This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD must be used.

PATIENT GROUP DIRECTION (PGD)

Supply of cytisinicline (cytisine) tablets as part of a smoking cessation service in combination with motivational support

Public Health in Dorset

Version Number 1.1

Reference Number: Cytisinicline (cytisine) V1.1 July 2025
Valid from: 4th February 2025
Review date: 3rd August 2027
Expiry date: 3rd February 2028

Change History

Version and Date	Change details
Version 1.0 April 2025	National cytisinicline (cytisine) PGD adopted
Version 1.1 July 2025	Updated the wording in the training sections to state that the requirements apply to all individuals operating under this PGD Updated authorisation organisation guidance in Appendix A

This Patient Group Direction (PGD) must only be used by registered professionals who have been named and authorised by their organisation to practice under it (See Appendix A). The most recent and in date final signed version of the PGD must be used.

This Patient Group Direction (PGD) should be used to support delivery of Public Health commissioned services. It must only be used by registered professionals who have been named and authorised by their organisation to practice under it, in line with Appendix A.

PGD DEVELOPMENT GROUP

Date PGD template comes into effect:	4th February 2025
Review date	3rd August 2027
Expiry date:	3rd February 2028

This PGD template has been peer reviewed by the smoking cessation Short Life Working Group in accordance with their Terms of Reference. It has been endorsed by the NHSE National specialty adviser for tobacco dependency and approved by the SPS Medicines Governance Do Once Programme Board in January 2025.

Note: The working group and approving organisation(s) agreement to the content only applies to the national template and does not extend to any local adaptations made to any of the content which are solely the responsibility of the organisation authorising the PGD. The most

up to date version of the template is available here:
https://www.sps.nhs.uk/home/guidance/patient-group-directions/templates/

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Anne Joshua	Deputy Director of Pharmacy Commissioning, Primary Care community Services, NHSE
Katie Evans	Specialist Mental Health Pharmacist and Consultations Lead for College of Mental Health Pharmacy (CMHP)
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Keith Kendall	Regional Senior Pharmacy Integration Lead – North East and Yorkshire Region
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Martyn Willmore	Tobacco Control Senior Programme Manager, Health Improvement: Alcohol, Drugs, Tobacco and Justice Division, Department of Health and Social Care
Dr Debbie Robson	Senior Lecturer in Tobacco Harm Reduction, National Addiction Centre, Addictions Department & NIHR ARC South London, Institute of Psychiatry, Psychology & Neuroscience, King's College London
Professor Sanjay Agrawal	NHSE National specialty adviser for tobacco dependency, Consultant in respiratory and critical care medicine University Hospitals of Leicester NHS Trust.
Peter Pratt	National specialist advisor for Mental Health Pharmacy, NHS England
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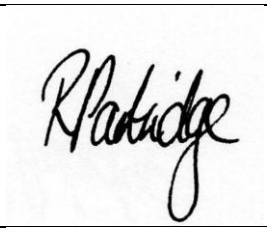
Rob Hebdon	National Pharmacy Integration Lead, NHS England
Stephen Riley	Deputy North West Regional Chief Pharmacist – Pharmacy Integration
Jo Jenkins	Associate Director – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Kurt Ramsden	Lead Medicines Optimisation Pharmacist, NHS North of England Commissioning Support Unit
Kieran Reynolds (SLWG co-ordinator)	Advanced Specialist Pharmacist – Medicines Governance, Medicines Use and Safety Division, Specialist Pharmacy Service
Claire Dearden	Chief Pharmaceutical Officer's and NHS Specialist Pharmacy Service National Pharmacy Technician Fellow
Tracy Rogers	Director, Medicines Use and Safety Division, Specialist Pharmacy Service

The working group gratefully acknowledge the specialist input of Dr Andy McEwen, Chief Executive, National Centre for Smoking Cessation and Training (NCSCT).

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

Name	Job title and organisation	Signature	Date
Senior doctor	Dr Jane Horne Consultant in Public Health, Dorset Council		08/04/25
Senior pharmacist via Integrated Medicines Optimisation Committee (IMOC)	Peter Cope, ICB Chief Pharmacist NHS Dorset		16/07/2025
Senior representative of professional group using the PGD	n/a	n/a	n/a
Person signing on behalf of authorising body	Rachel Partridge, Acting Director of Public Health and Prevention, Dorset Council		06/05/2025
Person signing on behalf of authorizing body	Rob Carroll, Director of Public Health & Communities, BCP Council		09/05/2025

Should you have any questions regarding this PGD please contact the Dorset Council Public Health team via email: phcontracts@dorsetcouncil.gov.uk

Commissioner Audit Requirements: As per the Public Health Smoking Cessation service specification, the Provider shall participate in any audit of service provision or assessment of user experience conducted or authorised by the commissioner.

