UK Health Security Agency

NHS

Publications approval reference: C1622

Patient Group Direction for COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant])

This Patient Group Direction (PGD) is for the administration of COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) to individuals in accordance with the national COVID-19 vaccination programme in England.

This PGD is for the administration of COVID-19 Vaccine AstraZeneca by registered healthcare practitioners identified in Section 3.

The national COVID-19 vaccination programme may also be provided under national protocol or on a patient specific basis (that is by or on the direction of an appropriate independent prescriber). Supply and administration in these instances are not covered by this PGD.

Reference no:	COVID-19 Vaccine AstraZeneca PGD
Version no:	V07.00 (Expiry extension of V06.00)
Valid from:	31 March 2022
Expiry date:	1 October 2022

The UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England and NHS Improvement (NHSEI) to facilitate the delivery of the national COVID-19 vaccination programme.

NHSEI and those providing services in accordance with this PGD must not alter, amend or add to the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended only by the person(s) authorising the PGD, in accordance with Human Medicines Regulations 2012 (HMR2012)[1] Schedule 16 Part 2, on behalf of NHS England and NHS Improvement. Section 7 is to be completed by registered practitioners providing the service and their authorising/line manager.

Operation of this PGD is the responsibility of NHS England and NHS Improvement and service providers. The final authorised copy of this PGD should be kept by NHSEI for 8 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 8 years.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a counter signature, unless there are contractual arrangements for self-declaration.

Providers must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE/UKHSA developed COVID-19 vaccine PGDs can be found via: COVID-19 vaccination programme - GOV.UK (www.gov.uk)

The most current national recommendations should be followed. This may mean that a Patient Specific Direction (PSD) is required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

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

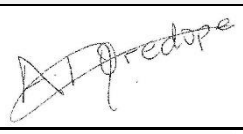
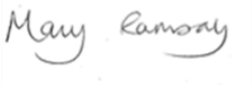
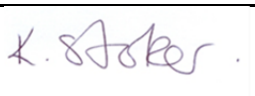
Change History

Version	Change details	Date
V01.00	New COVID-19 Vaccine AstraZeneca PGD	05/01/2021
V02.00	COVID-19 Vaccine AstraZeneca PGD amended to: • identify the national protocol or patient specific provision as an alternative to use of this PGD • cover JCVI recommendations for phase 2 • include vaccination in pregnancy in accordance with the Green Book Chapter 14a, remove additional information on pregnancy and in cautions refer to Chapter 14a and the Royal College of Obstetricians and Gynaecologists (RCOG) decision aid • include JCVI advice for homelessness and detained settings • update of cautions which pertain to anaphylaxis, allergy and reactions to 1st dose • add paragraph about post vaccination observation • move participation in a clinical trial from the criteria for exclusion section to the caution section • move recommendations for individuals with bleeding disorder to the cautions section • include a paragraph in the legal category section to allow for PGD use to continue should the vaccine be provided a marketing authorisation in the future, so long as the PGD remains clinically appropriate • include JCVI advice that the second dose of COVID-19 Vaccine AstraZeneca should be given between 8 and 12 weeks after the first dose • reword advice pertaining to the extraction of full doses from a vial and not pooling excess vaccine • remove specific reference to supply via ImmForm • remove detail on management of anaphylaxis which is outside the required scope of this PGD • update key references • remove Appendix A and refer directly to the Green Book Chapter 14a	17/03/2021
V03.00	COVID-19 Vaccine AstraZeneca PGD amended to: • inclusions, exclusions, cautions, identification & management of adverse reactions, written information and advice to patient sections, relating to vaccination and thromboembolic events • recommend that those under 30 years of age commence COVID-19 vaccination with an alternative COVID-19 vaccine where possible	22/04/2021
V04.00	COVID-19 Vaccine AstraZeneca PGD amended to: • identify in the Criteria for inclusion and Cautions sections the preference for an alternative COVID-19 Vaccine for healthy individuals under 40 years of age • identify in the Cautions section COVID-19 mRNA vaccine BNT162b2 (Pfizer BioNTech) or COVID-19 Vaccine Moderna as the preferred vaccines to offer to pregnant women • minor rewording of breastfeeding paragraph	14/05/2021
V05.00	COVID-19 Vaccine AstraZeneca PGD V04.00 amended to: • align with the current national programme recommendations, latest guidance and regulatory approval and this includes significant update to the criteria for inclusion, criteria for exclusion, cautions, actions if excluded, dose, interactions, adverse reactions and additional information sections • signpost to a Patient Group Direction for Vaxzevria Covid-19 vaccine for administration of Vaxzevria conditional marketing authorisation approved supplies	17/10/2021

