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## National protocol for Vaxzevria,

## COVID-19 Vaccine (ChAdOx1-S [recombinant])

Reference no: Vaxzevria protocol

Version no: V01.00

Valid from: 10 May 2022

Expiry date: 1 April 2023

This protocol is for the administration of Vaxzevria, COVID-19 Vaccine (ChAdOx1-S [recombinant]), to individuals in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of Vaxzevria, COVID-19 Vaccine (ChAdOx1-S [recombinant]), by appropriately trained persons in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of the [Human Medicines Regulations 2012](https://www.legislation.gov.uk/uksi/2012/1916/contents) (HMR 2012), inserted by [The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020](https://www.legislation.gov.uk/uksi/2020/1125/contents/made)

**The UK Health Security Agency (UKHSA) has developed this protocol for authorisation by or on behalf of the Secretary of State for Health and Social Care to facilitate the delivery of the national COVID-19 vaccination programme commissioned by NHS England and NHS Improvement (NHSEI).**

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Characteristics of staff](#_Characteristics_of_staff)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The provider/contractor is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol under [Characteristics of staff](#_Characteristics_of_staff) must be adhered to.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

Persons must be authorised by name to work under this protocol. They must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing. This can be done by completing [Section 4](#PractitionerAuthorisationSheet) of this protocol or maintaining an equivalent electronic record.

A clinical supervisor[[1]](#footnote-2), who must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol, must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. The drawing up of the vaccine has its own supervision requirements in accordance with [Part 1](https://www.legislation.gov.uk/uksi/2012/1916/part/1) of the HMR 2012 and will need to be done by, or under the supervision of, a registered doctor, nurse or pharmacist. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the drawing up of the vaccine if this can be done safely alongside their overarching role. Any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol must be recorded for the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains overall responsibility. Staff working to the protocol must understand who the clinical supervisor for their practice at any time is and can only proceed with their authority. The clinical supervisor may withdraw this authority for all members of staff or individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Operation under this protocol is the responsibility of service providers/contractors. Provider organisations/contractors using this protocol should retain copies, along with the details of those authorised to work under it, for 8 years after the protocol expires.

Persons must check that they are using the current version of this protocol and current versions of any documents this protocol refers to. Amendments may become necessary prior to the published expiry date. Current versions of national protocols for COVID-19 vaccines, authorised by or on behalf of the Secretary of State for Health and Social Care in accordance with regulation 247A of the HMR 2012, can be found via:

[COVID-19 vaccination programme](https://www.gov.uk/government/collections/covid-19-vaccination-programme)

Any concerns regarding the content of this protocol should be addressed to: immunisation@phe.gov.uk

**Change History**

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| **Change historyVersion**  | **Change details** | **Date** |
| V01.00 | New National protocol for Vaxzevria | 29/04/2022 |

1. **Ministerial authorisation**

This protocol is not legally valid, in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of the [HMR 2012](https://www.legislation.gov.uk/uksi/2012/1916/contents), inserted by the [Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020](https://www.legislation.gov.uk/uksi/2020/1125/contents/made), until it is approved by or on behalf of the Secretary of State for Health and Social Care.

On 10 May 2022, Department of Health and Social Care Ministers approved this protocol in accordance [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of HMR 2012.

Any provider/contractor administering COVID-19 Vaccine AstraZeneca under this protocol must work strictly within the terms of this protocol and contractual arrangements with the commissioner, for the delivery of the national COVID-19 vaccination programme.

Assembly, final preparation and administration of vaccines supplied and administered under this protocol must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer’s instructions in the product’s UK Summary of Product Characteristics ([SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca)) or in accordance with official national recommendations.

Note: The national COVID-19 vaccination programme may also be provided under a patient group direction or on a patient specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient specific direction (PSD)). Supply and administration in these instances should be in accordance with contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme and are not related to this protocol.

#### Characteristics of staff

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| Classes of persons permitted to administer medicinal products under this protocol |
| This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Table 2](#Table2)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that there is a clinical supervisor present at all times and that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.This protocol is separated into operational stages of activity as outlined in [Table 1](#Table1).The clinical supervisor1 must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see [page 1](#Page1ClinicalSupervisor), for the overall provision of clinical care provided under the legal authority of the protocol.**Table 1: Operational stages of activity under this protocol**

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| Stage 1 | 1. Assessment of the individual presenting for vaccination
2. Provide information and obtain informed consent[[2]](#footnote-3)
3. Provide advice to the individual
 | Specified Registered Healthcare Professionals Only (see [Table 2](#Table2)) |
| Stage 2 | * Vaccine Preparation
 | Registered or non-registered persons |
| Stage 3 | * Vaccine Administration
 | Registered or non-registered persons |
| Stage 4 | * Record Keeping
 | Registered or non-registered persons |

