

**PATIENT GROUP DIRECTION for the Supply of:**

**Cytisinicline (cytisine)**

**By: Accredited Pharmacists/Pharmacy Technicians (under Authorising Person for PGD at the Pharmacy)**

**In: Community Pharmacies in Barnsley, Calderdale, Doncaster and Sheffield accredited by Yorkshire Smokefree**

- It is the responsibility of the professional working under this PGD to verify that the client fulfils the stated criteria for supply of the treatment concerned
- It is not appropriate to have a PGD in place that is infrequently used by health care professionals because of progressive unfamiliarity with its contents. Any healthcare professional that works to a PGD infrequently should consider whether to cease doing so
- Cytisinicline is a licensed Prescription Only Medicine as defined by the Medicines Act 1968 and Prescription Only Medicines (Human Use) Order 1997

Cytisinicline is subject to standard MHRA safety monitoring procedures, healthcare professionals are asked to report any adverse reactions via the Yellow Card Scheme

- This PGD takes the place of a Prescription, as defined by The Human Medicines Regulations 2012
- Clinical indications, Contraindications, and Cautions are as set out in the Summary of Product Characteristics
- Inclusion and Exclusion criteria are summarised within the PGD
- "Off Label" use is not supported by the PGD

It is the responsibility of Clinicians issuing Cytisinicline under the PGD to assess patients' suitability against the PGD Inclusion and Exclusion criteria and the SPC Indications/Contraindications. Patients falling outside of these criteria cannot receive Cytisinicline under the PGD.

PGD Review date: 9<sup>th</sup> March 2029

<b>1. Purpose of the PGD</b>		
For accredited pharmacists/ <b>Pharmacy Technicians (under Authorising Person for PGD at the Pharmacy – see page 14 for definition of this role)</b> to supply Cytisinicline within its licensed indications as an option for smokers who have expressed a desire to quit smoking and who will be supported and monitored by Yorkshire Smokefree or may be referred to an accredited pharmacy by Yorkshire Smokefree contracted local Stop Smoking Service.		
<b>2. Clinical condition or situation to which this PGD applies</b>		
2.1	Define condition/situation	Tobacco dependence treatment and reduction of nicotine cravings in individuals who smoke and who are willing to seek treatment for tobacco dependence.
2.2	Qualifications & 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.
2.3	Initial training	The registered healthcare professional authorised to operate under this PGD must have: <ul style="list-style-type: none"> <li>• Undertaken appropriate training for working under PGDs for the supply and administration of medicines. Recommended training - <a href="#">eLfh PGD elearning programme</a></li> <li>• Completed locally required training (including updates) in safeguarding vulnerable adults.</li> </ul> Individuals operating under this PGD must be familiar with the product and alert to changes in the <a href="#">Summary of Product Characteristics</a> (SPC). Individuals operating under this PGD must have access to the PGD and associated online resources.
2.4	Competency assessment	Staff operating under this PGD are encouraged to review their competency using the <a href="#">NICE Competency Framework for health professionals using patient group directions</a>
2.5	Ongoing training & 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.
2.6	Criteria for inclusion	<ul style="list-style-type: none"> <li>• Clients over 18 years of age</li> <li>• Informed consent including consent to</li> </ul>

		<p>share relevant information with the individual's GP Practice (via local systems), where registered.</p> <ul style="list-style-type: none"> <li>• Individual agrees to receive advice and treatment from the registered healthcare professional in line with this PGD</li> <li>• Tobacco users identified as sufficiently motivated to quit</li> <li>• Individuals sufficiently motivated to stop tobacco dependence no later than on the 5th day of treatment &amp; continue a course of treatment for 25 days.</li> <li>• 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.</li> <li>• Individuals who have experienced tobacco dependence treatment failure with cytisinicline can resume treatment 2 months after stopping taking cytisinicline.</li> <li>• Tobacco users who are receiving support to stop smoking with Yorkshire Smokefree or a Yorkshire Smokefree contracted Stop Smoking Service</li> <li>• A medical history is taken and documented to establish that there are no contraindications for treatment with Cytisinicline and that any cautions for use are recorded (see Criteria for exclusion). Refer to Appendix A for <i>cytisinicline voucher</i></li> </ul>
2.7	Criteria for exclusion	<p><b>Individual</b></p> <ul style="list-style-type: none"> <li>• Consent to treatment refused and/or consent refused to share information with the individual's registered GP Practice</li> <li>• Tobacco users not sufficiently motivated to quit or to use cytisinicline</li> <li>• Clients under 18 years of age</li> <li>• Clients 66 years of age or older</li> <li>• Individuals receiving Cytisinicline and/or tobacco dependence treatment (i.e. Bupropion or Varenicline) from another provider</li> <li>• Individuals who report they are not sufficiently motivated to stop smoking</li> </ul>