	• update from PHE to UKHSA and further minor update in other sections to align with update and for consistency with other PGDs where appropriate	
V06.00	COVID-19 Vaccine AstraZeneca PGD V05.00 amended to: • update list of UKHSA health professionals and signatories • update Criteria for inclusion in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Cautions to include immune thrombocytopenia (ITP) and Past history of COVID-19 infection in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Action to be taken if the patient is excluded in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Dose and frequency of administration and off-label sections for boosting in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Written information to be given to patient or carer section to include COVID-19 vaccination: A guide to booster vaccination • update Special consideration and additional information section on previous incomplete vaccination to be in line with the updated Chapter 14a of the Green Book 11 January 2022 • update the Special considerations and additional information section with regard to use of heterologous schedules for primary immunisation in line with updated Chapter 14a of the Green Book 14 December 2021 • update to Key references to link to most recent published documents • update 'the' before UKHSA, wording 'patient' to 'individual' and Pfizer and Moderna vaccines as per licensed brand names	31/01/2022
V07.00	COVID-19 Vaccine AstraZeneca PGD V06.00 approved with expiry extension to 1 October 2022.	25/03/2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Diane Ashiru-Oredope Lead Pharmacist HCAI & AMR, UKHSA		28 March 2022
Doctor	Mary Ramsay Consultant Epidemiologist, UKHSA		28 March 2022
Registered Nurse (Chair of Expert Panel)	Kelly Stoker Lead Immunisation Nurse Specialist, UKHSA		28 March 2022

In addition to the signatories above the working group included:

Name	Designation
Beth Graham	Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHS England and NHS Improvement
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHS England and NHS Improvement
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSEI
Eleanor Harvey	Chief Pharmaceutical Officer Clinical Fellow, UKHSA
Joshua Igbineweka	Senior Pharmacy Advisor, Clinical Workstream, COVID-19 Vaccination Programme, NHSEI
Gul Root	Principal Pharmaceutical Officer, Department of Health and Social Care and National lead pharmacy public health, Office for Health Improvement and Disparities
Naveen Dosanjh	Senior Clinical Advisor, Clinical Workstream, COVID-19 Vaccination Programme, NHSEI

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel in accordance with UKHSA PGD Policy. It has been ratified by the UKHSA Medicines Governance Group and the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA

Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSEI South (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSEI (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSEI (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHSEI completed below.

NHSEI accepts governance responsibility for this PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, relevant NHS standard operating procedures (SOPs) and contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

NHSEI authorises this PGD for use by the services or providers delivering the national COVID-19 vaccination programme.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, COVID-19 Vaccination Programme, NHS England and NHS Improvement	Dr Jonathan Leach OBE		28 March 2022

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation records, specifying the PGD and version number, may be used where appropriate in accordance with local policy. This may include the use of electronic records.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD 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 must also be in accordance with the instructions for usage that are conditions of the authorisation to supply the product. These conditions for usage are in the Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca (Regulation 174), published alongside the Conditions of Authorisation for COVID-19 Vaccine AstraZeneca (Regulation 174).

