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)

Community pharmacy supply of cytisinicline tablets as part of the tobacco dependence treatment services across the North-East of England

Version Number 1.1

Change History

Version and date	Change details
Version 1.0 February 2025	New national template *Cytisinicline National PGD template V1.0 FINAL Feb 2025* published by the Specialist Pharmacy Service (SPS) at https://www.sps.nhs.uk/articles/cytisinicline-for-smoking-cessation/
Version 1.1 November 2025	**National template adapted for the North-East of England region by:** Removal of the word 'cytisine' (except where embedded in references) **Regional North-East England authorisations** Addition of organisational authorisation by the lead local authority, and clinical authorisation by lead clinicians. Addition of list of participating local authority areas that have signed a MOU with the lead local authority and adopted this PGD through their governance processes. **Initial training** Added: *As described in the accompanying pharmacy service specification*, undertaken appropriate training. Removed the need for additional local safeguarding training. **Competency assessment** Kept the same format and wording in Appendix A. **Criteria for exclusion: Medical** Added patients taking clozapine (very high risk drug) and patients taking the high risk drugs haloperidol or olanzapine; theophylline or aminophylline; erlotinib and riociguat (Note: Addition of haloperidol to the listing of high risk drugs following cross-referencing of information at https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/). Altered patients with known or suspected renal impairment (Chronic Kidney

Version and date	Change details
	Disease (CKD) stages 2, 3a, 3b, 4 or 5 (eGFR <90ml/min/1.73m2)) to patients with known or suspected renal disease. Altered patients with known or suspected hepatic impairment (i.e. ALT or AST > 2 X ULN) to patients with known or suspected hepatic disease. **Cautions: Medication related cautions when an individual stops smoking** Altered wording to reflect GP practice PharmOutcomes email notification up to 5 days prior to client quit attempt. Removed description of additional actions to take 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. Moved patients taking clozapine (very high risk drug) and patients taking the high risk drugs to exclusions. Added agomelatine to listing of moderate risk drugs, following cross-referencing of information at https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/. Removed description of the development of local protocols to guide prescribing (the signposting to recommended sources of information remains). **Drug interactions** Added *See Appendix B* **Management of and reporting procedure for adverse reactions** Added that the pharmacy will directly notify the stop smoking service adviser if concerns on the supply of cytisinicline are received from the GP practice. **Records** Text amended to state that the GP practice should be notified within one day of provision via PharmOutcomes email notification. **Appendix B** Alterations made to Appendix B to: Added drug-drug interactions and hence exclusions with anti-tuberculosis treatments and systemically acting hormonal contraceptives (where the individual is unable to use a second barrier method of contraception). For drug-smoking interactions, made it clear which drugs are excluded (with the addition of haloperidol to high-risk drugs), and which moderate risk drugs carry a caution, the actions to take, and that the GP practice is informed up to 5 days before the client quit attempt by PharmOutcomes email.

National PGD Development Group

Date national PGD template comes into effect:	4 February 2025
Review date of national template:	3 August 2027
Expiry date of national template:	3 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/

Working Group

Name	Designation
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Louise Ross	Clinical Consultant National Centre for Smoking Cessation and Training
Martyn Willmore	Tobacco Control Senior Programme Manager, Health Improvement: Alcohol, Drugs, Tobacco and Justice Division, Department of Health and Social Care
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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).

Regional North-East England Authorisations

Date regional PGD template comes into effect:	01 January 2026
Expiry date of regional template:	28 February 2028

This regional PGD has been developed by the following health professionals, using the national SPS template and making the amendments to the national template as described in the Change History.

Clinical authorisation			
Name	**Job title and organisation**	**Signature**	**Date**
Senior doctor Ruth Sharrock	Dr Ruth Sharrock Consultant Respiratory Physician Gateshead NHS Foundation Trust		08/12/25
Senior pharmacist Claire Jones	Public Health Pharmacy Adviser Public Health Team Durham County Council		11/12/25
Senior pharmacist Kurt Ramsden	Medicines Adviser Public Health South Tees		16/12/25
Senior representative of professional group using the PGD Ann Gunning	Head of Services and Support Community Pharmacy North of Tyne		12/12/25

Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation.

It is the responsibility of the organisation that has legal authority to authorise the PGD, and to ensure that all legal and governance requirements are met. The authorising body accepts governance responsibility for the appropriate use of the PGD.