Persons must only work under this protocol where they are competent to do so. Non-professionally qualified persons operating under this protocol must be adequately supervised by experienced registered healthcare professionals. Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must also abide by their professional code of conduct.To undertake the assigned stage(s) of activity under this protocol, persons working to this protocol must meet the criteria specified in [Table 2](#Table2) (see below).**Table 2: Protocol stages and required characteristics of persons working under it**

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| **Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol:** | **Stage 1** | **Stage 2** | **Stage 3** | **Stage 4** |
| must be authorised by name as an approved person under the current terms of this protocol before working to it, see [Section 4](#PractitionerAuthorisationSheet) | Y | Y | Y | Y |
| must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent2 and must be an appropriately qualified prescriber or one of the following registered professionals who can operate under a PGD or as an occupational health vaccinator in accordance with HMR 2012:* nurses, nursing associates and midwives currently registered with the Nursing and Midwifery Council (NMC)
* pharmacists currently registered with the General Pharmaceutical Council (GPhC)
* chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC)
* dental hygienists and dental therapists registered with the General Dental Council
* optometrists registered with the General Optical Council.
 | Y | N | N | N |
| must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see [Page 1](#Page1ClinicalSupervisor)) | N | Y | N | N |
| must be competent in the handling of the vaccine product and use of aseptic technique for drawing up the correct dose  | N | Y | Y | N |
| must be familiar with the vaccine product and alert to any changes in the [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca), and familiar with the national recommendations for the use of this vaccine | Y | Y | Y | N |
| must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) | Y | Y | Y | N |
| must be familiar with, and alert to changes in the relevant standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme | Y | Y | Y | Y |
| must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and SOPs and in line with the [Training recommendations for COVID-19 vaccinators](https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators) | Y | Y | Y | N |
| must have completed the [national covid-19 vaccination e-learning programme](https://www.e-lfh.org.uk/programmes/covid-19-vaccination/), including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training | Y | Y | Y | N |
| must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine | N | Y | Y | N |
| must be competent in intramuscular injection technique if they are administering the vaccine | N | N | Y | N |
| must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions | Y | N | Y | N |
| must have access to the protocol and relevant [COVID-19 vaccination programme](https://www.gov.uk/government/collections/covid-19-vaccination-programme) online resources such as the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book), particularly [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a), and the [COVID-19 vaccination programme: Information for healthcare practitioners](https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners) document | Y | Y | Y | N |
| must understand the importance of making sure vaccine information is recorded on the relevant data system, meeting the relevant competencies of the [COVID-19 vaccinator competency assessment tool](https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool) | Y | Y | Y | Y |
| must have been signed off as competent using the [COVID-19 vaccinator competency assessment tool](https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool) if new to or returning to immunisation after a prolonged period (more than 12 months), or have used the tool for self-assessment if an experienced vaccinator (vaccinating within past 12 months) | Y | Y | Y | Y |
| should fulfil any additional requirements defined by local or national policy | Y | Y | Y | Y |
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**STAGE 1: Assessment of the individual presenting for vaccination**