1. Characteristics of staff

Qualifications and professional registration	Current contract of employment within a Local Authority or NHS commissioned service or an NHS Trust/organisation. Registered healthcare professional listed in the legislation as able to practice under Patient Group Directions.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and

	successfully completed the competencies to undertake clinical assessment of individuals leading to diagnosis of the conditions listed. Before offering the service, all individuals providing treatment under this PGD must: • complete the online National Centre for Smoking Cessation Training's (NCSCT) Practitioner Training and Assessment Programme. • complete the CPPE Safeguarding Adults (e-course) at least every 3 years • undertake appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme • be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC). • have access to the PGD and associated online resources
Competency assessment	Individuals operating under this PGD: • must be assessed as competent or complete a self-declaration of competence to operate under this PGD (see an example authorisation record sheet in Appendix A) • are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	Individuals operating under this PGD: • are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD. If any training needs are identified these should be discussed with the senior individual responsible for authorising individuals to act under the PGD and further training provided as required • must repeat the courses outlined in the Initial Training section every 3 years • must complete organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies. This PGD may be used only within the confines of the service specification commissioned by Dorset Council for public health within the Dorset ICS.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Tobacco dependence treatment and reduction of nicotine cravings in individuals who smoke and who are willing to seek treatment for tobacco dependence.
Criteria for inclusion	• Informed consent including consent to share relevant information with the individual's GP Practice (via local systems), where registered • Individuals between the ages of 18 and 65 years. • Individuals who smoke identified as having a long-term goal of tobacco abstinence • Individuals sufficiently motivated to stop tobacco dependence no later than on the 5th day of treatment. • Individuals who smoke and are motivated to engage in a gradual approach to stopping smoking but who are not able to stop abruptly. This cohort should reduce smoking during the first few days and stop smoking no later than the 5th day of treatment, as this may aggravate adverse reactions. • Individuals willing to continue a course of treatment with cytisinicline for 25 days, and behavioural support (which may be longer than 25 days), at agreed intervals from their referring tobacco dependence treatment support service. • Individuals who have experienced tobacco dependence treatment failure with cytisinicline can resume treatment 2 months after stopping taking cytisinicline. • Individual agrees to receive advice and treatment from the registered healthcare professional in line with this PGD.

Criteria for exclusion	**Individual** • Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice • Individuals under 18 years of age or aged 66 years and over • Individuals receiving cytisinicline and/or tobacco dependence treatment (i.e. varenicline or bupropion) from another provider • Individuals who have no intention to stop smoking • Individuals who report they are not sufficiently motivated to stop smoking or who are not willing to continue a course of tobacco dependence treatment for 25 days and engage in behavioural support. • Individuals who have experienced tobacco dependence treatment failure with cytisinicline in the last 2 months (i.e. have received treatment with cytisinicline in the last 2 months). • Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets) **Pharmaceutical** • Known hypersensitivity to cytisinicline or any of the components within the formulation – see Summary of Product Characteristics • Previous intolerable adverse reactions with cytisinicline • Concurrent use of any interacting medicine as listed in Drug Interactions section of this PGD
	Medical • Individuals taking clozapine • Known or suspected pregnancy (or pregnancy planned during treatment period) [See NICE NG209 guidance for information on recommended tobacco dependence treatment interventions in pregnant individuals]. • Currently breastfeeding • Individuals of childbearing potential unable to use barrier method of contraception while taking cytisinicline • Unstable angina (symptoms persist despite resting) • History of recent (in the previous 48 hours) myocardial infarction • History of recent (in the previous 48 hours) stroke • Clinically significant acute cardiac arrhythmias requiring hospitalisation • Known or suspected renal impairment (Chronic Kidney Disease (CKD) stages 2, 3a, 3b, 4 or 5 (eGFR <90ml/min/1.73m^2)) • Known or suspected hepatic impairment (i.e. ALT **or** AST > 2 X ULN) If there are any doubts about the individual's suitability for cytisinicline the registered healthcare professional must refer the individual to their GP Practice /appropriate specialist and not initiate treatment under this PGD.