		<p>or who are not willing to continue a course of tobacco dependence treatment for 25 days and engage in behavioural support.</p> <ul style="list-style-type: none"> <li>• 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).</li> <li>• Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets)</li> </ul> <p><b>Pharmaceutical</b></p> <ul style="list-style-type: none"> <li>• Known sensitivity to Cytisinicline or any of its excipients</li> <li>• Previous intolerable adverse reactions with cytisinicline</li> <li>• Not to be used with anti-tuberculosis drugs.</li> <li>• Known to be taking 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.)</li> </ul> <p><b>Medical</b></p> <ul style="list-style-type: none"> <li>• Pregnancy/ breastfeeding</li> <li>• Individuals of childbearing potential unable to use barrier method of contraception while taking cytisinicline</li> <li>• Unstable angina (symptoms persist despite resting)</li> <li>• History of recent (in the previous 48 hours) myocardial infarction</li> <li>• History of recent (in the previous 48 hours) stroke</li> <li>• Clinically significant acute cardiac arrhythmias requiring hospitalisation</li> <li>• Known or suspected renal impairment (Chronic Kidney Disease (CKD) stages 2, 3a, 3b, 4 or 5 (eGFR &lt;90ml/min/1.73 m<sup>2</sup>))</li> <li>• Known or suspected hepatic impairment (i.e. ALT or AST &gt; 2 X ULN)</li> <li>• Patients on Clozapine excluded from this PGD through community pharmacy (can be looked at separately through</li> </ul>
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		<p>service users consultant – prescribed through them with support from YSF)</p> <ul style="list-style-type: none"> <li>• Taking drugs for the treatment of Tuberculosis (TB).</li> </ul> <p>If there are any doubts about the individual's suitability for cytisinicline the registered healthcare professional working under this PGD must refer the individual to their GP Practice/appropriate specialist and not initiate or continue treatment under this PGD.</p>
2.8	Criteria for cautions [to include consideration of Concurrent medication]	<p><b>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.</b></p> <p><b>Cardiovascular symptoms:</b> 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.</p> <p><b>Contraception:</b> 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.</p> <p><b>Individuals with current or past history of psychiatric disorders:</b> The health benefits of treatment for tobacco dependence are widely acknowledged and any opportunity to stop smoking should be widely supported.</p> <p>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</p>

