

Clinical Guidance on Exemption from COVID-19 Vaccination or Vaccination and Testing

1. Introduction

Individuals who are fully vaccinated present a lower risk of transmitting COVID-19. For this reason, some venues in England require proof of vaccination or testing status as a condition of entry. Similarly, restrictions on individuals' lives, such as travel-related quarantine or self-isolation requirements, have been eased for those who are fully vaccinated. Individuals can use the NHS COVID Pass to demonstrate their COVID-19 vaccination details or test results. This is an individual's COVID status.

Exemptions from self-isolation and requirements to complete vaccination (or in some cases testing) are being introduced to reduce transmission of COVID-19 whilst limiting onerous restrictions on individuals lives.

Individuals may need to show their covid-status to:

- Work or volunteer in a CQC-regulated care home from 11 November 2021.
- Be exempt from self-isolating for 10 days if they are a close contact of a confirmed COVID-19 case.
- Be exempt from self-isolation and completing a test on Day 8 if they travel from a non-red list country.
- Enter a venue in England that requires the NHS COVID Pass as a condition of entry.

Those who are unable to be vaccinated and / or tested for medical reasons will therefore need a means of proving an exemption through the NHS COVID Pass. The NHS COVID Pass will be indistinguishable from the pass used by people who are fully vaccinated for domestic use, and will not show why individuals have a medical exemption.

A careful balance in issuing exemptions is needed to ensure the volumes of exemptions do not undermine the public health benefits of certification, or create a system that can be used by individuals to circumvent certification requirements. Exemptions from certification will require clinical sign off. Further details on this process are found at: https://digital.nhs.uk/services/summary-care-record-application/covid-pass-medical-exemption.

2. Criteria

Clinical guidance has been developed upon the advice of senior clinicians and using the Green Book.

Illustrations are provided below but this list is by no means exhaustive. None of these are reasons in themselves for a person not to be vaccinated.

Examples for potential exemption from vaccination and testing could include individuals:

- Receiving **end of life care** where vaccination is not in the individual's interests.
- With learning disabilities or autistic individuals, or with a combination of impairments which result in the same distress, who find vaccination and testing distressing because of their condition and cannot be achieved through reasonable adjustments such as provision of an accessible environment.
- Those with **medical contraindications** to the vaccines such as:
 - severe allergy to all Covid-19 vaccines or their constituents (e.g. PEG).
 - those who have had adverse reactions to the first dose (e.g. myocarditis).

Consideration should be given to the special warnings and precautions for use found in section 4.4 of the Summary of Product Characteristics for each product, only where an appropriate vaccine cannot be found or sourced for vaccination should an exemption be considered. A caution to one vaccine or vaccine type where safe alternatives are available should not lead to exemption.

Further information on vaccines and their cautions can be found in the COVID 19: The Green Book, Chapter 14a

Anticoagulation and clotting disorders would only be viewed as need for exemption in exceptional circumstances.

3. Time-limited exemptions to Vaccination

Time-limited exemptions for those with short-term conditions and for pregnant women may be considered. When entering your decision onto the Summary Care Record application, you will be given the option to enter an expiry date up to a year after the date of entry. We recommend the expiry date should allow individuals enough time to acquire two doses of the vaccine plus two weeks.

1. Short term medical conditions: Some individuals will apply for an exemption on the grounds that they have a time-limited medical reason for deferring vaccination (e.g. they are receiving hospital care or receiving medication which may interact with vaccination). They will require a time-limited deferral and therefore we are recommending that they are granted a short-term exemption, until they are able to be vaccinated.

2. Pregnant women:

- COVID Vaccination in pregnancy is considered safe and is recommended by the <u>Royal College of Obstetricians</u>, <u>Royal College of Midwives and the</u> <u>UK Tetralogy Service</u>.
- Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data from over 160,000 vaccinations in pregnancy in the US, and 90,000 in <u>England</u> and <u>Scotland</u>, do not indicate any harm to the foetus or infant.

- JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group.
- The Green Book has advised that pregnant women should be offered COVID-19 vaccination on the balance of benefits and risks (as pregnant women are at risk of direct and indirect COVID-19 complications, including preterm birth).
- In line with the NHS guidance, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told that the vaccine is recommended, but that there remains limited evidence of safety for the vaccine in pregnancy. For the latest advice, please see the:
 - Public Health England leaflet for all women of childbearing age, pregnant or breastfeeding
 - o RCOG/RCM information leaflet and decision aid.
- Whilst clinicians should continue to clearly recommend the vaccine for pregnant women (at any gestation), the option of a time-limited exemption to pregnant women who express concerns surrounding the vaccine after counselling can be considered.
- There are fewer concerns surrounding the safety of the vaccine and breastfeeding so these women would not be considered exempt unless there are alternative indications for exemption.
- Those who are trying to get pregnant are not eligible for an exemption.
- We recommend the expiry date for an exemption for pregnant women should be 16 weeks post-partum, in order to allow them to acquire two doses of the vaccine after birth (plus two weeks).
- Women who are 20 weeks or further into their pregnancy can use their paper-based Maternity Certificate (MAT B1).
- Women in their 1st trimester (or those concerned with showing their MAT B1) may wish to be considered for an exemption.

4. Evidence of Diagnosis

The clinician issuing the exemption should be familiar with the person and their medical history.

It is noted that for some of the learning disabilities and autism diagnoses, particularly the extent to which they impair the individual's ability to access vaccination without severe distress, may not be documented well within their clinical records. A diagnosis of a neuro-disability should not necessarily lead to an exemption, but a decision should be made as part of a clinical assessment and the ability for reasonable adjustments to the vaccination process to be made which enable access.

It is accepted that some individuals with a neuro-disability will have only historic evidence within their clinical notes as to the way their problem impacts them. The clinician may need to make a clinical judgement on the basis of the documented diagnosis and the individual's challenges in accessing vaccination as to whether exemption is justified. Access to the GP records may be helpful in this regard.

5. Reasonable adjustments

Before administering an exemption, ensure that the person has been offered a vaccination and that they have had the necessary communications surrounding vaccination. Where a reasonable adjustment can be made to enable vaccination this should be sought rather than issuing an exemption e.g. needle phobia clinics, adjusted vaccination location / time. NHSE have published guidance for clinicians: NHSE England » COVID-19 vaccination training.

6. Payment for GPs

General Practices will be paid for each review of a medical exemption completed, whether this review grants or does not grant the exemption. Payment for GPs will be triggered by the input of the medical exemption review onto the SCRa by the practice. SCRa inputs will automatically generate a report detailing the number of assessments per month and send these to the payment system to issue a payment. General Practices will be paid by the end of the month following the extraction of assessments from the SCRa inputs.