

Tobacco: preventing uptake, promoting quitting and treating dependence - Cytisinicline for smoking cessation

**Consultation on draft guideline - Stakeholder comments table
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Action on Smoking and Health	Guideline	General	General	<p>We would like to congratulate NICE for undertaking this rapid process to address available evidence regarding the use of cytisinicline as a stop smoking aid. The addition of Cytisinicline in January 2024 to the British National Formulary was long awaited. The proposed amendments to the NG209 are critical to the ability of organisations to support the use of cytisinicline as a treatment for individuals who seek to stop smoking or remain temporarily abstinent. NCSCT provides our overwhelming support that that the available evidence supports the use of cytisinicline as stop smoking aid is very strong and sufficient for cytisinicline to be identified alongside varenicline, combination nicotine replacement therapy and nicotine containing vapes as first choice stop smoking aids.</p> <p>ASH also acknowledges that the Summary of Product Characteristics (SPC) for cytisinicline includes a number of contraindications and cautions. The majority of contraindication and cautions are included due to a lack of research and do not reflect evidence of an increased risk of adverse events. While we must take these contraindications seriously, we expect as a nicotine receptor partial agonist that general safety profile of cytisinicline is likely to be similar to that of varenicline, but with fewer side effects. High quality data is available for</p>	Thank you for your comment and for sharing the additional resources.

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				<p>varenicline to support safety in the majority of groups. The exceptions being pregnant and breastfeeding women, people under the age of 18, and people with end stage renal failure or a previous allergic reaction. We would expect with more research that the list of contraindications and cautions for cytisinicline will be reduced or removed.</p> <p>NCSCT has available on their website additional resources to support the field with introduction of cytisinicline:</p> <p>A briefing on Cytisine: https://www.ncsct.co.uk/library/view/pdf/Cytisine.pdf </p>	
Action on Smoking and Health	Guideline	General	General	<p>We acknowledge as summarised in the evidence review that the committee discussed the possibility of including research recommendations specific to cytisinicline to cover key gaps in the evidence. We understand the decision was made that the existing research recommendations in the guideline on Stop smoking interventions for under-served groups and support for people with mental health conditions to stop smoking covered key gaps in the evidence.</p>	<p>Thank you for your comment. We note your suggestion for additional research recommendations specific to cytisinicline but as cytisinicline is not recommended for use with people over 65 years of age in the SPC and BNF we can't make research recommendations for this group or other areas without the recommended dosage regimen.</p>

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				<p>We do believe that the inclusion of research recommendations specific to Cytisine are warranted namely to address:</p> <p>1-Safety and efficacy</p> <ul style="list-style-type: none"> - safety and efficacy in persons over the age of 65 years - Safety and efficacy for other populations identified in list of contraindications and cautions <p>2 – Duration of treatment (extended use beyond 25 days)</p> <p>We suggest that these questions are equally as important as those research questions included in the “other recommendations for research” section of the guidance and that the aforementioned themes have important implications to practice and as identified in the NICE evidence summary like sufficient research. While the existing research recommendations for Stop smoking interventions for under-served groups and support for people with mental health conditions to stop smoking are important and sufficient they do not cover #1 and #2 above.</p>	

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Action on Smoking and Health	Guideline	006	012	<p>Rec. 1.12.4, The SPC for cytisinicline does not recommend use of this product in persons who are over 65 years of age. Importantly the inclusion of the contraindication is due to the lack of research in this area and not as a result of a known contraindication. The population of people over the age of 65 is an important group and should be the focus of future research to close this evidence gap. The safety and efficacy of treatment for people over 65 years of age has been well studied for other smoking aid including varenicline, which like cytisinicline is a nicotine receptor partial antagonist.</p> <p>We recommend this statement be modified to: 1) include wording to acknowledge that this contraindication is included as the result of lack of data in these population and not due to known adverse events.</p> <p>The suggested wording is below:</p> <p>“Due to the lack of clinical experience do not offer cytisinicline to people aged 66 or older.”</p>	<p>Thank you for your comment.</p> <p>NICE recommendations need to align with the licensed indications of medicines and this is reflected in the recommendations.</p>
Aflofarm Farmacja Polska Sp. z o.o.	Guideline	General	General	<p>We suggest to include throughout the document the name “cytisine”. We also suggest to add at the beginning of the document “cytisinicline (commonly known as cytisine)” and to add later one in brackets f.ex. “cytisinicline (cytisine)”. The name cytisine has been</p>	<p>We understand that cytisine has been the commonly used name historically and is widely recognised. However, for clarity and consistency with the British National Formulary (BNF) and the medicine's</p>

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				used since decades and is widely used in medical and scientific environment and widely recognised all over the world. Moreover, this name is the original botanical compound, with INN being assigned as cytisinicline. Moreover, cytsine is also consistently used throughout the WHO clinical treatment guideline for tobacco cessation in adults document. https://www.who.int/publications/i/item/9789240096431	marketing authorisation in the UK, we use the International Non-proprietary Name (INN) "cytisinicline" throughout the guideline. This approach aligns with NICE's standard practice of using the INN for medicines. We have added a further explanation to note the use of the name cytsine to the overview section.
Aflofarm Farmacja Polska Sp. z o.o.	Guideline	005 - 006	024, 001-004	Point 1.12.2 provides information on available interventions, but elaboration on the type of aids would be beneficial, in terms of nicotine containing and none-nitotine containing. We suggest to add this division so help providers and patients will have more precise knowledge on the smoking cessation aids. The medicinal products division may have a form: medicinally licensed products: none niciotine containg: -bupropion [2021] – cytisinicline [2025] - varenicline [2021] Nicotine-containing : nicotine replacement therapy (NRT) – short and long acting [2021]	Thank you for your comment. The recommendations do include nicotine where they are in the products, such as NRT or nicotine containing e-cigarettes.