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • nurses 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, 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. Practitioners must also fulfil all of the Additional requirements.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Regulation 174 Information for UK Healthcare Professionals for the vaccine and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant NHS standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and SOPs and in line with the Training recommendations for COVID-19 vaccinators. • must have completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Mental Capacity Act 2005) and to discuss issues related to vaccination. For further information on consent see Chapter 2 of 'The Green Book'. • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product and use of aseptic technique for drawing up the correct dose • must be competent in the intramuscular injection technique • must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions

Continued over page

Additional requirements (continued)	• must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and COVID-19 vaccination programme: Information for healthcare practitioners • must have been signed off as competent using the 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 experienced vaccinator (vaccinated within past 12 months) • should fulfil any additional requirements defined by local or national policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis. Practitioners should be constantly alert to any subsequent recommendations from the UKHSA and/or NHSEI and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	COVID-19 Vaccine AstraZeneca is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book', and subsequent correspondence/publications from UKHSA and/or NHS England and NHS Improvement.
Criteria for inclusion	COVID-19 Vaccine AstraZeneca 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 of the Green Book. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the Dose and frequency of administration section).
Criteria for exclusion[2]	Individuals for whom valid consent, or a 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Regulation 174 Information for UK recipients for 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 COVID-19 Vaccine AstraZeneca or to any component of the vaccine or residues from the manufacturing process[3] • have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with COVID-19 Vaccine AstraZeneca • 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	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. JCVI issues advice on vaccine preference specific to the current UK context and available data. An alternative COVID-19 vaccine to COVID-19 Vaccine AstraZeneca 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 of the Green Book). Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely

[2] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

[3] Contains polysorbate 80. Refer to Regulation 174 Information for UK Healthcare Professionals for a full list of excipients.

Cautions, including any relevant action to be taken (continued)	following vaccination with COVID-19 Vaccine AstraZeneca during post authorisation use. JCVI currently advises a preference for a vaccine other than COVID-19 Vaccine AstraZeneca 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 age group, 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 still be offered the AstraZeneca vaccine, and 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. Those who have already received a dose of COVID-19 Vaccine AstraZeneca 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 Regulation 174 Information for Healthcare Practitioners currently states that, as a precautionary measure, administration of the COVID-19 Vaccine AstraZeneca 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 the COVID-19 Vaccine AstraZeneca. 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 COVID-19 Vaccine AstraZeneca but without concomitant thrombocytopenia. Individuals who have received the first dose of AstraZeneca 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 AstraZeneca 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 AstraZeneca 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.

Continued over page

Cautions, including any relevant action to be taken (continued)	Guidance produced by the UK ITP Forum Working Party therefore 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). Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine follow the guidance in Chapter 14a of the Green Book 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 subsequent doses of vaccine in any vaccination setting. The rate of anaphylaxis reported to date after the AstraZeneca vaccine is in line with the expected rate of anaphylaxis to non-COVID vaccines. The AstraZeneca vaccine does not contain PEG but does contain a related compound called polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (including the adjuvanted influenza vaccine, Fluad® and the GlaxoSmithKline vaccine Fluarix®) are likely to tolerate the AstraZeneca vaccine. 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. Such individuals should not be vaccinated with the Comirnaty® or Spikevax® vaccines, except on the expert advice of an allergy specialist. The AstraZeneca vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated the adjuvanted influenza vaccine. The vaccine should be administered in a setting with full resuscitation facilities (such as a hospital), and a 30-minute observation period is recommended. 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 COVID-19 Vaccine AstraZeneca. 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 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. The individual/carer should be informed about the risk of haematoma from the injection.