	<p>behaviour or thinking, or seek immediate medical advice if they develop suicidal ideation or suicidal behaviour.</p> <p>This will be discussed weekly for 4 weeks, then biweekly thereafter and documented by the YSF representative supporting the patient.</p> <p><b>Effect of Smoking Cessation: (Appendix B)</b></p> <ul style="list-style-type: none"> <li>• Cigarette smoke stimulates a liver enzyme responsible for metabolising some medicines in the body, such as theophylline, warfarin, clozapine and insulin, meaning that the metabolism of these medications increases. Clients should be warned that physiological changes resulting from smoking cessation, <b>with or without</b> treatment with cytidine, may alter the pharmacokinetics or pharmacodynamics of some medicinal products for which dose adjustment may be necessary.</li> </ul> <p><b>YSF service should enquire if the patient is taking Warfarin, Theophylline and if so, email a letter to the client's GP/warfarin clinic (if client consents) to see if they would be happy to make dose adjustments and/or monitoring through the period of smoking cessation. YSF service to inform the client that they must contact their GP to inform them that they intend to stop smoking in the next few weeks. If the client agrees to do this the voucher may be issued.</b></p> <p><b>Community pharmacy supplying the medication through the PGD should ascertain that this step has taken place before the supply to comply with the PGD</b></p> <p><b>High Risk secondary care medicines including Olanzapine, Erlotinib &amp; Riociguat will require informing secondary care consultant if considering stopping smoking to they can ensure they either amend dosages/monitor for side effects once treatment started. This should preferably be completed before sending to community pharmacy.</b></p> <p>- If a client is a diabetic on insulin treatment a judgement must be made by YSF/PGD user on their ability to test and manage their blood glucose or for a carer to do it for them. If so they should be advised to monitor their blood glucose levels more closely after stopping smoking and adjust insulin doses as necessary.</p>
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		<ul style="list-style-type: none"> <li>- When the client stops smoking, metabolism of theophylline/aminophylline is reduced which could cause plasma levels to rise, possibly to toxic levels if the dose is not adjusted. Signs of theophylline toxicity are: - vomiting, dilated pupils, sinus tachycardia and hyperglycaemia</li> <li>- Clients on Warfarin need to have a plan for weekly INR's during the period of smoking cessation and for one month after to ensure dose adjustments are made if necessary to avoid a raised INR</li> <li>- Clients on Olanzapine need authorisation from the consultant and a plan for side effects to be monitored on smoking cessation. A dose reduction prior is not normally advised but may be recommended by the consultant if side effects including dizziness, sedation, hypotension develop.</li> <li>- Clients on Erlotinib from cancer services should not cease smoking without discussion with their consultant.</li> <li>- Clients on Riociguat from pulmonary hypertension specialist should not cease smoking without discussion with their specialist.</li> </ul> <p><b>Please note: 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. Appendix B contains medications with moderate risk of increases on smoking cessation. Appendix C is a list of potential side effects and actions required which is from SPS and NICE guidelines.</b></p> <p><b><u>Other Cautions:</u></b></p> <p>Caution should be exercised when supplying cytosinicline to individuals with:</p> <ul style="list-style-type: none"> <li>- Cardiovascular disease (including: Ischemic heart disease, heart failure, hypertension)</li> <li>- Pheochromocytoma (a tumour of the adrenal gland)</li> <li>- Atherosclerosis (hardening of the arteries)</li> <li>- Peripheral vascular disease</li> <li>- Gastric and duodenal ulcers</li> <li>- Gastroesophageal reflux disease (GORD)</li> <li>- Hyperthyroidism (overactive thyroid)</li> <li>- Diabetes</li> <li>- Schizophrenia</li> </ul>
2.9	Client consent [verbal, written, implied]	Informed consent as stated in the local consent policy, including consent to the use of the PGD, and informing GP of supply of cytosinicline

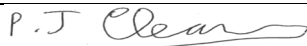


2.10	Action if client excluded	Pharmacies providing Yorkshire Smokefree contracted Stop Smoking Services should offer clients the option of NRT. This might include any of the conditions referred to as exclusion criteria above, but also previously unrecognised co-morbidities. Other pharmacies should direct the client back to Yorkshire Smokefree. Document action in client's medication record (PMR) and 'Inform service provider of the outcome'
2.11	Action if treatment declined by client	Pharmacies providing Yorkshire Smokefree contracted Stop Smoking Services should offer other available smoking cessation options if appropriate. Other pharmacies should direct the client back to Yorkshire Smokefree.  Document action in client's medication record (PMR) and inform the Service Provider of the outcome
<b>3. Characteristics of staff</b>		
3.1	Class of healthcare professional for whom PGD is applicable & professional qualifications required	Pharmacist or pharmacy technician registered with General Pharmaceutical Council, working within and for a pharmacy with an agreement with Yorkshire Smokefree to provide cytisinicline under PGD.  It is the responsibility of the individual pharmacist or pharmacy technician to ensure that they and their staff are competent in all aspects of supply of Cytisinicline.  This PGD will only apply whilst the pharmacist or pharmacy technician is employed or contracted/working at the time in an accredited Pharmacy within <b>Barnsley, Calderdale, Doncaster or Sheffield.</b>
3.2	Additional requirements/specialist qualifications required	Accredited pharmacies will have a suitable private consultation room / area which is available for all client consultations.
3.3	Continued training requirements	The practitioner should be aware of any change to the recommendations for the medicine listed. It is the responsibility of the individual to keep up-to-date with continued professional development and to work within the limitations of individual scope of practice.
<b>4. Description of treatment</b>		
4.1	Generic name of medicine and form (e.g. tablets)	Cytisinicline (cytisine) 1.5mg tablets
4.2	Legal status POM/P/GSL	POM
	Licensed or unlicensed use	Licensed