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Aflofarm Farmacja Polska Sp. z o.o.	Evidence review A	General	General	We propose to use in the document: Cytisinicline (cytisine), taking under consideration that the scientific evidence taken under analysis were using, in most of the cases, the common name i.e cytisine	<p>Thank you for your comment.</p> <p>Cytisinicline is used throughout the guideline as this is the International Non-proprietary Name (INN) and the term used in the British National Formulary. While we acknowledge that 'cytisine' is widely used in published literature and clinical practice, NICE's standard approach is to use a single consistent term throughout our guidance to avoid potential confusion. For clarity the search strategy included the term cytisine to ensure that all relevant evidence was identified.</p> <p>We have added a further explanation to note the use of the name cytisine to the overview section.</p>
Aflofarm Farmacja Polska Sp. z o.o.	Evidence review A	004	013	We propose to add in brackets the commonly and widely used name, i.e. cytisine, similarly to the Guideline document. The proposition would be: evidence suggests that cytisinicline (commonly known as cytisine), a plant-based alkaloid with a mechanism	<p>Thank you for your comment.</p> <p>Cytisinicline is used throughout the guideline as this is the International Non-proprietary Name (INN) and the term used in the British National Formulary. While we acknowledge that 'cytisine' is widely used in published literature and clinical practice, NICE's standard approach is to use a single</p>

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					<p>consistent term throughout our guidance to avoid potential confusion.</p> <p>We have added a further explanation to note the use of the name cytisine to the overview section.</p>
Aflofarm Farmacja Polska Sp. z o.o.	Evidence review A	005	002	<p>Table 1: Summary of the protocol: Please verify if Electronic cigarettes should be named as</p> <ul style="list-style-type: none"> Other smoking cessation pharmacotherapies with or without behavioural support 	<p>Thank you for your comment.</p> <p>The review protocol was agreed and approved in advance of the evidence review, this will not be changed.</p>
Aflofarm Farmacja Polska Sp. z o.o.	Evidence review A	031	009 - 010	<p>We would like to add that even though the dosing regimen might be challenging for some patients, in the Ofori et al it has been concluded that <i>In trials comparing cytisine to varenicline, there was no difference in medication adherence rates despite differences in dosing frequency. Ofori S, et al. Cytisine for smoking cessation: A systematic review and meta-analysis. Drug Alcohol Depend. 2023 Oct 1;251:110936.</i></p> <p>https://www.sciencedirect.com/science/article/abs/pii/S0376871623011742</p>	<p>Thank you for your comment and additional information.</p>

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Bonteque Consulting Ltd	Guideline	General	General	We suggest to add additional (traditional) name of the product (i.e. in brackets: (Cytisine)) as it has been recognized for decades and refers to the plant origin of the alkaloid/substance. Cytisine is the original botanical compound. The International Non-proprietary Name (INN) for cytisine is cytinicline. Cytisine is used consistently throughout this document because it is widely recognized all over the world and the WHO clinical treatment guideline for tobacco cessation in adults refers to cytisine.	<p>We understand that cytisine is the traditionally used name and reflects the compound's botanical origin. However, for clarity and consistency with the British National Formulary (BNF) and your product's marketing authorisation in the UK, we use the International Non-proprietary Name (INN) "cytinicline" throughout the guideline. This approach aligns with NICE's standard practice of using INNs for medicines.</p> <p>We have added a further explanation to note the use of the name cytisine to the overview section.</p>
Bonteque Consulting Ltd	Guideline	004	017	We suggest to add the information after "new pharmacotherapy" that cytisine has been marketed as smoking cessation aid from 1960.	<p>Thank you for your comment. We think your comment refers to the evidence review not the guideline as the section you are referring to (p.4, line 17) does not appear in the guideline document. We have added wording in response to this comment to the evidence review.</p> <p>The focus of this guideline update is on cytinicline as a newly available licensed medicinal product in the UK market.</p>

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Bonteque Consulting Ltd	Guideline	004	021	We suggest to add in brackets the information that cytisine is included in the WHO recommendations https://www.who.int/publications/i/item/9789240096431	Thank you for your comment. NICE guidelines are based on a review of the evidence and committee discussions, developed specifically for use in the UK healthcare system. The evidence review and recommendations have been developed following NICE's standard methods and processes. Therefore, we have not added this reference to the WHO recommendations in the guideline.
Bonteque Consulting Ltd	Guideline	006	001 - 004	We suggest to clearly mark the division of pharmacological agents, separating nicotine-free forms (cytisine, varenicline, bupropion) from nicotine forms (NRT).	Thank you for your comment. The recommendations do include nicotine where they are in the products, such as NRT or nicotine containing e-cigarettes. Further distinction is not needed
Bonteque Consulting Ltd	Guideline	007	004 - 007	We suggest to clearly mark the division of pharmacological agents, separating nicotine-free forms (cytisine, varenicline, bupropion) from nicotine forms (NRT).	Thank you for your comment. The recommendations do include nicotine where they are in the products, such as NRT or nicotine containing e-cigarettes.