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| **ACTIVITY STAGE 1a:** | **Assess the individual presenting for vaccination. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.** |
| **Clinical condition or situation to which this Protocol applies** | Vaxzevria, COVID-19 Vaccine (ChAdOx1-S [recombinant]), hereafter referred to a Vaxzevria, is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This protocol is for administration of Vaxzevria in accordance with the national COVID-19 vaccination programme (see [COVID-19 vaccination programme page](https://www.gov.uk/government/collections/covid-19-vaccination-programme)) and recommendations given in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) of Immunisation Against Infectious Disease: the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) (hereafter referred to as [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) and subsequent correspondence or publications from the UKHSA or NHSEI. |
| **Criteria for inclusion**  | Vaxzevria should be offered to all individuals aged 18 years and over in accordance with the national COVID-19 vaccination programme and the recommendations in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). Individuals are eligible for different dose schedules based on their age and recognised risk group (see the [Dose and frequency of administration](#DoseAndFrequencyOfAdministration) section). |
| **Criteria for exclusion[[3]](#footnote-4)** | Individuals for whom valid consent, or ‘best-interests’ decision in accordance with the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents), has not been obtained (for further information on consent see [Chapter 2](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) of the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)). The [Patient Information Leaflet for Vaxzevria](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) should be available to inform consent. Individuals who:* are less than 18 years of age
* have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of Vaxzevria (or COVID-19 Vaccine AstraZeneca) or to any component of the vaccine or residues from the manufacturing process[[4]](#footnote-5)
* have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with an AstraZeneca COVID-19 vaccine
* have previously experienced episodes of capillary leak syndrome (CLS)
* are suffering from acute severe febrile illness or acute infection (the presence of a minor infection is not a contraindication for vaccination)
* have received a full dose of COVID-19 vaccine in the preceding 28 days
 |
| **Cautions including any relevant action to be taken**Continued over page**Cautions including any relevant action to be taken**(continued)Continued over page**Cautions including any relevant action to be taken**(continued)Continued over page**Cautions including any relevant action to be taken**(continued)Continued over page**Cautions including any relevant action to be taken**(continued) | Facilities for management of anaphylaxis should be available at all vaccination sites (see [Chapter 8](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8) of the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)) and advice issued by the [Resuscitation Council](https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings).JCVI issues advice on vaccine preference specific to the current UK context and available data. Vaxzevria is an AstraZeneca COVID-19 vaccine. An alternative to an AstraZeneca COVID-19 vaccine may be advised as preferable for some groups eligible for COVID-19 vaccination. Recommendations current at the time of vaccination should be followed (see [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).A very rare condition involving serious thromboembolic events accompanied by thrombocytopenia (TTS), has been reported after COVID-19 AstraZeneca vaccination (see [Chapter 14a](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1057798/Greenbook-chapter-14a-28Feb22.pdf)). Although it is very rare, a higher incidence is seen in younger individuals.JCVI currently advises a preference for a vaccine other than Vaxzevria to be offered to healthy people under 40 years of age, including health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. This advice may change if there is a change in the epidemiology or an interruption in the supply of the alternative vaccines. Within this group of healthy adults aged 18 to 39 years, those who are older (over 30 years of age), male, from certain minority ethnic backgrounds, in certain occupations at high risk of exposure, and those who are obese, remain at high risk of COVID-19. In the absence of a suitable alternative these individuals should be offered the AstraZeneca vaccine (Vaxzevria) and Individuals may choose to receive the vaccine, provided they have been informed and understand the relative risks and benefits. They should be given the latest version of the [COVID-19 vaccination and blood clotting leaflet](https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting). Those who have already received a dose of an AstraZeneca COVID-19 vaccine should complete the primary course with the same vaccine. Where the same vaccine is not available or suitable, or if the first product received is unknown, one dose of the locally available product should be given to complete the primary course.The [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) for Vaxzevria currently states that, as a precautionary measure, administration of the Vaxzevria in individuals with a history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) or cerebral venous sinus thrombosis should only be considered when the benefit outweighs any potential risks.Individuals with past clotting episodes and those diagnosed with thrombophilia, whether or not they are on long term anti-coagulation, remain at risk of COVID-19 disease. There is no evidence that those with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing this immune-mediated condition of thrombosis in combination with thrombocytopenia after an AstraZeneca COVID-19 vaccine. For most of these individuals, the risk of recurrent thrombosis due to COVID-19 infection remains far greater than the risk of this syndrome. Therefore, individuals aged 40 years and over with such a history should be vaccinated with any of the available vaccines (provided they are not otherwise contra-indicated). The same consideration applies to those who experience common clotting episodes after the first dose of an AstraZeneca COVID-19 vaccine but without concomitant thrombocytopenia.Individuals who have received the first dose of an AstraZeneca COVID-19 vaccine without developing this rare condition, TTS, are advised to receive the second dose of the same vaccine at the currently recommended interval. To date, there is no signal of an increased risk of this condition after the second dose and the rate of other reactions is lower after the second dose than after the first dose of this vaccine. Using an alternative product for the second dose is more likely to lead to common side effects.Previous immune thrombocytopenia (ITP) is not a contra-indication for vaccination but platelet monitoring is advised for individuals with a history of ITP who receive an AstraZeneca COVID-19 vaccine. Cases of thrombocytopenia, including ITP, have been reported, typically within the first four weeks after vaccination. Individuals who experience ITP in the four weeks after the first dose of an AstraZeneca COVID-19 vaccine should be assessed by a haematologist and the risk benefit of further vaccination and with which product should be considered on an individual basis. If receiving further vaccination, the platelet count should be monitored.Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in individuals with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after the vaccine ([British Society for Haematology-COVID-19](https://b-s-h.org.uk/about-us/news/covid-19-updates/)).There is no routine requirement for observation following Vaxzevria. Following COVID-19 vaccine administration, individuals should be:* observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre
* informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.