The PGD has been approved for use by Middlesbrough Council as the lead authority.

Organisational authorisation			
Role	**Name**	**Signature**	**Date**
Director of Public Health	Mark Adams		19/01/26

National SPS guidance at https://www.sps.nhs.uk/articles/patient-group-directions-in-complex-commissioning-scenarios/ states: *Where multiple organisations are involved*

all parties must be involved in an MOU and a lead commissioner may be identified as agreed. Where a lead commissioner is identified to act to authorise a PGD/s on behalf of other commissioning organisations, it is essential that all involved organisations have the necessary governance processes in place to ensure any authorisations undertaken by the lead organisation are formally noted. This should be reflected in the MOU.

Middlesbrough Council as the lead authority authorises this PGD for use by community pharmacies in the following local authority areas:

Authorised for use in the following local authority areas
County Durham
Darlington
Middlesbrough
Redcar & Cleveland
Hartlepool
Stockton on Tees
Newcastle
Sunderland
Northumberland
South Tyneside
North Tyneside
Gateshead

It is the responsibility of the provider organisation to ensure that all legal and governance requirements for using the PGD are met.

Registered Health Professional Authorisation Sheet

PGDs do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct. Individual practitioners must declare that they have read and understood the PGD and agree to supply/administer medication(s) listed only in accordance with the PGD. Individual practitioners must be authorised by name to work to this PGD. Appendix A provides a registered health professional authorisation sheet.

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 PGDs.
Initial training	The registered healthcare professional authorised to operate under this PGD must have: • As described in the accompanying pharmacy service specification, undertaken appropriate training and successfully completed the competencies to undertake clinical assessment of individuals leading to diagnosis of the conditions listed. • Undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - eLfH PGD elearning programme • Completed training (including updates) in safeguarding vulnerable adults. Individuals operating under this PGD must be familiar with the product and alert to changes in the Summary of Product Characteristics (SPC). Individuals operating under this PGD must have access to the PGD and associated online resources.
Competency assessment	• Individuals operating under this PGD must complete a self-declaration of competence to operate under this PGD (see authorisation record sheet in *Appendix A*). • Staff operating under this PGD 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. • 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.	

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 (very high-risk drug – see Appendix B). • Individuals taking haloperidol or olanzapine, theophylline or aminophylline, erlotinib and riociguat (high risk drugs – see Appendix B) • 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 disease. • Known or suspected hepatic disease. 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** 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 that their GP practice will be notified via email up to 5 days before their quit attempt (i.e. the client will set a quit date by day 5 of the medication). This email describes the interacting medicine(s) and the actions that the client has been advised to take so that any relevant monitoring and/or dose adjustments can be carried out by the individual/their health care professional. 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: - **Very high risk** (risk of death AND dosage adjustments required) see *Criteria for exclusion* for clozapine. - **High risk** (narrow therapeutic index drug and potential toxicity OR rapid dosage adjustments required) see *Criteria for exclusion* for haloperidol or olanzapine, theophylline or aminophylline, erlotinib and riociguat. - **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**: see *Appendix B* ○ Insulin ○ Warfarin **MODERATE RISK**: see *Appendix B* ○ Agomelatine ○ Chlorpromazine ○ Flecainide ○ Fluvoxamine ○ Melatonin ○ Methadone ○ Mexiletine ○ Riluzole ○ Ropinirole ○ Tacrine (may not be commercially available in the UK) Resources to help guide prescribers make any required dosage changes required in response to smoking cessation (and individuals re-starting smoking) include: - Considering drug interactions with smoking

	- Managing specific interactions with smoking
	- Individual drug SPCs: accessible via:
	  o Electronic medicines compendium
	  o MHRA
	- Young AH, Taylor D, Barnes TRE. The Maudsley Prescribing Guidelines in Psychiatry. John Wiley & Sons, Ltd.; 2021. Print ISBN: 9781119772224 https://onlinelibrary.wiley.com/doi/book/10.1002/9781119870203
	
	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 any action taken (e.g. referred to smoking cessation 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 smoking cessation 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 1.5mg tablets
Legal category	Prescription Only Medicine (POM)
Route / method of	Orally, swallowed whole with water

administration	
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: See Appendix B** 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: See Appendix B** 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. • The pharmacy should directly notify the stop smoking service adviser if concerns on the supply of cytisinicline are received back from the GP practice.
Written information to be given to individual or	• Provide marketing authorisation holder's patient information leaflet (PIL) provided with the product.

carer	• 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.

