the NHS COVID app and ZOE health study app still loaded on their smartphones, never mind reporting their test results or symptoms.

There are also variations from country to country in reporting rates of incidences of infection and mortality rates due to differences such as definitions, culture, population characteristics, accuracy of diagnoses, healthcare systems and reporting mechanisms.

These and other factors not yet highlighted, mean that it is difficult to get an accurate picture of the situation. In an ideal world, there would be data provided by each person on the planet however this is unrealistic, so inferences must be made from small samples and from the data we have. Research aims to generalise from these smaller samples to larger populations, as well as make predictions from observations of the available data using statistical equation modelling techniques. This does however mean that we must take research generalisations with a pinch of salt as they may not fully reflect the "real world" situation.

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