Individuals with a personal history of allergy should be managed in line with [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) Table 5.Special precautions are advised for individuals with a personal history of allergy including a:* prior non-anaphylaxis allergic reaction to COVID-19 vaccine
* history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy).
* history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative)
* history of idiopathic anaphylaxis

Individuals with undiagnosed PEG allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis. Vaxzevria does not contain PEG but does contain a related compound called polysorbate 80. Rarely, people with PEG allergy may also be allergic to polysorbate 80. Individuals with PEG allergy who have tolerated injections that contain polysorbate 80 (including the adjuvanted influenza vaccine, Fluad® and the GlaxoSmithKline vaccine Fluarix®) are likely to tolerate Vaxzevria. The vaccine should be administered in a setting with full resuscitation facilities (such as a hospital), and a 30-minute observation period is recommended.Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine follow the guidance in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) in relation to the administration of subsequent doses. Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive the subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals.No specific management is required for individuals with a family history of allergies.Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.There is no routine requirement for 15 minutes observation following Vaxzevria. However, as fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should either be driven by someone else or should not drive for 15 minutes after vaccination.Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled International Normalised Ratio (INR) testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least two minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy. If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least two minutes. The individual/carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca COVID-19 vaccine, for any future doses Comirnaty® and Spikevax® vaccines are preferred **Past history of COVID-19 infection**There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. For adults, vaccination after COVID-19 infection, should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen. This is to avoid confusing the differential diagnosis as clinical deterioration can occur up to two weeks after infection. This recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the JCVI or UKHSA and published in NHSEI operational guidance.There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person’s underlying condition to the vaccine.  |
| **Dose and frequency of administration**Continued over page**Dose and frequency of administration** (continued) | **Interval post SARS-CoV-2 infection**For adults, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen, to avoid confusing the differential diagnosis. The recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the JCVI or UKHSA and published in NHSEI operational guidance.There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical and epidemiological features to suggest the episode was COVID-19 infection.**Primary vaccination**A two-dose course should be administered to eligible individuals, with the exception of individuals who were severely immunosuppressed when they received their first or second dose of COVID- 19 vaccination for whom JCVI have provided recommendations for a third primary dose.The two-dose course consists of 0.5ml followed by a second dose of 0.5ml after an interval of at least 28 days. However, the programme schedule, including both the number of doses and the intervals between them, should be administered in accordance with official national guidance which, at the time of writing, recommends a minimum interval of eight weeks between primary doses for adults, as set out in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). There is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used. Based on this evidence, longer intervals are likely to provide more durable protection.At the time of writing, JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. Operationally using the same minimum interval for all products will simplify supply and booking, and this will help to ensure a good balance between achieving rapid and long-lasting protection. If the primary course is interrupted or delayed, it should be resumed (using the same vaccine as was given for the first dose if possible, see [Additional Information](#AdditionalInformation)) but doses should not be repeated. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the licensed minimal interval of at least 28 days may be followed to enable the vaccine to be given whilst their immune system is better able to respond.**Primary vaccination of severely immunosuppressed individuals**JCVI advises a preference for mRNA vaccines for the third primary dose. Vaxzevria is an option for individuals who have received an AstraZeneca COVID-19 vaccine previously, where mRNA vaccines are clinically contra-indicated. JCVI advises that a third primary dose be offered to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see ‘Box 1: Criteria for a third primary dose of COVID-19 vaccine’in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)). The third dose should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment ‘holiday’ or when the degree of immunosuppression is at a minimum (see [Additional information](#AdditionalInformation)).**Booster vaccination**Boosters should be offered to individuals eligible as part of the national COVID19 vaccination programme in accordance with the recommendations from the JCVI and [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). The JCVI have advised that a full dose (30 micrograms) of Comirnaty® or a half dose (50 micrograms) of Spikevax® should be offered for boosting irrespective of the vaccine used for the primary course (see [Protocols for COVID-19 vaccines](https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds))). Where mRNA vaccines are clinically contra-indicated, Vaxzevria may be considered in those who had received at least one dose of an AstraZeneca COVID-19 vaccine previously. Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters.Boosters should be given at a minimum interval of three months from the previous dose. |
| **Action to be taken if the individual is excluded**Continued over page**Actions to be taken if the individual is excluded** (continued) | This protocol is for individuals aged 18 years and over in accordance with recommendations in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) for the use of an AstraZeneca COVID-19 vaccine. For individuals under 18 years of age, Comirnaty® vaccine is recommended (see the appropriate [Comirnaty® protocol](https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds))).The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may only be provided by an appropriate prescriber or on a patient specific basis, under a PSD.Individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of Vaxzevria (or COVID-19 Vaccine AstraZeneca) may be given an alternate mRNA COVID-19 vaccine in any setting, with observation for 30 minutes, for subsequent doses of COVID-19 vaccine indicated.Individuals who experience a clotting episode with concomitant thrombocytopenia following the first dose of an AstraZeneca COVID-19 vaccine should be properly assessed. If they are considered to have TTS, further vaccination should be deferred until their clotting has completely stabilised. Current evidence would support a decision to complete the primary course or boost individuals with a history of TTS with an mRNA vaccine, provided at least 12 weeks has elapsed from the implicated dose.Individuals who have previously experienced episodes of CLS syndrome may be offered vaccination with an appropriate alternative, COVID-19 vaccine.In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged.Document the reason for exclusion and any action taken. |
| **Action to be taken if the individual or carer declines treatment**  | Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents), a decision to vaccinate may be made in the individual’s best interests. For further information on consent see [Chapter 2](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) of the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book).Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.Document advice given and the decision reached. |
| **Arrangements for referral**  | As per local policy. |

