

## Evidence review for Area Prescribing Committee (APC)

<b>Medicine details</b>	
<b>Name, brand name</b>	Cytisine (also known as cytisinicline)
<b>Manufacturer</b>	Consilient Health Ltd, Alliance Healthcare Ltd, AAH Pharmaceuticals
<b>Proposed indication</b>	Smoking cessation and reduction of nicotine cravings in smokers willing to stop. Treatment goal is the permanent cessation of use of nicotine-containing products.
<b>Requested by</b>	Surrey County Council Public Health

### SUMMARY

#### Clinical Effectiveness

The clinical evidence for the effectiveness of cytisine as a stop smoking intervention is summarised in a number of published evidence summaries.

NICE published an exceptional surveillance report in 2023 that concluded that the available evidence confirms that cytisine has a comparable effect, safety and cost to currently recommended products. As a result they will be updating guideline NG209 on smoking cessation. No timescales are currently available for the update the guideline.<sup>1</sup>

The recently published World Health Organisation (WHO) Clinical Treatment guideline for tobacco cessation concluded there is moderate-certainty evidence that cytisine is more effective than placebo/no intervention/usual care in supporting smokers to quit smoking for 6 months or longer; and there is very low- to low-certainty evidence for a significant difference in the likelihood of quitting smoking between cytisine and varenicline, and between cytisine and NRT.<sup>2</sup>

The All Wales Therapeutics and Toxicology Centre (AWTTC) review for the All Wales Medicines Strategy Committee have recommended cytisine for use within NHS Wales for smoking cessation. The AWMSG has issued guidance recommending cytisine as an option for use within NHS Wales for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking.<sup>3</sup>

The Drug and Therapeutics Bulletin drug review of cytisine concludes the evidence from randomised controlled trials suggests that cytisine increased the chance of stopping smoking at 12 months relative to placebo or no treatment and is about as effective as varenicline or NRT.<sup>4</sup>

#### Safety

##### WHO

The balance of benefits against harms favours cytisine on the basis of large benefits (cytisine versus placebo, NNT: 15 for one more case of continuous long-term abstinence; cytisine versus NRT, NNT: 18 to achieve one additional case of long-term abstinence) and small harms (more harms than placebo were reported in five out of six trials; however, differences were not statistically significant in most trials and no serious harms were reported).

AWTTC review notes that cytisine containing products have been in use for more than 50 years in the EU. Clinical studies and observational data suggest that it has good tolerability. That the proportion of people who discontinued treatment because of adverse reactions was low and comparable to those who discontinued placebo treatment. Adverse reactions observed have usually been mild to moderate and have most frequently concerned the gastrointestinal tract.

Commonly reported adverse effects include: change in appetite, weight gain, dizziness, irritability, mood changes, anxiety, sleep disorders, headaches, tachycardia, hypertension, dry mouth, diarrhoea, nausea, heartburn, constipation, vomiting, abdominal pain, rash, myalgia and fatigue.

### Patient factors

Cytisine is contraindicated in patients:

- <18 years or >65 years,
- patients with liver or kidney impairment,
- patients with unstable angina, recent MI or stroke or clinically significant arrhythmias.

It is also contraindicated in pregnancy and breastfeeding. Women of childbearing potential taking hormonal contraception should add a secondary barrier method whilst taking cytisine, since the impact of cytisine on efficacy of hormonal contraception is not known.

The dose regime is complex and so harder for patients to take than other oral treatments but is a shorter treatment course than other treatments. See section on medicine details for dose regime. These factors limit the potential patient group quite considerably compared to varenicline and to a lesser extent bupropion.

Access to the local stop smoking service is not a problem. There is currently no waiting list and the capacity has been increased with additional grant money.

### Cost implications

Cost of cytisine is £115 per 25 day course

This is similar to varenicline “Champix” (£164 per 12 week course) and more than bupropion (£83.52 per 9 week course). Note varenicline will become available as a generic medicine later this year, so the Drug Tariff price is expected to be less than the previous price of “Champix” the brand of varenicline.

The cost impact to the ICB is likely to be neutral, or a small increase in overall costs for all licensed stop smoking medications as they become available again and used at pre-pandemic levels. However, it is anticipated that any increase would be minimal based on the introduction of e-cigarettes within the local stop smoking service (funded by public health) as a quit aid in April 2022.

#### Cost-effectiveness

A NICE evidence review of interventions to aid smoking cessation: behavioural support and pharmacotherapy found that **all** support interventions (behavioural support only, pharmacotherapy alone, pharmacotherapy with behavioural support) provided cost effectiveness.

‘This topic area was covered in the overall health economic modelling, which indicated that all interventions were cost effective and potentially cost saving to both NHS and local authorities. Eight of the included studies involved some element of pharmacotherapy; all were found to be cost-effective.’<sup>15</sup>

Improved quality of life will be achieved for anyone successfully quitting smoking.