Continued over page

Cautions, including any relevant action to be taken (continued)	Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in 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 vaccine, for any future doses Comirnaty® and Spikevax® vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. **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 but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen for that episode in those who are asymptomatic. This interval may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). The timing of any change will be advised by JCVI or UKHSA and published in operational guidance agreed by DHSC and NHSEI.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. **Vaccine Surveillance** The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, the Medicines and Healthcare products Regulatory Agency (MHRA) may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the UK. Administration under this PGD must be in accordance with the most up-to-date advice or amendments (see Green Book Chapter 14a and Regulatory approval of COVID-19 Vaccine AstraZeneca). These documents take precedence for the purposes of compliance with this PGD, if there is a delay in updating other provisions of this PGD that cut across them.
Action to be taken if the patient is excluded Continued over page	This PGD is for individuals aged 18 years and over in accordance with recommendations in Chapter 14a for the use of COVID-19 Vaccine AstraZeneca. For individuals under 18 years of age, Comirnaty® vaccine is recommended (see the appropriate Comirnaty® PGD). 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

Action to be taken if the patient is excluded (continued)	should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may 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 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 AstraZeneca 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 may be offered vaccination with an alternative, mRNA, 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 patient 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, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of '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.

5. Description of treatment

Name, strength and formulation of drug	COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]): • 5ml of solution in a 10-dose vial • 4ml of solution in an 8-dose vial One dose (0.5 ml) contains COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 x 10^{10} viral particles. *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	COVID-19 Vaccine AstraZeneca has been provided temporary authorisation by the MHRA for supply in the UK under Regulation 174 and 174A of HMR 2012. In accordance with the UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, a PGD may now be used to supply and/or administer a medicine authorised under Regulation 174. COVID-19 Vaccine AstraZeneca is categorised as a prescription only medicine (POM). Note: For administration of Vaxzevria COVID-19 vaccine (ChAdOx1 S [recombinant]), which has been granted a conditional marketing authorisation, see the Patient Group Direction for Vaxzevria Covid-19 vaccine when available.
Black triangle▼	As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	COVID-19 Vaccine AstraZeneca is supplied in the UK in accordance with Regulation 174. As part of the consent process, healthcare professionals must inform the individual/carer that this vaccine has been authorised for temporary supply in the UK by the regulator, MHRA, and that it is being offered in accordance with national guidance. The Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca should be available to inform consent.
Route / method of administration	COVID-19 Vaccine AstraZeneca is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccine should be prepared in accordance with the manufacturer's recommendations (see Regulation 174 Information for UK Healthcare Professionals) and NHS standard operating procedures for the service. Inspect visually prior to administration and ensure appearance is consistent with the description in the Regulation 174 Information for UK Healthcare Professionals, that is a colourless to slightly brown, clear to slightly opaque solution. Discard the vaccine if particulate matter or differences to the described appearance are observed. Do not shake the vial. Do not dilute the solution. 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.

Continued over page

Route / method of administration (continued)	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. COVID-19 Vaccine AstraZeneca 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 practicably possible and within 6 hours (stored at 2°C to 25°C). Discard any unused vaccine.
Dose and frequency of administration Continued over page	**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 or writing, recommends a minimum interval of eight weeks between primary doses for adults, as set out in 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, this consistent interval should be used for all vaccines with a two-dose primary schedule to avoid confusion and simplify booking, and this will help to ensure a good balance between achieving rapid and long-lasting protection. If an interval longer than the recommended interval is left between doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible, see Additional Information). The course does not need to be restarted. 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 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). The decision on the timing of the third dose should be undertaken by the specialist involved in the care of the individual. 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 (see Additional information).