**STAGE 1b: Description of treatment**

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| **ACTIVITY STAGE 1b:** | **Consider any relevant cautions, interactions or adverse drug reactions.** **Provide advice to the individual and obtain informed consent2.****Record individual’s consent2 and ensure vaccinator, if another person, is informed of the vaccine product to be administered.** |
| **Name, strength and formulation of drug** | Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant]) in multidose vial:* 5ml of suspension in a 10-dose vial
* 4ml of suspension in an 8-dose vial

One dose (0.5 ml) contains COVID-19 Vaccine (ChAdOx1-S\* recombinant) not less than 2.5 × 108 infectious units (Inf.U).\*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.  |
| **Legal category** | Prescription only medicine (POM). |
| **Black triangleq**  | Yes. As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product. |
| **Off-label use** | Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.**Primary immunisation**The Vaxzevria [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) describes a 2-dose primary course. A third primary dose may be administered under this protocol to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule in accordancewith the recommendations from the JCVI and [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a).**Booster immunisation**The Vaxzevria [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) recommends a booster dose may be administered 6 months after the second dose. Booster vaccination may be offered under this protocol at a minimum interval of 3 months from the previous dose, completion of the primary course or previous booster dose, in accordancewith the recommendations from the JCVI and [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). **Storage**Vaccine should be stored according to the conditions detailed in the [Storage section](#Storage) below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to [Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this protocol.In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this protocol should be supported by NHS operational guidance or standard operating procedure. |
| **Drug interactions**Continued over page**Drug interactions**(continued) | Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination.For further information about co-administration with other vaccines see [Additional Information](#coadminstration) section. |
| **Identification and management of adverse reactions**Continued over page**Identification and management of adverse reactions**(continued) | The most frequently reported adverse reactions are injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia (including feverishness and fever), chills, arthralgia and nausea. The majority of adverse reactions are mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, adverse reactions reported after the second dose are milder and reported less frequently. The reactogenicity observed in individuals who received a booster dose was consistent with the known reactogenicity profile of Vaxzevria and was lower than that of the first dose.Reactogenicity events are generally milder and reported less frequently in older adults (≥65 years old). Individuals should be provided with the advice within the leaflet [What to expect after your COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination), which covers the reporting of adverse reactions and their management, such as with analgesic and antipyretic medication. Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following vaccination with an AstraZeneca COVID-19 vaccine during post-authorisation use. The majority of the events occurred within 3 weeks following vaccination but have also been reported after this period. Risk factors have not been identified. Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Vaccinated individuals should also be instructed to seek immediate medical attention if four or more days after vaccination they develop new onset or worsening severe or persistent headaches with blurred vision, which do not respond to simple painkillers, or if they develop new symptoms such as shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain, any neurological symptoms or signs such as confusion or seizures or unusual skin bruising and/or petechiae beyond the site of vaccination.Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with an AstraZeneca COVID-19 vaccine should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia. Individuals with TTS require specialised clinical management and should be urgently referred to a secondary healthcare centre and to a specialist in haematology for advice on further management. Individuals should be provided with the advice within the leaflet [COVID-19 vaccination and blood clotting](https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting).Very rare cases of Capillary Leak Syndrome (CLS) have been reported in the first days after vaccination with Vaxzevria. CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Individuals with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted.GBS has been reported very rarely within six weeks of AstraZeneca COVID-19 vaccination, although it is not yet certain whether these are caused by the vaccine. Individuals should be advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face.A detailed list of adverse reactions is available in the product’s [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca). |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the [Coronavirus Yellow Card reporting scheme](https://coronavirus-yellowcard.mhra.gov.uk/) or search for MHRA Yellow Card in the Google Play or Apple App Store.As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product.Any adverse reaction to a vaccine should also be documented in the individual’s record and the individual’s GP should be informed.The Green Book [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) and [Chapter 8](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8) provide further details regarding the clinical features of reactions to be reported as ‘anaphylaxis’. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as ‘allergic reaction’. |
| **Written information to be given to individual or carer** | Ensure the individual has been provided appropriate written information such as the:* [Patient Information Leaflet for Vaxzevria](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca)
* [COVID-19 Vaccination Record Card](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Scovidvaccinerecordcard2doses)
* [What to expect after your COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination)

