

Immunisation Clinical Advice Response Service 24/09/21

For any COVID-19 vaccination related queries or to escalate an incident please contact:
england.swicars@nhs.net

Please note that since Monday 2nd August CARS has now become ICARS and will operate from 9am - 5pm Monday to Friday.

**PLEASE SHARE WITH ALL RELEVANT STAFF INVOLVED WITH THE
VACCINATION PROGRAMME**

Contents:

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1. Updated PGD and national protocols for Pfizer BioNTech Covid-19 Vaccine BNT162b2 and Comirnaty

Updated Patient Group Directions and national protocols for Pfizer BioNTech Covid-19 Vaccine BNT162b2 and Comirnaty have today been published and can be accessed via:

[https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-\(pgds\)](https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds))

2. Greenbook chapter 14a COVID-19 update as of 16 September 2021

Updated to include new recommendations on boosters and children and young people. Minor updates to guidance on managing allergies and giving additional doses after rare side effects. Clarification of clinical risk groups for children and adults and the use of the clinically extremely vulnerable definition.

3. 12-15-year-old programme resources

A number of resources are now available for the COVID-19 schools vaccination programme, links below to order stock or download the resources directly.

- Main COVID-19 vaccination programme collection
<https://www.gov.uk/government/collections/covid-19-vaccination-programme>
- COVID-19 resources for parents and schools



<https://www.gov.uk/government/publications/covid-19-vaccination-resources-for-schools>

- COVID-19 guide for schools
- COVID-19 vaccination factsheet for parents, guardians and carers
- Invitation template letter
- COVID-19 vaccination leaflets for children and young people
<https://www.gov.uk/government/publications/covid-19-vaccination-resources-for-children-and-young-people>
 - COVID-19 vaccination main guide for children and young people – this is the leaflet for school teams to send with the consent form and template letter in the schools page above.
 - What to expect after your COVID-19 vaccination leaflet – for all children and young people including schools, at risk and 16-17 years of age
 - COVID-19 vaccination simple text guide for at risk children aged 12 to 15
 - COVID-19 vaccination guide for young people aged 16 and 17 years of age
- Easy read guides to COVID-19 vaccination for at risk children
 – <https://www.gov.uk/government/publications/covid-19-vaccination-easy-read-resources-for-children-and-young-people>
 - Leaflet as above.
 - Easy read consent form – download only

4. **Vaccines for prisons/secure settings**

The posters and flyers for prisons are live and stock is waiting to be ordered. They were published on the .GOV website on as part of the [COVID-19 vaccination collection](#). Please encourage relevant settings to place an order. They will need to register on the [Health Publications website](#) as a prison/looked after setting with full address and then should be able to order up to 500 of each.

Title/link on .GOV COVID-19 vaccination collection	Product code to search on Health Publications website	Link on Health publications website
Don't delay your COVID-19 vaccination prison poster male	COV2021PS1	https://www.healthpublications.gov.uk/ViewArticle.html?sp=Sdontdelayyourcovid19vaccinationprisonpostermale
Don't delay your COVID-19 vaccination prison poster female	COV2021PS2	https://www.healthpublications.gov.uk/ViewArticle.html?sp=Sdontdelayyourcovid19vaccinationprisonpostermale-2078
Don't delay your COVID-19 vaccination - prisons flyer	COV2021PSF	https://www.healthpublications.gov.uk/ViewArticle.html?sp=Sdontdelayyourcovid19vaccinationprisonsflyer

5. **COVID-19 Vaccination After Stem Cell / Bone Marrow Transplant**

NHS England has been working with the British Society of Blood and Marrow Transplantation and Cellular Therapy and Anthony Nolan to ensure that those who

have received a Stem Cell Transplant or CAR-T therapy are offered COVID-19 re-vaccination. In patients who receive stem cell transplants or CAR-T therapy, any protective antibodies from exposure or vaccination prior to transplantation are likely to be lost and it is unclear whether the recipient acquires the donor's immunity. Any previous COVID-19 vaccination is to be discounted and it is recommended that the individual is re-vaccinated as if they have never received a COVID-19 vaccine. They are likely to require re-vaccination with other vaccines too (Green Book Chapter 7)¹.

In COVID-19: the green book, chapter 14a², the Joint Committee on Vaccination and Immunisation (JCVI) has advised that *“individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19”*.³

To note that this guidance applies to those who have received CAR-T therapy for haematological malignancies only. It does not apply to individuals who have received CAR-T therapy for other reasons.

The British Society of Blood and Marrow Transplantation and Cellular Therapy (BSBMTCT) has prepared statements on vaccination and re-vaccination of HSCT and CAR-T patients, available at <https://bsbmtct.org/bsbmtct-and-covid>. In summary:

- HSCT and CAR-T recipients who have received prior doses of a SARS-CoV-2 vaccine pre-procedure should be considered never-vaccinated in keeping with May 2021 Green Book guidance and offered full re-vaccination with a SARS-CoV-2 vaccine course. The JCVI has advised that individuals who were immunosuppressed at the time of their first two doses including those who have received a stem cell transplant in the previous 24 months receive a three-dose SARS-CoV-2 primary schedule.
- Consider re-vaccination with a SARS-CoV-2 vaccine from 2-6 months post autologous and allogeneic HSCT.
- Consider re-vaccination with a SARS-CoV-2 vaccine from 3-6 months following CAR-T therapy.

In addition, the BSBMTCT recommends vaccination or re-vaccination from 3-6 months after HSCT or CAR-T for individuals aged 12-15 years. This follows the recommendation from the JCVI in July 2021 that children aged 12-15 who are at increased risk of serious disease, including those who are immunosuppressed, are offered a UK-authorized COVID-19 vaccine.