	[If unlicensed state rationale for use]	
4.3	Dose [Where a range is applicable include criteria for deciding on a dose]	<p>Cytisinicline should be taken according to the following schedule:</p> <p><b>Days 1-3:</b> One cytisinicline 1.5 mg tablet every 2 hours (<b>Max 6 tablets daily</b>)</p> <p><b>Days 4-12:</b> One cytisinicline 1.5 mg tablet every 2.5 hours (<b>Max 5 tablets daily</b>) [<b>Smoking should be stopped no later than on the 5th day of treatment</b>]</p> <p><b>Days 13-16:</b> One cytisinicline 1.5 mg tablet every 3 hours (<b>Max 4 tablets daily</b>)</p> <p><b>Days 17-20:</b> One cytisinicline 1.5 mg tablet every 5 hours (<b>Max 3 tablets daily</b>)</p> <p><b>Days 21–25:</b> One cytisinicline 1.5 mg tablet once or twice a day (<b>Max 2 tablets daily</b>)</p> <p>See <a href="#">cytisine dosing v6</a> for further information.</p> <p><b>Missed/forgotten dose:</b> 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.</p>
4.4	Route / method of administration	Orally, swallowed whole with water
4.5	Total dose and number of times treatment can be administered; state time frame	<ul style="list-style-type: none"> <li>• Clients should be supplied with the full course of treatment (100 tablet)</li> <li>• Clients should be seen by the stop smoking Advisor, weekly for at least 4 weeks after the quit date, then fortnightly.</li> <li>• The treatment course is up to 25 days</li> </ul>
4.6	Information on follow-up management	Advise to seek medical advice if more severe reactions to medication occur
4.7	Written/verbal advice for client before/after treatment and management	<ul style="list-style-type: none"> <li>• Ensure a PIL is provided to the client and advise them to read this prior to starting</li> <li>• Provide a copy of (or a link to) the cytisinicline (Cytisine) <a href="#">dosing schedule from the National Centre for Smoking Cessation and Training</a></li> </ul> <p><b>Pharmaceutical</b></p> <ul style="list-style-type: none"> <li>• Explain the dose, frequency, and method of administration.</li> <li>• The individual/carer should be advised to read the PIL.</li> <li>• Inform the individual/carer of possible side effects and their management.</li> <li>• The individual/carer should be advised to seek medical advice in the event of a suspected adverse reaction.</li> </ul>

		<p>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.</p> <p><b>Medical/Psychological:</b></p> <ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• 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.</li> <li>• Individuals taking medications detailed within the Cautions section of this PGD should be advised on any required action.</li> <li>• 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.</li> </ul> <p><b>Individual:</b></p> <ul style="list-style-type: none"> <li>• Individuals should set a tobacco dependence stop date no later than on the 5th day of treatment with cytisinicline.</li> <li>• Discuss the major reasons for cytisinicline failure which are: <ul style="list-style-type: none"> <li>• Unrealistic expectations.</li> <li>• Lack of preparation for the potential for the tablets to cause side effects;</li> <li>• Insufficient or incorrect use.</li> <li>• Insufficient support from a trained tobacco dependence advisor.</li> </ul> </li> <li>• Further information that may support adherence as part of shared decision making:</li> </ul>
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		<ul style="list-style-type: none"> <li>o Cytisinicline works by acting on the parts of the brain which are affected by nicotine in tobacco</li> <li>o Cytisinicline does not remove all temptation to use/smoke tobacco, but it does make abstinence easier (“it takes the edge off the discomfort”).</li> <li>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.</li> <li>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.</li> <li>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.</li> <li>o Possible physical changes on stopping tobacco dependence e.g. weight gain and how to manage this.</li> <li>o Outline the expectations of both the individual and the PGD user with reference to the ongoing treatment and future appointments.</li> <li>o Details of next consultation with the PGD user.</li> </ul> <ul style="list-style-type: none"> <li>• 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.</li> </ul>
4.8	Communication with client’s General Practitioner	<p>In every case when a supply of cytisinicline is made in accordance with this PGD, the pharmacist or pharmacy technician must inform the client’s General Practitioner (GP) of the supply in a timely manner, using ‘Notification of supply of cytisinicline through the PGD’ (Appendix A).</p> <p>This must not exceed one calendar month. This applies whether the pharmacy is a Yorkshire Smokefree contracted Stop Smoking Service Provider or not.</p>
4.9	Instructions on identifying, managing & reporting adverse drug reactions	Smoking cessation with or without treatment is associated with various symptoms. For example, dysphoria or depressed mood; insomnia, irritability, frustration or anger;