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Bonteque Consulting Ltd	Guideline	014	019	<p>We would like to point out that there is at least one study on under-served groups in the case of cytisine. In this study invited smokers might have been different from the subjects of other studies on cytisine. One studied the medication with medium- dependent men working in the mining industry, and not attending specialised clinic for smoking cessation. The working conditions of these people predisposed them to heavier smoking in a stressful environment, where relapse was more probable.(Vinnikov D, Brimkulov N, Burjubaeva A. A Double-Blind, Randomised, Placebo-Controlled Trial of Cytisine for Smoking Cessation in Medium-Dependent Workers. <i>Journal of Smoking Cessation</i>. 2008;3(1):57-62. doi:10.1375/jsc.3.1.57; https://www.cambridge.org/core/journals/journal-of-smoking-cessation/article/abs/doubleblind-randomised-placebocontrolled-trial-of-cytisine-for-smoking-cessation-in-mediumdependent-workers/FD545EF13935E1F029600D6D1BC8A3DD)</p>	<p>Thank you for your comment.</p> <p>The Vinnikov et al (2008) study was identified in the evidence review and its findings were considered by the committee. The Vinnikov et al (2008) study provides some evidence about cytisinicline's effectiveness in a population identified in the equality and health inequalities assessment (EHIA) under socioeconomic deprivation as being at particular risk of increased smoking prevalence.</p> <p>The committee agreed that more research is on cytisinicline's effectiveness across different under-served groups and agreed that the research recommendations in the guideline requesting research development in the areas of "Stop-smoking interventions for under-served groups" and "Support for people with mental health conditions to stop smoking" will support the gathering of more robust evidence across a broader range of under-served populations.</p>

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Bonteque Consulting Ltd	Guideline	015	020 - 021	We suggest reformatting the paragraph to simplify that the evidence suggests that cytisinicline (cytisine) is effective in helping people stop smoking when used with behavioural support.	Thank you for your comment. We have reviewed the sentence and have removed any identified repeated word. We have not made any further changes to the paragraph as it accurately reflects the evidence considered by the committee and underpinning the recommendations made.
Bonteque Consulting Ltd	Guideline	019	022	2023 update: 11.9% (https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/healthandlifeexpectancies/bulletins/adultsmokinghabitsingreatbritain/2023)	Thank you for your comment and additional information. We think you are referring to the context section of the guideline document and have updated the data in line with the ONS report provided.
Bonteque Consulting Ltd	Evidence review A	031	010	Referring to Ofori et al. we would like to point out that <i>In trials comparing cytisine to varenicline, there was no difference in medication adherence rates despite differences in dosing frequency.</i> Ofori S, et al. Cytisine for smoking cessation: A systematic review and meta-analysis. <i>Drug Alcohol Depend.</i> 2023 Oct 1;251:110936. https://www.sciencedirect.com/science/article/abs/pii/S0376871623011742	Thank you for your comment and additional information.

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British Thoracic Oncology Group (BTOG)	Guideline	General	General	The British Thoracic Oncology Group welcomes the opportunity comment on the update to this document. We are broadly supportive of the updated recommendations and recognise the importance of inclusion of cytisine as an additional tool to help treatment of tobacco dependence for those aged between 18 and 65 years.	Thank you for your comment.
British Thoracic Oncology Group (BTOG)	EHIA	001	4.1.1	Under protected characteristics age section should there also be a reflection that cystisine is not recommended in those aged 66 years and older. This is particularly relevant to treatment of tobacco dependency in those with lung cancer, as the median age of diagnosis in the UK is 74 years, so this population are unable to access the drug.	Thank you for your comment. We noted this during development and there is a specific recommendation in the guideline (1.12.5) which states "Do not offer cytisinicline to people aged 66 and over. We have now updated the EHIA to make reference to this.
British Thoracic Oncology Group (BTOG)	Evidence review A	008	001 - 002	There is a duplicate sentence, which replicates the sentence on page 007 (lines 27-28)	Thank you for your comment. We will remove the duplicated sentence to improve readability of the document.
College of General Dentistry	Guideline	General	General	Signs of oral disease contributed to by smoking are regularly detected by dental professionals -showing thee to patients can be a powerful motivator to quitting:-	Thank you for your comments.