### Relevant guidance / reviews

#### **All Wales Medicines Strategy Group Recommendation<sup>6</sup>**

Cytisinicline (cytisine) is recommended as an option for use within NHS Wales for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking.

Additional note(s):

- cytisinicline (cytisine) should normally be prescribed only as part of a programme of behavioural support.

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 3708), which includes the Evidence Summary Report (ESR), the Preliminary Appraisal Recommendation (PAR), clinical expert opinion, the views of clients/patients/patient carers (where available) and the lay member perspective. This recommendation has been ratified by Welsh Government and will be considered for review after three years.

### **World Health Organisation**

Decisions regarding cytisine are not preference sensitive (small harms that do not appear serious), it requires small cost, and it is feasible and probably acceptable, with probably increased equity.

Because tobacco cessation medications have different advantages and disadvantages, with potential impacts on adherence, individuals and clinicians may prefer one medication over another or a particular combination. Thus, where feasible, having multiple medications available is preferable to increase patient and clinician choice.

### **NICE**

NICE are planning to update NG209 following the exceptional surveillance review in 2024 although no timescales are available for when the update will be published.

### **NCSCT<sup>7</sup>:**

Following review of the evidence for efficacy and safety, the National Centre for Smoking Cessation and Training (NCSCT) make the following recommendations:

- Practitioners can recommend cytisine as a treatment medication with confidence, provided they follow the manufacturer's instructions.
- Incorporating cytisine into the Standard Treatment Programme for delivering behavioural support will maximise patients' chances of quitting successfully.
- Outcomes should be recorded carefully, to assess effectiveness at both a local and national level. Cytisine is included as a treatment option by NHS Digital and can be recorded in stop smoking services' quarterly returns.
- Patients are advised to access a licensed formulation (i.e. prescribed) rather than purchasing online.

Overall the NCSCT concluded cytisine is a safe, effective and cost-effective treatment, with a similar mode of action to varenicline and a similar adverse effect profile (although less frequent). It is as effective as NRT.

### **Likely place in therapy relative to current treatments**

Cytisine offers a useful additional pharmacotherapy for smoking cessation, particularly in those patients who are unable to take varenicline or bupropion due to medicines shortages, treatment failure, not tolerated or contra-indicated.

One You Surrey (local smoking cessation service) have indicated that they would only initiate cytisine with an understanding of the patient's history of quit attempts and forms of pharmacotherapy previously used.

Full information about options shared with patients as well as understanding any contraindications.

### **Recommendation to APC**

The recommendation for the APC is to approve cytisine as green (see narrative). This would be the same status as varenicline and bupropion.

Current narrative on PAD for bupropion and varenicline:


"Referral of patients to a smoking cessation service is the preferred management pathway. GPs should only prescribe smoking cessation products for patients who decline referral in line with CKS guidance or

through requests from the smoking cessation service (see below).  
 The 'One You' Surrey Smoking cessation service has been commissioned by Public Health (Surrey County Council) since April 2019 and provides support to clients as part of a 12 week programme. Nicotine replacement therapy (NRT) will be provided as part of the service in pregnancy and for clients with defined long-term health conditions.  
 Requests to prescribe NRT will only be made to the GP in rare circumstances where the client requests further NRT beyond 12- weeks (at the discretion of the GP).  
 For clients requiring the following, a request form for prescribing (includes screening questions) will be sent to the client's GP by the service:

- Bupropion (Zyban)
- Varenicline (Champix)

Clients will be monitored by 'One You' Surrey on a weekly basis for any side effects. At the end of treatment, patients will be issued with a letter to be given to their GP to update records and book a medication review (where appropriate).  
 Patients can be referred by a health care professional or can self refer.  
 Further information on the service is available at: <https://oneyoursurrey.org.uk/>  
 There is a dedicated section for primary care health professionals: <https://oneyoursurrey.org.uk/primarycare/>