		<p>anxiety; difficulty concentrating; restlessness; decreased heart rate; increased appetite or weight gain have been reported in clients attempting to stop smoking. No attempt has been made in either the design or the analysis of the cytisinicline studies to distinguish between adverse events associated with study drug treatment or those possibly associated with nicotine withdrawal.</p> <p>Clients should be asked at every appointment about their mood. If the client develops suicidal thoughts or behaviour, they should be told to stop treatment and contact their GP immediately. Where the pharmacy is not the client's Yorkshire Smokefree contracted Stop Smoking Service Provider, the pharmacist or pharmacy technician should also inform the Service Provider.</p> <p>If the client, family or care givers have concerns about agitation, depressed mood or changes in behaviour cytisinicline should be stopped immediately.</p> <p>Please refer to current BNF and SPC for full details.</p> <p>List of side effects are available in the SPC and PIL (provided to patient).</p> <p>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.</p> <p>Report all Adverse Drug Reactions using the <a href="#">Yellow Card Scheme</a>:</p>
4.10	Arrangements for referral for medical advice	Pharmacist or pharmacy technician must be able to advise client/parent/carer what action to take in the event of the client experiencing any side effects and the most appropriate action (e.g. dose reduction or medical service to contact).
4.11	Precautions, facilities & supplies	<p>Store in a cool dry place.</p> <p>Order supplies from licensed pharmacy wholesalers.</p>
4.12	Specify method of recording supply sufficient to enable audit trail	<p>Pharmacists or pharmacy technician are required to keep a record of the consultation and supply in the Patient Medication Records (PMR). The supply of cytisinicline should also be recorded on Quitmanager:</p> <ul style="list-style-type: none"> <li>Client's name, address, date of birth and GP details.</li> </ul>

		<ul style="list-style-type: none"> <li>Referring Yorkshire Smokefree contracted Stop Smoking Service Provider.</li> <li>Date supplied and name of the pharmacist or pharmacy technician who supplied the medication.</li> <li>Reason for inclusion.</li> <li>Advice given to client.</li> <li>Details of any adverse drug reaction and actions taken including documentation in the client's medical record via GP (as well as reporting to the CSM using the 'Yellow Card' reporting system.</li> </ul>	
<b>5. Audit</b>			
The use of this PGD to be monitored by the service in which it is used.			
<b>6. Management</b>			
6.1	This PGD has been written by:		
Job title	Name	Signature	Date
Lead Pharmacist	Patrick Cleary		13/4/26
Health and Wellbeing community manager	Jan Spence		13/4/26
6.2	This PGD has been approved on behalf of South West Yorkshire Partnership Teaching NHS Foundation Trust by:		
Job title	Name	Signature	Date
Medical Director	Subha Thiyagesh		21.04.26
6.3	Persons permitted to authorise staff they are responsible for to operate this PGD		
	Commissioning Manager for the County Council or Deputy		
<b>7. References and Sources of Information</b>			
<ul style="list-style-type: none"> <li>Electronic Medicines Compendium <a href="http://www.emea.europa.eu/pressdocs/humans/EPAR/cyt/cyt.htm">http: Cytisinicline 1.5 mg tablets - Summary of Product Characteristics (SmPC) - (emc)   15789</a></li> <li>Electronic BNF <a href="https://bnf.nice.org.uk/">https://bnf.nice.org.uk/</a></li> <li>National Institute for Health and Care Excellence (2013). Overview   Patient group directions   Guidance   NICE   Updated March 2017 Available at: <a href="https://www.nice.org.uk/guidance/mpg2">https://www.nice.org.uk/guidance/mpg2</a></li> <li>National Institute for Health and Care Excellence (2007). Overview   Cytisinicline for smoking cessation   Guidance   NICE. Available at: <a href="https://www.nice.org.uk/guidance/psg20070001">Cytisinicline   Prescribing information   Smoking cessation   CKS   NICE</a></li> <li>Specialist Pharmacy Service (2023). Considering drug interactions with smoking. Available at: <a href="https://www.sps.nhs.uk/articles/considering-drug-interactions-with-smoking/">https://www.sps.nhs.uk/articles/considering-drug-interactions-with-smoking/</a></li> <li>Specialist Pharmacy Service (2023). Managing specific interactions with smoking. Available at: <a href="https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/">https://www.sps.nhs.uk/articles/managing-specific-interactions-with-smoking/</a></li> <li>Medicines and Healthcare products Regulatory Agency (2014). Smoking and smoking cessation: clinically significant interactions with commonly used medicines. GOV.UK. Available at: <a href="https://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines">https://www.gov.uk/drug-safety-update/smoking-and-smoking-cessation-clinically-significant-interactions-with-commonly-used-medicines</a></li> <li>National Institute for Health and Care Excellence CKS. Smoking cessation: Which drugs are affected by stopping smoking? Available at: <a href="https://cks.nice.org.uk/topics/smoking-cessation/prescribing-information/drugs-affected-by-smoking-cessation/">https://cks.nice.org.uk/topics/smoking-cessation/prescribing-information/drugs-affected-by-smoking-cessation/</a></li> </ul>			