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College of General Dentistry	Guideline	General	General	I advised one patient that the chance of their proposed dental implant being successful was significantly reduced because they were a smoker. When they returned 2 weeks later for the extraction they told me that they had not smoked since I had given that advice. They returned to me for routine care after then dental implant provision by a dental specialist..... they never went back to smoking! Such stories are commonly shared among dental professionals at dental meetings. The psychological “quit value” upon patients of seeing the effects of their smoking/vaping every day when brushing their teeth should be recognised somewhere in smoking/vaping cessation guidance.	Thank you for your comment
College of General Dentistry	Guideline	General	General	The harmful effect of vaping upon oral health is now established and can be accessed at the British Society of Periodontology's Dec 2023 review of the literature :- https://www.bsperio.org.uk/news/is-vaping-harmful-to-oral-health?	Thank you for your comment and the provision of the reference. For clarification e-cigarettes were not part of this update. If you would like to suggest a topic for future NICE guidance, you can do so by completing the NICE topic suggestion form.
College of General Dentistry	Guideline	015	001	Smoking/vaping habits enquiry are now an expected part of regular dental examinations and “short” interventions encouraged if a habit is admitted.	Thank you for your comment.
Consilient Health Ltd	Guideline	001	General	At the first mention of “cytisinicline” it would be helpful to advise readers that the molecule is also known as	Thank you for your comment.

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				<p>"cytisine". Although the official INN is now "cystisinicline", the vast majority of published literature uses the original generic name of "cytisine" and it is still widely used e.g. in the Medicines Awareness Service: Daily email alert of 19th Nov 2024; and the British Thoracic Society framework for clinicians, published in March 2024. The BNF monograph now notes both generic names, as does the National Centre for Smoking Cessation and Training website. This may help reduce the risk of confusion during this transition period.</p> <p>A similar approach of referring to alternative names is already taken within the guidelines when defining E-cigarettes (page 10, line 5).</p>	<p>We chose to use 'cytisinicline' throughout the guideline as this is the International Non-proprietary Name (INN) and the term used in the British National Formulary. While we acknowledge that 'cytisine' is widely used in published literature and clinical practice, NICE's standard approach is to use a single consistent term throughout our guidance to avoid potential confusion.</p> <p>We have added a further explanation to note the use of the name cytisine to the overview section.</p>
Consilient Health Ltd	Guideline	006	002	<p>At the first mention of "cytisinicline" it would be helpful to advise readers that the molecule is also known as "cytisine". Although the official INN is now "cystisinicline", the vast majority of published literature uses the original generic name of "cytisine" and it is still widely used e.g. in the Medicines Awareness Service: Daily email alert of 19th Nov 2024; and the British Thoracic Society framework for clinicians, published in March 2024. The BNF monograph now notes both generic names, as does the National Centre for Smoking Cessation and Training website. This may help reduce the risk of confusion during this transition period.</p>	<p>Thank you for your comment.</p> <p>Cytisinicline is used throughout the guideline as this is the International Non-proprietary Name (INN) and the term used in the British National Formulary. While we acknowledge that 'cytisine' is widely used in published literature and clinical practice, NICE's standard approach is to use a single consistent term throughout our guidance to avoid potential confusion.</p>

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				A similar approach of referring to alternative names is already taken within the guidelines when defining E-cigarettes (page 10, line 5).	We have added a further explanation to note the use of the name cytisine to the overview section.
Consilient Health Ltd	Evidence review A	002	001, 013	At the first mention of “cytisinicline” it would be helpful to advise readers that the molecule is also known as “cytisine”. Although the official INN is now “cystisinicline”, the vast majority of published literature uses the original generic name of “cytisine” and it is still widely used e.g. in the Medicines Awareness Service: Daily email alert of 19 th Nov 2024; and the British Thoracic Society framework for clinicians, published in March 2024. The BNF monograph now notes both generic names, as does the National Centre for Smoking Cessation and Training website. This may help reduce the risk of confusion during this transition period. A similar approach of referring to alternative names is already taken within the guidelines when defining E-cigarettes (page 10, line 5).	Thank you for your comment. Cytisinicline is used throughout the guideline as this is the International Non-proprietary Name (INN) and the term used in the British National Formulary. While we acknowledge that 'cytisine' is widely used in published literature and clinical practice, NICE's standard approach is to use a single consistent term throughout our guidance to avoid potential confusion. We have added a further explanation to note the use of the name cytisine to the overview section.
Fresh	Guideline	006	002	Fully support cytisinicline to be made accessible medicinally licensed product for adults who smoke	Thank you for your comment.

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Fresh	Guideline	016	003 - 004	<p>NCSCT published updated Commissioning, delivery & guidance in 2024, in which it categorised stop smoking aids by how effective they were, with Single NRT and Bupropion second choice with odds ratio of 1.55 and 1.43 respectively, compared to first choice products Combination NRT (OR 1.93), varenicline (OR 2.33), Nicotine vapes (OR 2.37) and cytisinicline (OR 2.21). Despite this in 2024/25 Q1 Stop Smoking Service data over 19% of participants used less effective second choice products (Single NRT 17%, Bupropion 2%) and a further 6% used no medication.</p> <p>It is likely that the introduction and availability of cytisinicline as a first choice treatment for tobacco dependency will impact the number of people using less effective second choice medication. This will have an impact on overall cost and cost effectiveness. Unpublished modelling done in the North East suggested that incorporating the use of cytisine would have negligible impact on medication cost per quit £219 vs £218, even factoring costs associated with a PDG but that the anticipated regional quit rate in Stop Smoking Services would increase 2% up to 51% which would result in a projected additional 348 people successfully quit at 4 wks.</p>	<p>Thank you for your comment and the additional information. The economic evidence reviewed by the committee, though limited, suggested that cytisinicline would be cost-effective, particularly given:</p> <ul style="list-style-type: none"> • The high costs and severe consequences of smoking-related diseases • Its current price compared to other options already recommended by NICE • The expectation that costs may decrease as more suppliers enter the market
Fresh	Evidence Review A	029	011 - 018	Acknowledging the highlighted limited evidence available in various population sub groups, the availability of	Thank you for your comment.