Cautions including any relevant action to be taken	**The health risks of tobacco dependence are widely acknowledged and the likelihood of experiencing risks from using cytisinicline is expected to be lower compared to the risk of continuing to smoke.** **Cardiovascular symptoms:** Individuals taking cytisinicline should be instructed to notify their GP Practice of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke. **Contraception:** Individuals of childbearing potential, including those using/taking systemically acting hormonal contraceptives **must use an additional barrier form of contraception** (e.g. condoms) for the duration of cytisinicline treatment. **Individuals with current or past history of psychiatric disorders** The health benefits of treatment for tobacco dependence are widely acknowledged and any opportunity to stop smoking should be widely supported. However, treatment for tobacco dependence, with or without pharmacotherapy, has been associated with the short-term exacerbation of underlying psychiatric illness (e.g., depression). Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in individuals attempting to quit smoking. Individuals should be advised to discontinue cytisinicline immediately and notify their relevant service provider if they experience serious neuropsychiatric symptoms such as agitation, depressed mood, changes in behaviour or thinking, or seek immediate medical advice if they develop suicidal ideation or suicidal behaviour. **Medication related cautions when an individual stops smoking - irrespective of stop smoking medication.** Physiological changes resulting from smoking cessation, (with or without treatment with cytisinicline), may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary. As ingredients in tobacco smoke induce CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Before supplying cytisinicline, PGD users must first establish (using the information presented below) if there is a potential interaction due to a change in smoking status and inform the individual of this. The individual should be informed to notify the prescriber(s) of the interacting medicine(s) **in advance** of their intention to stop smoking.

	Additionally, the service providing cytisinicline (i.e. the PGD user) **must** also inform the prescriber(s) of the interacting medicine(s) of the individual's attempt to stop smoking so that any relevant monitoring and/or dose adjustments can be carried out by the individual/their health care professional. How this is communicated should be clearly laid out in the service contract or locally developed SOP. Where an individual has already stopped smoking (or reduced their tobacco consumption or entered a period of temporary abstinence) prior to presenting for treatment with cytisinicline, the PGD user should ensure that the individual has already discussed the potential effect(s) of this action on their existing medication(s) with the relevant prescriber(s) and detail any actions taken. Where this has not occurred, advise the individual to contact the relevant prescriber(s) (or service(s)) as soon as possible, as monitoring (and follow up with the service) may be required. The PGD user must **ensure** the service provider who prescribes any interacting medicine to any individual supplied with cytisinicline under this PGD are aware of the individual's intention to stop smoking **AND** that a plan is in place re: monitoring and dose adjustments, if required. If the individual is unwilling to share information between services, cytisinicline **must not be** supplied under this PGD and the individual should be referred to an appropriate alternative service provider, as per local arrangements. If it is **not possible to inform** the prescriber(s) of the interacting medicine(s) of the individual's intention to stop smoking **so that any relevant monitoring and/or dosage adjustments can be carried out** by the individual/their health care professional, cytisinicline **must not be** supplied under this PGD and the individual should be **referred** to an appropriate alternative service provider. If individuals **relapse and start smoking again**, they are **required to notify all healthcare practitioners** involved in their care (so that any appropriate monitoring and/or dose adjustments can be actioned). They must be advised of this responsibility and ensure that this information is communicated. The impact of smoking cessation on the following medicines have been classified as: - **High risk** (narrow therapeutic index drug and potential toxicity OR rapid dosage adjustments required) - **Moderate risk** (increased risk of adverse effects +/- dosage amendments required). **This list is not exhaustive and these risk categories are provided as a guide and should not act as a substitute for the PGD user's own clinical judgement.**