* [COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding](https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding)
* [COVID-19 vaccination and blood clotting](https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting)
* [COVID-19 vaccination: a guide to booster vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-booster-dose-resources)

For other leaflets available see [Leaflets, posters and resources](https://www.gov.uk/government/collections/covid-19-vaccination-programme#leaflets,-posters-and-resources) on the [UKHSA Covid-19 vaccination programme](https://www.gov.uk/government/collections/covid-19-vaccination-programme) webpage.  |
| **Advice / follow up treatment**Continued over page**Advice / follow up treatment** (continued) | As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Inform the individual/carer of possible side effects and their management. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination.The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction.Vaccinated individuals should be advised to seek immediate medical attention if four or more days after vaccination they develop new onset or worsening severe or persistent headaches with blurred vision, which do not respond to simple painkillers or if they develop new symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, any neurological symptoms or signs (such as confusion or seizures) or unusual skin bruising and/or petechiae. Individuals with thromboembolic events and concurrent thrombocytopenia should be urgently referred to a secondary healthcare centre and to a specialist in haematology for advice on further management.Vaccinated individuals should be advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face (Guillain-Barré syndrome). This has been reported very rarely after vaccination.Advise the individual/carer that they can report side effects directly via the national reporting system run by the MHRA known as the [Coronavirus Yellow Card reporting scheme](https://coronavirus-yellowcard.mhra.gov.uk/) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines.When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due. |
| **Special considerations / additional information**Continued over page**Special considerations / additional information** (continued)Continued over page**Special considerations / additional information** (continued) | Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.JCVI advises a preference for mRNA vaccines for the third primary dose, with the option of the AstraZeneca vaccine for individuals who have received this vaccine previously where mRNA vaccines are clinically contra-indicated. In exceptional circumstances, persons who received a mRNA COVID-19 vaccine previously may be offered a third primary dose of AstraZeneca vaccine following a decision by a health professional on a case-by-case, individualised basis. In such instances a prescriber or PSD would be required for administration. For those under 18 years the Comirnaty® vaccine remains the preferred choice, as set out in [JCVI advice](https://www.gov.uk/government/collections/covid-19-vaccination-programme#programme-documents) of [4 August 2021](https://www.gov.uk/government/publications/jcvi-statement-august-2021-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years/jcvi-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-4-august-2021) and [16 February 2022](https://www.gov.uk/government/publications/jcvi-update-on-advice-for-covid-19-vaccination-of-children-aged-5-to-11).Where mRNA vaccines are clinically contra-indicated, AstraZeneca vaccine may be considered for a booster dose in those who had received at least one dose of this vaccine previously. In exceptional circumstances, persons aged 40 years or over who received an mRNA COVID-19 vaccine primary course may be offered boosting with AstraZeneca vaccine following a decision by a health professional on a case-by-case basis. In such instances a prescriber or PSD would be required for administration (see [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).**Pregnancy**Comirnaty® and Spikevax® vaccines are the preferred vaccines for eligible pregnant women, because of more extensive experience of their use in pregnancy. Pregnant women who have already received a dose of AstraZeneca vaccine can complete with the same vaccine or with an mRNA product.Vaccination in pregnancy should be offered in accordance with recommendations in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a), following a discussion of the risks and benefits of vaccination with the woman. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended for COVID-19 vaccination.If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination during pregnancy using the same vaccine product (unless contra-indicated).**Breastfeeding**There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women should be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring; mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk.The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19.**Previous incomplete vaccination**If the primary course is interrupted or delayed, it should be resumed using the same vaccine, if possible, but the earlier doses should not be repeated. Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with heterologous doses are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency ([EMA](https://www.ema.europa.eu/en/news/ema-ecdc-recommendations-heterologous-vaccination-courses-against-covid-19)). For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course. Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech (Comirnaty*®*) vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. In these circumstances, this protocol may be used.For individuals with a history of thrombosis combined with thrombocytopenia following vaccination with an AstraZeneca COVID-19 vaccine, current evidence would support completion of the course with an mRNA vaccine, provided a period of at least 12 weeks has elapsed from the implicated dose. Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccination should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least 3 months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes).Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice on [Vaccination of those who received](https://www.gov.uk/government/publications/covid-19-vaccinations-received-overseas)[COVID-19 vaccine overseas](https://www.gov.uk/government/publications/covid-19-vaccinations-received-overseas) is available from the UKHSA.**Co-administration with other vaccines**Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two or more vaccines. It is generally better for vaccination to proceed and it may be provided under this protocol, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and HPV, MenACWY and Td-IPV vaccines). The only exceptions to this are the shingles vaccines, where a seven-day interval should ideally be observed. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects.**Non-responders / immunosuppressed**Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. JCVI advises that a third primary vaccine dose be offered to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see ‘Box 1: Criteria for a third primary dose of COVID-19 vaccinein [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)). Most individuals whose immunosuppression commenced at least two weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination.JCVI advises a preference for mRNA vaccines for the third primary dose. Vaxzevria is an option for individuals who have received an AstraZeneca COVID-19 vaccine previously, where mRNA vaccines are clinically contra-indicated.Third primary doses should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment ‘holiday’ or when the degree of immunosuppression is at a minimum. 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 (see [Chapter 7](https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-chapter-7) of the Green Book). This is not covered by this protocol and should be provided on a patient specific basis. |