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				cytisinicline particularly in Stop Smoking Service settings and NHS Inpatient Tobacco Dependency Treatment Services with comprehensive data reporting will enable monitoring of real life data of population subgroups including those with high smoking prevalence.	
Fresh	Evidence Review A	029	029 - 031	With the development of NHS Inpatient Tobacco Dependency Treatment Services and smokefree hospital admissions, further guidance is required on use of cytisinicline alongside NRT to manage acute withdrawal symptoms during hospital stay.	<p>Thank you for your comment.</p> <p>This update to NICE's existing guideline (NG209) focused on the 'effectiveness of cytisinicline for smoking cessation in adults who smoke'. The evidence review only considered interventions that used cytisinicline with or without behavioural support (as outlined in the review protocol in appendix a of the evidence review)</p> <p>As noted in the recommendations, cytisinicline is one of several options that, when combined with behavioural support, are more likely to result in successfully stopping smoking.</p> <p>The guideline includes recommendations about treating tobacco dependence in secondary care settings.</p>
Fresh	Evidence Review A	031	004 - 007	Trained Stop Smoking Advisors and Tobacco Dependency Advisors are skilled at supporting people to	Thank you for your comment.

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				effectively utilise existing stop smoking aids including fast acting NRT products that have more complex dosing regimen than once a day patches or twice a day varenicline. Training and resources are already available to support Advisors including NCSCT Dosing guide.	
Fresh	EHIA	004	4.3.1	Whilst we agree with the potential impact of the more complex dosing regimen, particularly for individuals with lower health literacy or cognitive impairments, or those with irregular schedules such as carers – this is would be similar challenges to those who utilise fast acting NRT as a single product or as part of combination therapy. In addition the availability of cytisinicline as a single prescription would have potential benefits, including single prescription cost as opposed to multiple prescription costs over a 12 week period. This is particularly relevant in relation to cost of living for those. A shorter treatment period may also be particularly attractive to those with caregiving responsibilities who would not be able to commit to longer treatment.	<p>Thank you for your comment.</p> <p>As noted, the committee did discuss this.</p> <p>In terms of the prescription of cytisinicline this is in line with the BNF. Treatment and prescribing decisions would be for the individual and their health care professional.</p>
Fresh	EHIA	005	4.6.1	The recommendation for cytisinicline for adults will be of benefit to all adult smokers, particularly those who are unable to commit to a longer treatment plan. It is important that this is part of a discussion and individual choice. Tobacco Dependency is a long term chronic relapsing condition and as such it can take multiple attempts to quits, people who smoke should be encouraged to make regular quit attempts. Recent insight	<p>Thank you for your comment and additional information.</p> <p>The recommendations in this guideline do note the importance of discussions with and choice for an individual and the committee discussions underpinning these did note that for many people stopping smoking may</p>

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				<p>& segmentation work done in the North East suggested that cold turkey & no medication is still the most popular intended method to quit so it is important to consider communications and promotion, for both health professionals and public facing (taking into account health literacy), in order to maximise the reach and impact of cytisinicline.</p> <p>Smoking prevalence nationally is highest in the younger age groups with those aged 25-34yrs most likely to smoke at 14% compared to those aged 65+ at 8.2%, however 2024/25 Q1 Stop Smoking Service Data for the North East shows that older age groups are more likely to access Stop Smoking Services with only 13% of those accessing services in the 18-34 age group and more than a third were aged above 60 years old. Shorter treatment regimen may benefit younger adult smokers and encourage more to access support services.</p>	require multiple attempts, and that there are individual preferences in the stop smoking support chosen.
National Centre for Smoking Cessation and Training	Guideline	General	General	We would like to congratulate NICE for undertaking this rapid process to address available evidence regarding the use of cytisinicline as a stop smoking aid. The addition of Cytisinicline in January 2024 to the British National Formulary was long awaited. The proposed amendments to the NG209 are critical to the ability of organisations to support the use of cytisinicline as a treatment for individuals who seek to stop smoking or remain temporarily abstinent. NCSCT provides our	Thank you for your comment.