	HIGH RISK: ○ **Olanzapine -** see Appendix B ○ **Insulin** - see Appendix B ○ **Theophylline or aminophylline** - see Appendix B ○ **Warfarin** - see Appendix B ○ **Erlotinib -** see Appendix B ○ **Riociguat** - see Appendix B **MODERATE RISK:** ○ **Chlorpromazine** – see Appendix B ○ **Flecainide** - see Appendix B ○ **Fluvoxamine** - see Appendix B ○ **Haloperidol** - see Appendix B ○ **Melatonin** - see Appendix B ○ **Methadone** - see Appendix B ○ **Mexiletine** - see Appendix B ○ **Riluzole** - see Appendix B ○ **Ropinirole** - see Appendix B ○ **Tacrine (may not be commercially available in the UK)** - see Appendix B **Other cautions** Caution should be exercised when supplying cytisinicline to individuals with: - Cardiovascular disease (including: Ischemic heart disease, heart failure, hypertension) - Pheochromocytoma (a tumour of the adrenal gland) - Atherosclerosis (hardening of the arteries) - Peripheral vascular disease - Gastric and duodenal ulcers - Gastroesophageal reflux disease (GORD) - Hyperthyroidism (overactive thyroid) - Diabetes - Schizophrenia
Action to be taken if the individual is excluded	• Record reasons for exclusion in the appropriate clinical record and any advice given to the individual along with the action taken (e.g. referred to GP Practice) • Any individual who is excluded should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist, or mental health service as appropriate. • Recommend alternative tobacco dependence interventions if appropriate.
Action to be taken if the individual or carer declines treatment	• Document the reason for why the individual declined and any advice given to the individual along with the action taken (e.g. referred to tobacco dependence service). • Any individual who declines treatment should be signposted back to the referring service, another relevant provider, their GP Practice, appropriate specialist or mental health service as appropriate.

	• Recommend alternative tobacco dependence interventions if appropriate.
Arrangements for referral for medical advice	Refer to the referring service, another relevant provider, an individual's GP Practice, appropriate specialist, or mental health service as appropriate.

3. Description of treatment

Name, strength & formulation of drug	Cytisinicline (cytisine) 1.5mg tablets
Legal category	Prescription Only Medicine (POM)
Route / method of administration	Orally, swallowed whole with water.
Indicate any off-label use (if relevant)	**Temperature variations** Medicines should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions the pharmacist must ensure the medicine remains pharmaceutically stable and appropriate for use if it is to be issued. Where medicines have been assessed by a pharmacist in accordance with national or specific product recommendations/manufacturer advice as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected medicines for use lies with the pharmacist.
Dose and frequency of administration	Cytisinicline should be taken according to the following schedule: **Days 1-3:** One cytisinicline 1.5 mg tablet every 2 hours (**Max 6 tablets daily)** **Days 4-12:** One cytisinicline 1.5 mg tablet every 2.5 hours (**Max 5 tablets daily) [Smoking should be stopped no later than on the 5th day of treatment]** **Days 13-16:** One cytisinicline 1.5 mg tablet every 3 hours (**Max 4 tablets daily)** **Days 17-20:** One cytisinicline 1.5 mg tablet every 5 hours (**Max 3 tablets daily)** **Days 21–25:** One cytisinicline 1.5 mg tablet 1-2 tablets a day (**Max 2 tablets daily)** See cytisinicline (Cytisine) dosing schedule from the National Centre for Smoking Cessation and Training for further information. **Missed/forgotten dose:** Do not take a double dose to make up for a missed dose. Due to the dosing frequency changing frequently, individuals may be advised to use phone reminders (or alarms) to help them to remember to

	take cytisinicline on time. Individuals should reduce tobacco dependence during the first few days and stop tobacco dependence no later than the 5th day of treatment. Tobacco dependence should not be continued after the 5th day as this may aggravate adverse reactions. Individuals need to complete the 25-day course of treatment. In case of tobacco dependence treatment failure with cytisinicline, discontinue treatment and resume at least 2 months later.
Duration of treatment	25 days
Quantity to be supplied	Appropriately labelled pack of 100 x 1.5mg tablets
Storage	Stock must be securely stored according to organisation medicines policy and in conditions in line with SPC, which is available from the electronic Medicines Compendium website
Drug interactions	**Drug-drug interactions:** Where it is known an individual is concurrently taking one of the following medicines, cytisinicline must not be supplied under this PGD and the individual referred to a prescriber: - Anti-tuberculosis drugs - Systemically acting hormonal contraceptives† (where the individual is unable to use a second barrier method of contraception). † *As per the SPC, it is unknown if cytisinicline reduces the effectiveness of systemically acting hormonal contraceptives.* All concurrent medications must be checked for interactions in case of updated SPC advice. Where a clinically significant drug interaction is identified, the individual should be referred to a prescriber for consideration of suitability. **Drug-smoking interactions:** Physiological changes resulting from smoking cessation, with or without treatment with cytisinicline, may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary. As smoking induces CYP1A2, smoking cessation may result in an increase of plasma levels of CYP1A2 substrates. Refer to Cautions section for specific advice. For further advice see: Considering drug interactions with smoking Managing specific interactions with smoking
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website and the BNF The following side effects are listed in the product SPC as **very**