**STAGE 2: Vaccine preparation**

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| **ACTIVITY STAGE 2:** | **Vaccine preparation** |
| **Vaccine presentation** | Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant]) in multidose vial:* 5ml of solution in a 10-dose vial
* 4ml of solution in an 8-dose vial
 |
| **Supplies** | Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider.NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Vaxzevria, which ensure use is in accordance with the product’s [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca) and official national recommendations. |
| **Storage** | Vaxzevria unopened multidose vial:* Store in a refrigerator (2 to 8°C).
* Do not freeze.
* Keep vials in outer carton to protect from light.
* Shelf life is 6 months.

After first dose withdrawn, administer remaining doses from the vial as soon as practicably possible and within 6 hours of first use of the vial. The vaccine may be stored between 2°C and 25°C during this in-use period.Once a dose is withdrawn from the vial it should be administered immediately.The vaccine does not contain preservative.The above details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer’s recommendations in the product’s [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca).In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to [Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). |
| **Vaccine preparation**Continued over page**Vaccine preparation** (continued) | Vaccine should be prepared in accordance with the manufacturer’s recommendations (see [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca)) and NHS standard operating procedures for the service.Inspect visually prior to administration and ensure appearance is consistent with the description in the [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca), that is a colourless to slightly brown, clear to slightly opaque suspension. Discard the vaccine if particulate matter or differences to the described appearance are observed. Do not shake the vial. Do not dilute the suspension.The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.Check product name, batch number and expiry date prior to administration.Aseptic technique should be used for withdrawing each vaccine dose of 0.5ml into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. Vaxzevria vials are multidose and, if low dead volume syringes and/or needles are used, one vial contains at least the number of doses stated. Care should be taken to ensure a full 0.5ml dose is administered. Where a full 0.5ml dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials.The vaccine does not contain any preservative. After first dose withdrawal, use the vial as soon as practically possible and within 6 hours (stored at 2°C to 25°C). Discard any unused vaccine. The vaccine may be drawn up and administered by the same person or separate persons with the required competence and supervision. If the vaccine is to be administered by a person other than the person preparing it, ensure that there are clear procedures for transferring the vaccine to the vaccinator in a safe way, allowing for appropriate checks of vaccine particulars, batch number and date by both parties. |
| **Disposal** | Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.Equipment used for vaccine preparation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely, according to local authority arrangements and guidance in the [technical memorandum 07-01](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/): Safe management of healthcare waste (Department of Health, 2013).Vaxzevria contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant, with activity against adenovirus, should be available for managing spills in all settings where vaccine is administered.  |

**STAGE 3: Vaccine administration**

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| **ACTIVITY STAGE 3:** | **Before administering the vaccine, ensure:**1. **The individual has been assessed in accordance with stage one of this protocol.**
2. **The vaccine to be administered has been identified, by the registered practitioner consenting the individual, as Vaxzevria.**
3. **Consent for vaccination has been provided and documented2.**

**Administer Vaxzevria and provide any post-vaccination advice.** |
| **Vaccine to be administered** | Vaxzevria 0.5ml dose |
| **Quantity to be supplied / administered** | Administer 0.5ml per dose. |
| **Route / method of administration**  | Vaxzevria is for administration by intramuscular injection only, preferably into deltoid region of the upper arm.Vaccinators should administer a 0.5ml dose prepared in accordance with [Stage 2](#Stage2) above. If vaccine is not drawn up by the vaccinator, safe procedures must be in place for the vaccinator to safely receive, check, and use the vaccine immediately after preparation. Inspect visually prior to administration and ensure appearance is consistent with the description in the [SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca), that is a colourless to slightly brown, clear to slightly opaque suspension. Discard the vaccine if particulate matter or differences to the described appearance are observed. Do not shake the vaccine. Do not dilute the suspension.The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.Check product name, batch number and expiry prior to administration.Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.  |
| **Disposal** | Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority arrangements and guidance in the [technical memorandum 07-01](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/): Safe management of healthcare waste (Department of Health, 2013).Vaxzevria contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant, with activity against adenovirus, should be available for managing spills in all settings where vaccination is administered. |
| **Post-vaccination advice**  | Ensure the individual has been provided appropriate written information such as the:* [Patient Information Leaflet for Vaxzevria](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca)
* [COVID-19 Vaccination Record Card](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Scovidvaccinerecordcard2doses)
* [What to expect after your COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination)
* [COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding](https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding)
* [COVID-19 vaccination and blood clotting](https://www.gov.uk/government/publications/covid-19-vaccination-and-blood-clotting)
* [COVID-19 vaccination: a guide to booster vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-booster-dose-resources)