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				<p>overwhelming support that that the available evidence support the use of cytisinicline as stop smoking aid is very strong and sufficient for cytisinicline to be identified alongside varenicline, combination nicotine replacement therapy and nicotine containing vapes as first choice stop smoking aids.</p> <p>NCSCT also acknowledges that the Summary of Product Characteristics (SPC) for cytisinicline includes a number contraindications and cautions. The majority of contraindication and cautions are included due to a lack of research and do not reflect evidence of an increased risk of adverse events. While we must take these contraindications seriously, we expect as a nicotine receptor partial agonist that general safety profile of cytisinicline is likely to be similar to that of varenicline, but with fewer side effects. High quality data is available for varenicline to support safety in the majority of groups. The exceptions being pregnant and breastfeeding women, people under the age of 18, and people with end stage renal failure or a previous allergic reaction. We would expect with more research that the list of contraindications and cautions for cytisinicline will be reduced or removed.</p>	

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				<p>NCSCT has available on our website additional resources to support the field with introduction of cytisinicline:</p> <p>A briefing on Cytisine: https://www.ncsct.co.uk/library/view/pdf/Cytisine.pdf</p>	
National Centre for Smoking Cessation and Training	Guideline	General	General	<p>We acknowledge as summarized in the evidence review that the committee discussed the possibility of including research recommendations specific to cytisinicline to cover key gaps in the evidence. We understand the decision was made that the 2 existing research 10 recommendations in the guideline on 11 Stop smoking interventions for under-served groups and support for people with 12 mental health conditions to stop smoking covered key gaps in the evidence.</p> <p>We do believe that the inclusion of research recommendations specific to Cytisine are warranted namely to address:</p> <p>1-Safety and efficacy</p> <ul style="list-style-type: none"> - safety and efficacy in persons over the age of 65 years - Safety and efficacy for other populations identified in list of contraindications and cautions 	<p>Thank you for your comment.</p> <p>As cytisinicline is not recommended for use with people over 65 years of age in the SPC and BNF we can't make research recommendations without the recommended dosage regimen.</p>

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				<p>2 – Duration of treatment (extended use beyond 25 days)</p> <p>We suggest that these questions are equally as important as those research questions included in the “other recommendations for research” section of the guidance and that the aforementioned themes have important implications to practice and as identified in the NICE evidence summary like sufficient research. While the existing research recommendations for Stop smoking interventions for under-served groups and support for people with 12 mental health conditions to stop smoking are important and sufficient they do not cover #1 and #2 above.</p>	
National Centre for Smoking Cessation and Training	Guideline	006	012	<p>Rec. 1.12.4, The SPC for cytisinicline does not recommend use of this product in persons who are over 65 years of age. Importantly the inclusion of the contraindication is due to the lack of research in this area and not as a result of a known contraindication. The population of people over the age of 65 is an important group and should be the focus of future research to close this evidence gap. The safety and efficacy of treatment for people over 65 years of age has been well studied for other smoking aid including varenicline, which like cytisinicline is a nicotine receptor partial antagonist.</p>	<p>Thank you for your comment.</p> <p>NICE recommendations need to align with the licensed indications of medicines, this is reflected in the wording of this recommendation.</p>

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				<p>We recommend this statement be modified to: 1) include wording to acknowledge that this contraindication is included as the result of lack of data in these population and not due to known adverse events.</p> <p>The suggested wording is below:</p> <p>“Due to the lack of clinical experience do not offer cytisinicline to people aged 66 or older.”</p>	
NHS England	Guideline	General	General	The inclusion of cytisinicline is welcome as another smoking cessation aid.	Thank you for your comment.
NHS England	Guideline	General	General	The use of the term cytisinicline is technically correct, but the product is also known in the UK as cytosine. Should there be reference to this nomenclature?	<p>Thank you for your comment. Cytisinicline has been used throughout the guideline as this is the International Non-proprietary Name (INN) and the term used in the British National Formulary. While we acknowledge that 'cytosine' is also commonly used in the UK. This approach aligns with NICE's standard practice of using INNs for medicines.</p> <p>We have added a further explanation to note the use of the name cytosine to the overview section.</p>

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NICE GP reference panel	Guideline	General	General	We felt that the updated guidance is helpful, easy to follow, and comprehensive in scope. We recorded, however, some very strong themes in specific areas of the guidance.	Thank you for your comment.
NICE GP reference panel	Guideline	General	General	We would welcome a clear diagrammatic evidence-based pathway to help shared decision- making. The breadth of options, variations in effectiveness, and cautions/ contraindications of some preparations all lend themselves to a holistic pathway. There are good resources on the NCSCT website that could facilitate this.	Thank you for your comment. As you have highlighted the key to the decisions around using stop smoking interventions is shared decision making and the preferences of the person involved. NICE has a guideline on shared decision making . The National Centre for Smoking Cessation and Training (NCSCT) are referenced in the guideline for training requirements.
NICE GP reference panel	Guideline	006	002	We are pleased with the inclusion of cytisinicline. It could be especially useful if there are further supply issues with varenicline. We suspect, however, that now that varenicline is off patent and once again available, it will be prescribed more frequently.	Thank you for your comment.
NICE GP reference panel	Guideline	006	005	E-cigarettes: the panel expressed concern about an approach using e-cigarettes especially if open-ended in timescale. Many smokers struggle to stop completely.	Thank you for your comment. The recommendations about e-cigarettes were not reviewed as part of this update. The evidence and recommendations for e-cigarettes were last reviewed in 2021 and can be found in the full guideline .