- 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.pub Reference Number: 9/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/79/Suppl\\_1/3](https://thorax.bmj.com/content/79/Suppl_1/3)

**PGD for administration of Cytisinicline tablets by Community Pharmacists/Pharmacy technicians**

- **It is the responsibility of the Authorising Person to keep this list up to date and in a safe place for reference.** Any healthcare professionals who no longer meets the competency requirements or leave the service or practice must be removed from the list; likewise, any new healthcare professionals meeting the competency requirements should be added to the list in order to work under the Patient Group Direction.
  
- The Authorising Person is only expected to confirm that the Healthcare Professionals meets the minimum training and competency requirements under this PGD. It is the responsibility of the Healthcare Professional themselves and their Professional Body to ensure that they are fit to practice.
  
- This Patient Group Direction is to be read, agreed to and signed by all healthcare professionals it applies to. The original signed copy should be retained by the Authorised Person with responsibility for PGDs within the pharmacy. A copy should be retained by each pharmacist or pharmacy technician.

- I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work under it within my professional code of conduct

<b>Healthcare Professionals permitted to supply or administer under this PGD</b>				
Name & job title of Healthcare Professional	Signature	Authorised Person with responsibility for PGDs: Commissioning Manager or Deputy	Signature	Date approved

**Appendix A:**

**Notification of supply of Cytisinicline to your patient through the Cytisinicline PGD**

<b>Patient Name</b>	
<b>Address</b>	
<b>Date of Birth</b>	

**Dear Doctor**

**I have supplied the following stop smoking medication to your patient named above, through the South West Yorkshire NHS Foundation Trust/Yorkshire Smokefree Patient Group Direction for the Supply of Cytisinicline Tablets of which I am an accredited Pharmacist.**

Cytisinicline- 100 tablets
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**PGD Requirements**

	<b>Yes</b>	<b>No</b>
1. Aged 18 or above or under 66 years old		
2. Tobacco dependent and motivated to quit		
3. Agreed to behavioural support during course of Cytisinicline		
4. Is the client currently pregnant or breastfeeding		
5. 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).		
6. Individuals unable to absorb oral medications and/or inability to swallow solid oral dosage formulations (i.e. tablets)		
Does the client have history of:		
7. Unstable angina		
8. Recent history of MI or stroke (within 48 hours)		
9. Sensitivity to Cytisinicline or excipients, or serious side effects from previous course of Cytisinicline		
10. Clinically significant acute cardiac arrhythmias requiring hospitalisation		
11. Known or suspected renal impairment or hepatic impairment		
12. Currently having drug treatment for TB		
13. Currently taking systemically acting hormonal contraception and unable to use an additional barrier method of contraception		
14. Patients on Clozapine		

Clients must answer YES to Qs 1-3 to be eligible		
If clients answer YES to any of Qs 4-14 they are NOT eligible for cytisinicline through the PGD		