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: ○ Cytisinicline works by acting on the parts of the brain which are affected by nicotine in tobacco ○ Cytisinicline does not remove all temptation to use/smoke tobacco, but it does make abstinence easier ("it takes the edge off the discomfort"). ○ 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. ○ 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. ○ 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. ○ Possible physical changes on stopping tobacco dependance e.g. weight gain and how to manage this. ○ Outline the expectations of both the individual and the PGD user with reference to the ongoing treatment and future appointments. ○ 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 this 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 local authority service specification • GP Practice to be notified within 1 day of supply via PharmOutcomes email notification • 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-

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Appendix A: Registered health professional authorisation sheet

PGD Name: Community pharmacy supply of cytisinicline tablets as part of the tobacco dependence treatment services across the North-East of England
Version: 1.1
Valid from: 01 January 2026
Expiry: 28 February 2028

Before signing this PGD, check that the document has had the necessary authorisations. 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 *INSERT NAME OF ORGANISATION* **for the above named health care 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 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.
This information should be retained according to organisation PGD policy.

Appendix B:

Drug-drug interactions

Medication	Impact of taking cytisinicline	Action	When to implement action
Anti-tuberculosis treatments	As per the SPC, cytisinicline should not be used with anti-tuberculosis drugs.	Patients taking anti-tuberculosis treatments are excluded	Patients taking anti-tuberculosis treatments are excluded
Systemically acting hormonal contraceptives	As per the SPC, it is unknown if cytisinicline reduces the effectiveness of systemically acting hormonal contraceptives.	Individuals of childbearing potential unable to use barrier method of contraception while taking cytisinicline are excluded	Patient excluded where the individual is unable to use a second barrier method of contraception.

Useful information:

- https://bnf.nice.org.uk/treatment-summaries/tuberculosis/
- https://bnf.nice.org.uk/treatment-summaries/contraceptives-hormonal/

Drug-smoking interactions

VERY HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Clozapine	Metabolism of clozapine is reduced. Lower doses of clozapine needed.	Risk of significant adverse effects, including death and seizures, in individuals who abruptly stop smoking whilst taking clozapine, without dose adjustments.	Patients taking Clozapine are excluded	Patients taking Clozapine are excluded

Useful information:

- MHRA/CHM Drug Safety Update: clozapine and other antipsychotics: monitoring blood concentrations for toxicity

- Managing the risks associated with patients prescribed clozapine

HIGH RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
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 quit attempt i.e. patient advised on actions to take and GP practice informed via PharmOutcomes notification on the supply of the pack (which is a maximum of 5 days before the patient will stop smoking).
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 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.	Prior to quit attempt i.e. patient advised on actions to take and GP practice informed via PharmOutcomes notification on the supply of the pack (which is a maximum of 5 days before the patient will stop smoking).

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Haloperidol or Olanzapine	Metabolism of haloperidol and olanzapine are reduced.	Increased risk of adverse events (e.g. dizziness, sedation, hypotension).	Patients taking Haloperidol or Olanzapine are excluded	Patients taking Haloperidol or Olanzapine are excluded
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.	Patients taking Theophylline or Aminophylline are excluded	Patients taking Theophylline or Aminophylline are excluded
Erlotinib	Metabolism of erlotinib is reduced.	Rapid dose reduction required upon smoking cessation.	Patients taking Erlotinib are excluded	Patients taking Erlotinib are excluded
Riociguat	Metabolism of riociguat is reduced.	Increased risk of adverse effects of riociguat (e.g. dizziness, headache, nausea, diarrhoea).	Patients taking Riociguat are excluded	Patients taking Riociguat are excluded

MODERATE RISK:

Medication	Impact of smoking cessation	Possible adverse effects	Action	When to implement action
Agomelatine				
Chlorpromazine	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	Prior to quit attempt. i.e. patient advised on actions to take and GP practice informed via PharmOutcomes notification on the supply of the pack (which is a maximum of 5 days before the
Flecainide				
Fluvoxamine				
Methadone				
Mexiletine				
Melatonin				

Riluzole Ropinirole			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).	patient will stop smoking).
Tacrine† (may not be commercially available in the UK)				

† 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