For other leaflets available see [Leaflets, posters and resources](https://www.gov.uk/government/collections/covid-19-vaccination-programme#leaflets,-posters-and-resources) on the [UKHSA Covid-19 vaccination programme](https://www.gov.uk/government/collections/covid-19-vaccination-programme) webpage. |

**STAGE 4: Recording vaccine adminstration**

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| **ACTIVITY STAGE 4:** | **Complete a record of vaccination for the individual and in accordance with local policy.****The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.** |
| **Records** | Record: * that valid informed consent was given or a decision to vaccinate made in the individual’s best interests in accordance with the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents)
* name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP)
* name of supervisor, immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified
* name and brand of vaccine
* date of administration
* dose, form and route of administration of vaccine
* quantity administered
* batch number and expiry date
* anatomical site of vaccination
* advice given, including advice given if excluded or declines immunisation
* details of any adverse drug reactions and actions taken
* supplied via national protocol

All records should be clear, legible and contemporaneous.As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual’s records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual’s general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination.A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy.  |

1. **Key references**

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| --- | --- |
| **Key references** | **Vaxzevria vaccination** * Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 28 February 2022.

<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>* COVID-19 Vaccination and blood clotting

<https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting> * COVID-19 vaccination programme. Updated 17 March 2022.

<https://www.gov.uk/government/collections/covid-19-vaccination-programme>* Training recommendations for COVID-19 vaccinators. Updated 4 October 2021.

<https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators> * National COVID-19 vaccination e-learning programme

<https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>* COVID-19 vaccinator competency assessment tool. Updated 16 March 2021.

<https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool>* COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022.

<https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>* [Summary of Product Characteristics](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/information-for-healthcare-professionals-on-covid-19-vaccine-astrazeneca-regulation-174) and [Patient information leaflet](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/patient-information-leaflet-for-covid-19-vaccine-astrazeneca) for Vaxzevria. Published 26 January 2022.

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca> **General*** Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/>
* Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012, as amended.

<https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A> * UK Statutory Instrument 2022 No. 350, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022.

<https://www.legislation.gov.uk/uksi/2022/350/made> |

**4. Practitioner/staff authorisation sheet**

**Vaxzevria protocol v01.00 Valid from: 10 May 2022 Expiry: 1 April 2023**

This authorisation sheet should be retained to serve as a record of those persons authorised to work under this protocol.

By signing this protocol you are indicating that you agree to its contents and that you will work within it.

Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must abide by their professional code of conduct.

It is the responsibility of each person operating under this protocol to do so within the bounds of their own competence.

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| I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it. |
| Name | Designation | Activity Stage: | Signature | Date |
|  |  | 1 | 2 | 3 | 4 |  |  |
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**Authorising registered healthcare professional**

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| I confirm that I, as a registered healthcare professional who is familiar with the competence required in all aspects of this protocol, provide authority on behalf of the below named provider organisation, that the persons named above are competent to work under this protocol and may provide vaccination in accordance with this protocol in the course of working for insert name of organisation / service  |
| Name | Designation | Signature | Date |
|  |  |  |  |

**Note to authorising registered healthcare professional**

Score through unused rows in the list of persons to prevent additions post authorisation.

If the clinical supervisor is also the authorising registered healthcare professional, they may make a self-declaration of competency above

1. This role is different to the Band 6 ‘COVID-19 Vaccination Programme - RHCP Clinical Supervisor (Vaccinations)’ (see [Accountability and delegation under the national protocols for COVID-19 vaccines: visual diagram](https://www.england.nhs.uk/coronavirus/publication/summary-of-the-legal-mechanisms-for-administering-the-covid-19-vaccines/)). [↑](#footnote-ref-2)
2. For those lacking mental capacity, a decision may be made in the individual’s best interests in accordance with the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents) (for further information on consent see [Chapter 2](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) of the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)). [↑](#footnote-ref-3)
3. Exclusion under this protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required [↑](#footnote-ref-4)
4. Contains polysorbate 80. Refer to the product’s [[SPC](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca)](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) for a full list of excipients. [↑](#footnote-ref-5)