Annex A is a draft letter which can be used to inform a patient's registered general practitioner regarding the vaccination requirement. It is recommended that a copy of the letter is also sent to the patient as per normal practice.

Annex A: Patient /GP letter

Dear [Patient's GP],

Important information re [Patient's name, DoB and NHS number] COVID-19 vaccination

I am writing to inform you that the patient named above has received a haematopoietic stem cell transplant (HSCT) or CAR-T therapy.

In COVID-19: the green book, chapter 14a, the Joint Committee on Vaccination and Immunisation (JCVI) has advised that *“individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19”*. _

The British Society of Blood and Marrow Transplantation and Cellular Therapy (BSBMTCT) has prepared statements on vaccination and re-vaccination of HSCT and CAR-T patients, available at <https://bsbmtct.org/bsbmtct-and-covid>.

This patient's transplant team have assessed that this patient is suitable for re-vaccination with a further 3 doses of a SARS-CoV-2 vaccine.

The safety and immune response of SARS-CoV-2 re-vaccination are being investigated in the observational OCTAVE study, and HSCT and CAR-T patients are invited to participate. Further information can be found at www.birmingham.ac.uk/octave.

If the person named in this letter is under the age of 16, please note that in July 2021 the JCVI recommended that children aged 12-15 at increased risk of serious disease, including those who are immunosuppressed, are offered the Pfizer-BioNTech vaccine. The BSBMTCT recommends vaccination or re-vaccination from 3-6 months post-HSCT and CAR-T for individuals aged <16.

[Transplant/clinician to edit following sentence if a specific choice of vaccine is being requested] For individuals aged ≥16, choice of vaccine for re-vaccination should be made in accordance with guidelines in the Green Book.

Please see the note overleaf for practical guidance from NHS England on how to arrange and record re-vaccination after transplant.

If you need any further information or guidance please don't hesitate to contact this patient's transplant team using the details below.

Yours sincerely,

[Transplant clinician's name and contact details]

Note on re-vaccination in practice

This can be done using any age-appropriate vaccine following JCVI guidelines or as appropriate following specialist opinion on which vaccine maybe more appropriate. Details of repeated doses should be added using the standard point of care software and the record annotated to show that this is an intentional duplication following stem cell transplantation.

Timing of vaccination will be determined by the specialist but would normally be with first dose around 90 days, the second dose following 8 to 12 weeks later, and a third dose 8 weeks after the second. Further doses would follow the national advice at the time. Accelerated second dosing earlier than 8 weeks is not normally indicated.

Payment where relevant to the providing service should follow the re-vaccination, following local protocols and procedures.

Re-vaccination will not impact upon COVID Pass processes, where the individual had already been issued with a pass.

Further materials

1. Public Health England. Immunisation of individuals with underlying medical conditions: the green book, chapter 7, <https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7> (2020).
2. Public Health England. Immunisation against Infectious Disease; Chapter 14a, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948757/Greenbook_chapter_14a_v4.pdf (2021).

6. Temporary medical exemptions for care home staff

15th September 2021

Dear care colleagues,

Temporary medical exemptions for COVID-19 vaccination of people working or deployed in care homes

Regulations were approved by Parliament on 22 July 2021 to make vaccination a condition of deployment for staff working in CQC-regulated care homes in England, unless they have a medical exemption. A 16-week grace period was put in place to ensure staff who haven't been vaccinated could take up the vaccine before the regulations come into force on 11 November 2021.

Thanks to the incredible efforts of people across the care sector to encourage and reassure colleagues about vaccination, as of 9 September, 90.4% of care home workers have now had a first dose of a COVID-19 vaccine, with 82.2% of care home staff now fully vaccinated.

The Department of Health and Social Care has been working as quickly as possible to ensure that people who are not able to get the vaccine for medical reasons are not disadvantaged.

On a temporary basis, from today, people working or volunteering in care homes who have a medical reason why they are unable to have a COVID-19 vaccine will be able to self-certify that they meet the medical exemption criteria, using the forms attached to this letter.

Care home workers who are exempt will need to sign the form attached to this letter and give this to their employer as proof of their temporary exemption status. This temporary self-certification process has been introduced for a short period prior to the launch of the new NHS COVID Pass system which will go live imminently. Once the NHS COVID Pass system is launched, care home workers will need to apply for a formal medical exemption through that process. This temporary self-certification will expire 12 weeks after the NHS COVID Pass system is launched.

Who is exempt

While this list is not exhaustive, examples of medical exemptions from COVID-19 vaccination 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
- with medical contraindications to the vaccines such as severe allergy to all COVID-19 vaccines or their constituents
- who have had adverse reactions to the first dose (for example, myocarditis)

Time-limited exemptions will also be available for those with short-term medical conditions (for example, people receiving hospital care or receiving medication which may interact with the vaccination). A time-limited exemption is also available for pregnant women should they choose to take it.

Exemptions for conditions listed in section 4.4 (special warnings and precautions for use) in the Summary of Product Characteristics for each of the approved COVID-19 vaccines (Pfizer, AstraZeneca and Moderna) may also be considered.

Individuals that have received a COVID-19 vaccination abroad can also self-certify as medically exempt. This is because it is not clinically appropriate for them to be vaccinated in the UK if they have already received a partial or full course of vaccination overseas.

We have attached the forms needed for someone to self-certify as exempt. We will update the operational guidance we have already published in the coming days to reflect the temporary exemption system outlined in this letter.

Yours faithfully,

Claire Armstrong

Director of Adult Social Care Delivery

All COVID-19 vaccination queries and incidents should be directed to:
england.swicars@nhs.net