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NICE GP reference panel	Guideline	006	012	If cytisinicline is not to be used in certain groups we think the guideline would be strengthened by explaining the reasons. See also comments on P6 L21 and P8 L5	Thank you for your comment. The recommendations regarding who should not use cytisinicline are based on the current licensing of cytisinicline.
NICE GP reference panel	Guideline	006	021	There was a strong feeling that contraindications should be mentioned here as the conditions that preclude/ inhibit the use of cytisinicline themselves frequently trigger patient engagement in smoking cessation (eg recent MI). We also thought that the interaction with hormonal contraception should be highlighted.	Thank you for your comment. The guideline directs readers to the BNF for full prescribing information, including contraindications and drug interactions.
NICE GP reference panel	Guideline	007	001	Should there be more of a mandate within the guidance to ensure behavioural support is offered with licensed products and NRT? Please also confirm that this should only be done in the context of an adequately resourced and holistic smoking cessation service.	Thank you for your comment. The guideline recommends that behavioural support should be offered alongside stop-smoking products. How services are resourced and configured is outside the remit of this update.
NICE GP reference panel	Guideline	007	004	We question the order of options. Should it be rearranged in order of effectiveness or a hierarchical pathway (this links with some of our other comments)?	Thank you for your comment. The evidence review focused specifically on the effectiveness of cytisinicline compared to placebo, no medication, varenicline, and NRT. The review provides evidence about the effectiveness of cytisinicline. It does not have a definitive ordering of all treatment options, the recommendations within this guideline note the importance of shared decision making as different options to

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					support quitting smoking may be applicable to the individual trying to quit.
NICE GP reference panel	Guideline	007	018	One of the comments we received suggests that this sentence may be misunderstood: please clarify that it is the 'quit smoking date' that is pre-agreed, which should occur within the first five days of treatment.	Thank you for your comment. The current wording in recommendation 1.12.9 states "for cytisinicline, agree a quit date set within the first 5 days of treatment and reassess the person shortly before the prescription ends". The date agreed occurs within the first 5 days of treatment which is in alignment with the BNF
NICE GP reference panel	Guideline	007	019	Length of course: several respondents questioned the course length - please clarify if this is 25 days as there are other (off label) regimes. A Cochrane review has suggested trials of longer courses: https://pubmed.ncbi.nlm.nih.gov/27158893/	Thank you for your comment. The 25-day course length recommended in the guideline aligns with the licensing for cytisinicline in the UK.
NICE GP reference panel	Guideline	008	005	If cytisinicline is not to be used in certain groups we think the guideline would be strengthened by explaining the reasons.	Thank you for your comment. The recommendations about who should not receive cytisinicline reflect the current licensing for this drug.
NICE GP reference panel	Guideline	015	025	If both varenicline and cytisinicline have effects on mood, we feel this should be mentioned here.	Thank you for your comment. . NICE guidelines do not typically duplicate detailed safety information that is available in the SmPC and BNF.

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NICE GP reference panel	Guideline	016	003	In Wales the cost of cytisinicline was predicted to be £600,000/ year: https://awttc.nhs.wales/files/appraisals-asar-far/evidence-summary-report-cytisine-3708/ The figures may have changed with the subsequent introduction of generic varenicline. Cost-effectiveness is difficult to assess, though the Cochrane review https://pubmed.ncbi.nlm.nih.gov/27158893/ suggests cytisinicline is less effective	Thank you for your comment. The effectiveness review included broader, more up-to-date evidence than the Cahill 2016 review, and the committee concluded that cytisinicline was an effective option. The evidence review also included two economic evaluations of cytisinicline which showed that it was potentially cost effective. Although there may be additional drug acquisition costs, these are likely to be offset by broader NHS cost savings due to the high costs and severe consequences of smoking-related diseases. Additionally, some people may switch from less effective current treatments with similar or higher acquisition costs, potentially reducing overall NHS costs.
Reed Wellbeing	Guideline	006	012	Contradiction from NCSCT guidance which states 65 and over	Thank you for your comment. NICE recommendations must align with the licensed indications of medicines which is that it should not be use in people aged 66 and over.
Royal College of General Practitioners	Guideline	General	General	We support the importance of treating tobacco dependency in all people – and the need for behavioural support in association with medications available.	Thank you for your comment.

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Royal College of General Practitioners	Guideline	General	General	<p>The inclusion of cytisinicline as a smoking cessation intervention is a welcome addition, offering an alternative for patients who have not responded to other treatments. However, we believe that it is crucial to ensure that the complex dosing regimen and potential side effects (like insomnia and abnormal dreams) are clearly communicated to patients and providers.</p> <p>The dosing schedule is more intricate compared to other cessation aids, which could be challenging for patients with lower health literacy or cognitive impairments. Providers may need additional training to support patients effectively. We believe it may be helpful to develop simplified patient guides or apps to assist with adherence and ensure that behavioural support services are readily available.</p>	<p>Thank you for your comment.</p> <p>The committee acknowledged that the dosing schedule is more complex than some other cessation aids and that healthcare professionals will need to consider individual patient circumstances and preferences when prescribing cytisinicline.</p>
Royal College of General Practitioners	Guideline	General	General	<p>We have found that clinicians often question the role of vaping / electronic cigarettes in smoking cessation. Therefore, we believe a more detailed explanation of the guidance and deliberations would be useful to help clinicians.</p>	<p>Thank you for your comment.</p> <p>This guideline update focuses specifically on adding cytisinicline as a treatment option, detailed information about e-cigarettes can be found in the full guideline (NG209).</p> <p>The evidence and committee discussions regarding e-cigarettes are covered in several</p>