	common/common with cytisinicline, but may not reflect all reported side effects: ○ Change in appetite (mainly increase) ○ Weight gain ○ Dizziness ○ Irritability ○ Mood changes ○ Anxiety ○ Sleep disorders (insomnia, drowsiness, lethargy, abnormal dreams, nightmares), ○ Headaches ○ Difficulty in concentration ○ Tachycardia (increased heart rate) ○ Bradycardia (reduced heart rate) ○ Increased blood pressure (hypertension) ○ Dry mouth ○ Diarrhoea ○ Nausea ○ Changes flavour (alters taste) ○ Heartburn ○ Constipation ○ Vomiting ○ Abdominal pain (especially in the upper abdomen) ○ Abdominal distension ○ Burning tongue ○ Rash ○ Myalgia (muscle pain) ○ Fatigue Reassure the individual that these side effects occur mainly at the beginning of treatment and resolve quickly. These symptoms may also be the result of tobacco withdrawal symptoms and not treatment with cytisinicline. Additionally, fewer individuals report side effects with cytisinicline compared to varenicline. In the event of a severe adverse reaction (including exacerbation of known psychiatric illness: See Individuals with current or past history of psychiatric disorders for further information), the individual must be advised to stop treatment immediately and seek urgent medical advice.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and individuals/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme • Record all adverse drug reactions (ADRs) in the individual's clinical record. • Report and document in accordance with organisation incident policy. • It is considered good practice to notify the individual's GP Practice and/or other relevant healthcare providers in the event of an adverse reaction.

Written information to be given to patient or carer	• Provide marketing authorisation holder's patient information leaflet (PIL) provided with the product. • Provide a copy of (or a link to) the cytisinicline (Cytisine) dosing schedule from the National Centre for Smoking Cessation and Training • Give any additional information in accordance with the local service specification.

Patient advice / follow up treatment	**Pharmaceutical**
	• Explain the dose, frequency, and method of administration.
	• The individual/carer should be advised to read the PIL.
	• Inform the individual/carer of possible side effects and their management.
	• The individual/carer should be advised to seek medical advice in the event of a suspected adverse reaction.
	• The tablets should be swallowed whole with water, they can be taken either with or without food. Taking with food may reduce the likelihood of nausea.
	
	Medical/Psychological
	• Individuals taking cytisinicline, or any other treatment for tobacco dependence, should be advised to discontinue treatment and seek prompt medical advice if they develop agitation, depressed mood, or suicidal thoughts and to contact the PGD user or the tobacco dependence services.
	• Advise on actions to be taken by individuals with a history of mild to moderate mental health disorders and if their symptoms worsen i.e., discontinue treatment and report to the GP Practice and PGD user as soon as possible.
	• Individuals of childbearing potential, including those using/taking systemically acting hormonal contraceptives must use an additional barrier form of contraception (e.g. condoms) for the duration of cytisinicline treatment.
	• Tobacco dependence treatment may lead to a change in blood glucose levels. Individuals with diabetes should be advised to be vigilant for signs of hypo/hyperglycaemia and, where usually monitored, be advised to monitor blood glucose more frequently.
	• Individuals taking medications detailed within the Cautions section of this PGD should be advised on any required action.
	• Individual to notify their GP Practice of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke.
	
	Individual
	• Individuals should set a tobacco dependence stop date no later than on the 5th day of treatment with cytisinicline.
	• Discuss the major reasons for cytisinicline failure which are:
	  ◦ Unrealistic expectations.
	  ◦ Lack of preparation for the potential for the tablets to cause