Dose and frequency of administration (continued)	**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 of the Green Book. Where mRNA vaccines are clinically contra-indicated, AstraZeneca vaccine may be considered in those who had received at least one dose of this 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.
Duration of treatment	See Dose and frequency of administration above.
Quantity to be supplied / administered	Administer 0.5ml per dose.
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 COVID-19 Vaccine AstraZeneca, which ensure use is in accordance with Regulation 174 Information for UK Healthcare Professionals and Conditions of Authorisation for COVID-19 Vaccine AstraZeneca.
Storage	COVID-19 Vaccine AstraZeneca 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 the first dose is 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 Conditions of Authorisation for COVID-19 Vaccine AstraZeneca and Regulation 174 Information for UK Healthcare Professionals.
Disposal Continued over page	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, 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: Safe management of healthcare waste (Department of Health, 2013). COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed

Disposal (continued)	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.
Drug interactions	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 section.
Identification and management of adverse reactions	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. By day 7 the incidence of subjects with at least one local or systemic reaction is 4% and 13% respectively. When compared with the first dose, adverse reactions reported after the second dose are milder and reported less frequently. 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, which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected. Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following vaccination with COVID-19 Vaccine AstraZeneca during post-authorisation use. The majority of the events occurred within the first 14 days 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

Continued over page

Identification and management of adverse reactions (continued)	or seizures, or unusual skin bruising and/or petechiae beyond the site of vaccination. Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine AstraZeneca 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. Very rare cases of CLS have been reported in the first days after vaccination with COVID-19 Vaccine AstraZeneca/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 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 Regulation 174 Information for UK Healthcare Professionals.
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 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 and 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 patient or carer	Ensure the individual has been provided appropriate written information such as the: • Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding • COVID-19 vaccination and blood clotting • COVID-19 vaccination: a guide to booster vaccination
Patient advice / follow up treatment Continued over page	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. Nationally recommended protective measures should still be followed. Inform the individual/carer of possible side effects and their

Patient advice / follow up treatment (continued)	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 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	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. For those aged 16 years and over, 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 of 4 August 2021. 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).

Special considerations / additional information (continued)	**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, following a discussion of the risks and benefits of vaccination with the woman. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. Women who are planning pregnancy or in the immediate postpartum should be vaccinated with a suitable product for their age and clinical risk group. 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 may be offered any suitable COVID-19 vaccine. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunisation against COVID-19; at the same time, women should be informed about the emerging safety data for the vaccine in breastfeeding. **Previous incomplete vaccination** If the primary course is interrupted or delayed, it should be resumed using the same vaccine 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 after the second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency. 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 PGD may be used. For individuals with a history of thrombosis combined with thrombocytopenia following vaccination with the 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 with a history of CLS should be carefully counselled about the risks and benefits of vaccination and may be offered an alternative vaccine to complete a vaccination course. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. Eligible

Continued over page

Special considerations / additional information (continued)	persons who are enrolled in vaccine trials should then 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 three 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 COVID-19 vaccine overseas is available from 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 PGD, 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 vaccine' in 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. JCVI has previously advised that, the decision on the timing of the third primary dose should be undertaken by the specialist involved in the care of the individual. In general, vaccines administered during periods of minimum immunosuppression (where possible) are more likely to generate better immune responses. However, following the recognition

Continued over page

Special considerations / additional information (continued)	of the Omicron variant, JCVI has now advised that boosters should be offered from three months after the third dose. Those who have not yet received their third primary dose may be given their third dose now (8 weeks after the second dose) to avoid further delay. Boosters should be given at a minimum interval of three months from the previous dose in line with the clinical advice on optimal timing. 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 of the Green Book). This is not covered by this PGD and should be provided on a patient specific basis.
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 • 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 immuniser • 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 vaccination • details of any adverse drug reactions and actions taken • supplied via PGD 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 PGD should also be kept for audit purposes.

6. Key references

Key references	**COVID-19 Vaccine AstraZeneca vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 12 January 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 24 January 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 2 February 2022. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Regulation 174 Information for UK Healthcare Professionals and Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca and Conditions of Authorisation for COVID-19 Vaccine AstraZeneca. Published 9 September 2021. 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/ • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made • UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made

7. Practitioner authorisation sheet

COVID-19 Vaccine AstraZeneca PGD v07.00
Valid from: 01 March 2022 Expiry: 1 October 2022

By signing this Patient Group Direction (PGD) you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered healthcare professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

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