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					evidence reviews in the full guideline, including: <ul style="list-style-type: none"> Evidence review K: cessation and harm-reduction treatments Evidence review L: barriers and facilitators to using e-cigarettes for cessation or harm reduction Evidence review M: long-term health effects of e-cigarettes
Royal College of General Practitioners	Guideline	General	General	We question who will be responsible for monitoring cytinicline i.e. will it be the GP or the cessation clinic?	Thank you for your comment. The guideline does not specify which healthcare professionals should be responsible for monitoring cytinicline, as service delivery models vary across different areas.
Royal College of General Practitioners	Guideline/ EHIA	General	General	The rationale is well-supported by evidence. Emphasising the importance of individualised treatment plans based on patient preference and medical history is commendable. However, the EIA highlights significant gaps in evidence for vulnerable groups, including those with mental health conditions, socioeconomically disadvantaged populations, and those with lower health literacy. Therefore, we find it essential that the guidance addresses these gaps in future research. National subsidies or targeted funding could improve access to rural and socioeconomically disadvantaged populations.	Thank you for your comment. The committee agrees that evidence gaps exist for certain population groups and acknowledges these limitations in the evidence base. While some evidence was available for people with mental health conditions, evidence was lacking for many other subgroups such as those from socioeconomically disadvantaged

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				Targeted interventions should be developed for populations with mental health issues or those in socioeconomically deprived areas, as these groups face higher barriers to quitting	populations and those with lower health literacy. There is also an existing research recommendation within the tobacco guideline on the need for research in stop-smoking interventions for under-served groups.
Royal College of General Practitioners	Guideline	007	014	We are concerned that the guidance places bupropion ahead of cytisnicline and other options despite the above stating that it would be less likely for it to result in a successful cessation of smoking. We recommend changing the order around and have bupropion at the end of this list.	Thank you for your comment. The ordering here is alphabetical as the prescribing decision will have been made. The key in prescribing decisions is the discussion with the person and the preferred choices of stop smoking support.
Royal College of General Practitioners	Evidence Review A	General	General	Implementing cytisnicline may incur higher upfront costs compared to existing NRT or varenicline options. The economic reviews suggest that cytisnicline's effectiveness could lead to reduced long-term healthcare costs associated with smoking-related illnesses. We suggest conducting a cost-benefit analysis that covers different population groups, with a focus on long-term savings and reduced hospital admissions.	Thank you for your comment. The committee carefully considered the economic implications of recommending cytisnicline. While the initial cost of cytisnicline (£115 per course) is higher than originally modelled in the economic analyses we reviewed, it remains lower than varenicline (£230 per course). The committee acknowledged that most interventions that are clinically effective for smoking cessation tend to be cost-effective due to the high costs and severe consequences of smoking-related diseases. The available economic evidence, though limited, showed that cytisnicline is likely to be

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					<p>cost-effective. The committee noted that the current price of £115 reflects costs of MHRA approval and distribution setup, and they expect this may decrease as more suppliers enter the market. They also noted that this price remains below the £250 threshold identified in the Leaviss 2014 analysis, above which cytisinicline would no longer be considered cost-effective.</p> <p>While we agree that additional economic analyses focusing on specific population groups would be valuable, the committee considered that the existing research recommendations on smoking cessation interventions for under-served groups and people with mental health conditions adequately cover the need for further research in key populations. These recommendations encompass both effectiveness and cost-effectiveness considerations.</p>
Royal College of Physicians	Guideline	General	General	The Royal College of Physicians (RCP) is grateful for the opportunity to comment on the draft guideline. In doing so, we have liaised with Professor Sanjay Agrawal, the RCP's special adviser on tobacco and chair of the RCP	Thank you for your comment and the additional information provided.

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				Tobacco Advisory Group (TAG). We would like to make the following comments.	
Royal College of Physicians	Guideline	General	General	<ul style="list-style-type: none"> It is effective - see Cochrane review of pharmacotherapies and e-cigarettes. It would provide patients with an additional option that is not nicotine related and in tablet form. In addition, the length of treatment is only 25 days.	Thank you for your comment and the additional information provided.
Royal College of Physicians	Guideline	General	General	It has a very good place in the hospital pathways (NHS LTP in-patient tobacco dependency treatment). This is because it would not need to be re-prescribed in the community after hospital discharge – due to it being a 25 day course, rather than 12 weeks for NRT and varenicline.	Thank you for your comment and the additional information provided.
Royal College of Physicians	Guideline	General	General	<ul style="list-style-type: none"> The RCP's recent report on e-cigarettes and harm reduction states that 'there was no clear difference in effectiveness between e-cigarettes with nicotine, varenicline, or cytisine'. It was also referenced in our 2018 report, Hiding in Plain Sight. 	Thank you for your comment and the additional information provided.

**None of the stakeholders who comments on this clinical guideline have declared any links to the tobacco industry.*

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