	side effects; • Insufficient or incorrect use. • Insufficient support from a trained tobacco dependence advisor. • Further information that may support adherence as part of shared decision making: o Cytisinicline works by acting on the parts of the brain which are affected by nicotine in tobacco o Cytisinicline does not remove all temptation to use/smoke tobacco, but it does make abstinence easier ("it takes the edge off the discomfort"). o Due to the dosing frequency changing frequently, individuals may be advised to use phone reminders (or alarms) to help them to remember to take cytisinicline on time. o Less than 10% of individuals may experience mild nausea after taking cytisinicline and most people tolerate it without problems. If severe, individuals should be referred to their G.P. o Tobacco dependence treatment with or without medication and aids are associated with various symptoms (e.g. irritability, poor sleep etc.). Individuals should be made aware that they may experience any of these side effects and on discontinuation of therapy, but it is not clear whether the effects are linked to therapy or to nicotine withdrawal. Advise this is a short-term treatment for long-term benefit. o Possible physical changes on stopping tobacco dependance e.g. weight gain and how to manage this. o Outline the expectations of both the individual and the PGD user with reference to the ongoing treatment and future appointments. o Details of next consultation with the PGD user. • Advise individual/carer to return any unused medicines to a pharmacy for disposal: Do not dispose of medicines in the bin, down the sink or toilet.
Records	Appropriate records must include the following: • That valid informed consent has been given • Individual's name, address, and date of birth • Name of GP Practice where individual is registered or record the individual is not registered with a GP Practice • Name of registered healthcare professional operating under the PGD • Declaration, professional registration (e.g. NMC, GPhC) number and name of registered healthcare professional who supplied the medication. • Specify how the individual has/has not met the criteria of the PGD • Relevant past and present medical history and medication history • Name/dose/form/quantity of medicine supplied • Date and time of supply • Documentation of cautions as appropriate

	• Advice given if individual excluded or declines treatment. • Details of any ADRs/allergy status and actions taken • The supply must be entered in the Patient Medication Record (PMR) • That supply was made under a PGD • Any safety incidents, such as medication errors, near misses and suspected adverse events • Any additional requirements in accordance with the service specification • GP Practice to be notified on the day of provision or next working day via usual communication channels • **Details of any drug-smoking interactions, monitoring required and any actions taken.** • All records should be kept in line with national guidance. This includes individual data, master copies of the PGD and lists of authorised practitioners. **Records should be signed and dated (or a password-controlled e-records).** **All records should be clear, legible and contemporaneous.** **A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.**

4. Key references

Key references	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • National Institute for Health and Care Excellence (2013). Overview | Patient group directions | Guidance | NICE | Updated March 2017 Available at: https://www.nice.org.uk/Guidance/MPG2 • National Institute for Health and Care Excellence (2007). Overview | Varenicline for smoking cessation | Guidance | NICE. Available at: https://www.nice.org.uk/guidance/ta123 • Specialist Pharmacy Service (2023). Considering drug interactions with smoking. Available at: https://www.sps.nhs.uk/articles/considering-drug-interactions-with-smoking/ • Specialist Pharmacy Service (2023). Managing specific interactions with smoking. Available at: https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/ • Medicines and Healthcare products Regulatory Agency (2014). Smoking and smoking cessation: clinically significant interactions with commonly used medicines. GOV.UK. Available at: https://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines • National Institute for Health and Care Excellence CKS. Smoking cessation: Which drugs are affected by stopping smoking? Available at: https://cks.nice.org.uk/topics/smoking-cessation/prescribing-information/drugs-affected-by-smoking-cessation/

	• West R, Evins AE, Benowitz NL, Russ C, McRae T, Lawrence D, St Aubin L, Krishen A, Maravic MC and Anthenelli RM. (2018). Factors associated with the efficacy of smoking cessation treatments and predictors of smoking abstinence in EAGLES. Addiction (Abingdon, England), 113(8), pp.1507–1516. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6055735/ • Livingstone-Banks J, Fanshawe TR, Thomas KH, Theodoulou A, Hajizadeh A, Hartman L, Lindson N. Nicotine receptor partial agonists for smoking cessation. Cochrane Database Syst Rev. 2023 May 5;5(5):CD006103. Available at: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD006103.pub9/full#CD006103-sec-0037 • National Centre for Smoking Cessation and Training (NCSCT) (2024). Cytisine. Available at: https://www.ncsct.co.uk/library/view/pdf/Cytisine.pdf • National Centre for Smoking Cessation and Training (NCSCT). NHS Standard Treatment Plan (STP) for Inpatient Tobacco Dependence in Mental Health Hospitals. Available at: https://www.ncsct.co.uk/publications/STP-inpatient-mental-health • Agrawal S, Evison M, Ananth S, Fullerton D, McDill H, Perry M, Pollington J, Restick L, Spencer E, Vaghela A. (2024) Medical management of inpatients with tobacco dependency. *Thorax*; **79:**3-11. Available at: https://thorax.bmj.com/content/thoraxjnl/79/Suppl_1/3.full.pdf

Appendix A - example registered health professional authorisation sheet (example – local versions/electronic systems may be used)

PGD Name/Version **Valid from:** **Expiry:**

Before signing this PGD, check that the document has had the necessary authorisations in section 2. Without these, this PGD is not lawfully valid.