**Pharmacist/Pharmacy Technician Name**

**Date of supply**

**Name and Address of Pharmacy**

## 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 <b>before</b> cytisinicline is supplied.	Prior to cytisinicline supply
Insulin	May affect insulin resistance and enhance insulin sensitivity.	Increased risk of <a href="#">hypoglycemia</a> .	Individuals on insulin may be supplied with cytisinicline but must be advised to monitor their blood glucose levels closely and of the <a href="#">symptoms of hypoglycemia</a> . 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.	Service users advised to increase monitoring of BM's and followed up at appointments. Advised contact GP/diabetes team if any issues develop with high or low BM's
Theophylline or aminophylline	Metabolism of theophylline and aminophylline are reduced.	Could cause plasma theophylline levels to rise, possibly to toxic levels	The PGD user must inform the individual's prescriber of their intention to stop smoking and agree subsequent additional monitoring by the prescriber <b>before</b> 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 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 cytisinicline supply
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 <b>before</b> cytisinicline is supplied.	Prior to cytisinicline supply
Riociguat	Metabolism of riociguat 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 <b>before</b> cytisinicline is supplied.	Prior to cytisinicline supply

**Moderate risk:**

<b>Medication</b>	<b>Impact of smoking cessation</b>	<b>Possible adverse effects</b>	<b>Action</b>	<b>When to implement action</b>
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 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).	Will be assessed on a weekly basis in the first 4 weeks, asking if any new side effects or concerns
Flecainide				
Fluvoxamine				
Haloperidol				
Methadone				
Mexiletine				
Melatonin				
Riluzole				
Ropinirole				

**Appendix C: List of medications affected by stop smoking and potential signs and symptoms (derived from SPS & NICE guidelines)**

	Action required & Urgency
Theophylline	Aim to reduce dose by 25-30% over first week. Monitor the patient closely for signs of toxicity (vomiting, restlessness, agitation, dilated pupils, hyperglycaemia, tachycardia, haematemesis, convulsions, hypokalaemia and ventricular arrhythmias). Any signs of toxicity arrange urgent admission to acute hospital.
Erlotinib	Smoking cessation should not commence without seeking specialist advice first.
Warfarin	Service monitoring warfarin (GP or warfarin clinics) should be contacted prior to stopping smoking. Risk of bleeding increased due to rising INR. Recommended weekly INR through smoking cessation period until stable. As it is longer acting medication it is prudent to continue monitoring weekly for up to a month or until INR levels appear stabilised. Advice patient to consult yellow book on the signs of increased bleeding and seek urgent assessment should these signs develop.
Olanzapine	Specialist contacted prior to stopping smoking. Be alert for adverse effects such as dizziness, sedation, hypotension. If concern about side effects then a dose reduction of up to 25% may be required.
Haloperidol	Be alert for adverse effects such as dizziness, sedation, extra-pyramidal effects, anti-cholinergic effects, arrhythmias. If concerns do ECG and reduce dose by 25%.
Chlorpromazine	Be alert for adverse effects such as dizziness, sedation, extra-pyramidal effects, tachycardia, arrhythmia, hypothermia, hypotension, respiratory depression, seizures. If concerns do ECG and reduce dose.
Fluvoxamine	Monitor for side effects such as nausea, tremor and nystagmus. If side effects, consider dose reduction.
Agomelatine	Monitor for side effects such as nausea, dizziness and sedation. If side effects, consider dose reduction
Methadone	Monitor for signs of opiate toxicity such as drowsiness, respiratory depression, pinpoint pupils, hypotension and loss of consciousness. Reduce dose if needed. Patient likely to get supplies from substance misuse teams who can help with any queries/advice on dose.
Melatonin	Drowsiness, headache and dizziness can increase. If occurs reduce dose.

Cinacalcet	While not expected to cause major changes it is advised to seek advice from the specialist who initiated (likely renal). May need to monitor parathyroid levels.
Mexiletine	Monitor for side effects such as nausea, tremor and hypertension. Any concerns contact specialist who manages the drug.
Riluzole	Monitor for side effects of drowsiness, headache and dizziness. Discuss with specialist involved (likely neurology)
Riociguat	Need to contact specialist initiator (likely pulmonary hypertension specialist) prior to stopping smoking. Levels increase by up to 60%. Monitor for nausea, diarrhoea, dizziness and headache.
Ropinirole	Monitor for side effects of nausea and dizziness. May need to adjust dose if necessary (Parkinsons disease).
Pifenidone	Seek advice from specialist initiator (likely respiratory) as trials suggest increased levels of up to 50%. Monitor for signs of hepatic toxicity. Need LFT's.
Flecainide	Monitor for side effects such as dizziness and visual disturbances, levels can increase up to 50%, consider dose reduction.