Registered health professional

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

Patient group directions 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 Patient Group Direction 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 health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of the organisation below for the above-named health care professionals who have signed the PGD to work under it.

Name of organisation:

Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

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

Appendix B: Drug-smoking interactions

HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse Effects	Action	When to implement action
Olanzapine	Metabolism of olanzapine is reduced.	Increased risk of adverse events of olanzapine (e.g. dizziness, sedation, hypotension).	Ensure the service provider who prescribes olanzapine to any individual supplied with cytisinicline under this PGD are aware of the individual's intention to stop smoking **before** cytisinicline is supplied.	Prior to cytisinicline supply
Insulin	May affect insulin resistance and enhance insulin sensitivity.	Increased risk of hypoglycemia.	Individuals on insulin may be supplied with cytisinicline but must be advised to monitor their blood glucose levels closely and of the symptoms of hypoglycemia. If the PGD user has any doubts around the ability of the individual to monitor their blood glucose levels, cytisinicline must not be supplied under this PGD and the individual should be referred to an appropriate care provider.	Prior to cytisinicline supply
Theophylline or aminophylline	Metabolism of theophylline and aminophylline are reduced.	Could cause plasma theophylline levels to rise, possibly to toxic levels if the dose of theophylline/aminophylline is not adjusted.	The PGD user must inform the individual's prescriber of their intention to stop smoking and agree subsequent additional monitoring by the prescriber **before** the individual is supplied with cytisinicline.	Prior to cytisinicline supply
Warfarin	Metabolism of warfarin is reduced.	Increased risk of adverse effects of warfarin (i.e. bleeding).	Individuals on warfarin may be supplied with cytisinicline but must advise the INR clinic of their intention to stop smoking using cytisinicline. A blood	Prior to cytisinicline supply

			test should be arranged with the clinic as per their instructions. The pharmacist should check the individual's yellow book on every scheduled consultation ensuring that their INR is being checked regularly, and that it is within the individual's normal range. If the individual is unwilling to disclose this information, cytisinicline must not be supplied under this PGD and the individual should be referred to an appropriate care provider.	
Erlotinib	Metabolism of erlotinib is reduced.	Rapid dose reduction required upon smoking cessation.	Ensure the service provider who prescribes erlotinib to any individual supplied with cytisinicline under this PGD are aware of the individual's intention to have tobacco dependence treatment and the dose is adjusted accordingly **before** cytisinicline is supplied.	Prior to cytisinicline supply
Riociguat	Metabolism of rioiguat is reduced.	Increased risk of adverse effects of riociguat (e.g. dizziness, headache, nausea, diarrhoea).	Ensure the service provider who prescribes riociguat to any individual supplied with cytisinicline under this PGD are aware of the individual's intention to stop smoking and the dose is adjusted accordingly **before** cytisinicline is supplied.	Prior to cytisinicline supply

MODERATE RISK:

Medication	**Impact of smoking cessation**	**Possible adverse effects**	**Action**	**When to implement action**
Chlorpromazine				
Flecainide				
Fluvoxamine				
Haloperidol				
Methadone				

Mexiletine Melatonin Riluzole Ropinirole Tacrine† (may not be commercially available in the UK)	Metabolism of medication is reduced	Increased risk of adverse effects (see below for further information)	Individuals taking any of the following medicines should be informed of the increased risk of adverse effects when stopping smoking. Ensure the service provider who prescribes any of these interacting medicines to any individual supplied with cytisinicline under this PGD are aware of the individual's intention to stop smoking and the dose is adjusted accordingly prior to stopping smoking, (if required).	Prior to cytisinicline supply

† Data to support this interaction is lacking and the possible clinical significance of this effect for this medicine is unknown.

Useful information:

- Managing specific interactions with smoking
- Individual drug Summary of Product Characteristics (SPC): accessible via:
  - Electronic medicines compendium
  - MHRA