<b>Medicine details</b>	
<b>Name and brand name</b>	Cytisine/Cytisinicline
<b>Licensed indication, formulation and usual dosage</b>	<p>Cytisine should be taken according to the following schedule:</p> <ul style="list-style-type: none"> <li>Days 1-3: 1 tablet every 2 hours (max 6 per day)</li> <li>Days 4-12: 1 tablet every 2.5 hours (max 5 per day)</li> <li>Days 13-16: 1 tablet every 3 hours (max 4 per day)</li> <li>Days 17-20: 1 tablet every 5 hours (max 3 per day)</li> <li>Days 21-25: 1 to 2 tablets per day (max 2 per day)</li> </ul>
<b>Summary of mechanism of action, and relevant pharmacokinetics</b>	<p>Note that "cytisine" is the same as "cytisinicline"; both are generic names for the same active substance, an alkaloid present in the seeds and many other parts of plants of the Leguminosae (Fabaceae) family, including Laburnum, Sophora, Baptisia and Ulex spp, and used as a smoking cessation treatment.</p> <ul style="list-style-type: none"> <li>• Cytisine has a similar structure to nicotine, acting on nicotinic receptors as a partial agonist (like nicotine, but weaker).</li> <li>• Cytisine also increases dopamine in the brain, helping alleviate some central symptoms of nicotine withdrawal.</li> <li>• Cytisine stimulates adrenal catecholamines, helping some peripheral symptoms of nicotine withdrawal</li> </ul> <p>Cytisine has a short half-life of ~4 hours. The SPC says there is no data for use in renally or hepatically impaired patients.</p>
<b>Important drug interactions</b>	<p>Cytisine may decrease the efficacy of combined hormonal contraceptives. The manufacturer recommends using additional highly effective contraceptive precautions.</p> <p>Should not be used with anti-tuberculosis drugs.</p> <p>Simultaneous use with products containing nicotine could lead to aggravated adverse reactions of nicotine.</p>

<b>Monitoring requirements</b>	No specific monitoring requirements
<b>Prescribing considerations</b>	<ul style="list-style-type: none"> <li>Likely traffic light status (see attached guidelines)</li> </ul>  <p>Colour classification guidelines</p> <p>Green – non-specialist drugs as per current considerations for bupropion and varenicline.</p>
<b>Other considerations</b>	<p>The local stop smoking service (One You Surrey) is delivered by Thrive Tribe. As part of their delivery model and standard operating procedure, if a client chooses to use a licensed medication as their preferred quit aid then then a prescription request for oral pharmacotherapy will be sent to that individuals GP.</p> <p>A GP prescription request form from One You Surrey for cytisine would need to be developed.</p> <p>NICE recommends behavioural support and pharmacological approaches are most effective for stopping smoking.</p> <p>Varenicline has been unavailable in the UK since July 2021, however generic varenicline will become available in October 2024.</p>

### Potential patient group (if appropriate to include)

<b>Brief description of disease</b>	<p>Smoking is one of the biggest preventable causes of early death and illness and contributes to the biggest gap in healthy life expectancy between the rich and the poor. The burden that smoking places on health and care providers in Surrey is significant with 6,331 hospital admissions a year being attributed to smoking.</p> <ul style="list-style-type: none"> <li>Around 113,000 adults (18+) smoke in Surrey. Smoking prevalence across Surrey in 2022 was 11.9%, compared to the 2011 value of 14.9%.</li> <li>Smoking causes nearly 1000 premature deaths a year in Surrey.</li> <li>34,000 smoking households live in poverty.</li> <li>3,600 people are out of work due to smoking.</li> <li>Smoking is said to be responsible for 9 in 10 diagnoses of COPD. The rate of COPD attributable mortality per 100,000 population was 30.6 in 2020-22.</li> </ul> <p>For further information about the impacts of smoking in Surrey, morbidity and mortality please see the <a href="#">Smoking, Vaping and Tobacco Control Joint Strategic Needs Assessment</a> published in August 2024.</p>			
<b>Potential patient numbers per 100,000</b>	One You Surrey data	Quit Dates Set per 100k	No of clients using Champix/Varenicline	No of clients using Zyban/Bupropion
	2021/22 (Q1)	2,171	Estimated 200	
	2022/23(Q1-Q3)		n/a	180
	2023/24 (Q4)			57

EPACT	2021/22 prescribing		2022/23 prescribing		2023/24 prescribing	
	items	Spend	items	Spend	items	Spend
Bupropion	1,497	£48,198	1,361	£43,100	504	£24,613
Varenicline	1,207	£46,497	16	£792	0	£0

The introduction of E-cigarettes into the local stop smoking service in April 2022 has reduced the need for licenced medicines for stop smoking. We would not expect total prescribing for pharmacotherapy for smoking cessation to go back to prescribing levels of 2021/22 because of the demand for e-cigarettes as a popular and effective quit aid.

There were also the following drug shortages which affected uptake:

- Varenicline from July 2021 and ongoing (October 2024)
- Zyban from December 2022 through to October 2023

<b>Outcomes required</b>	<p>Efficacy outcomes required by EMA in trials of pharmacotherapy include 1 year quit rate, continuous abstinence and biomarkers can include carbon monoxide status</p> <p>Increased choice in smoking cessation treatment. Increased likelihood of a successful and sustained quit for many patients.</p>
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### Summary of current treatment pathway

No additional primary care clinics will be required. Patients should only be prescribed Cytisine while engaged in the Stop Smoking Service (SSS) (where staff are Level 2 smoking advisors who are trained/supported/contracted by the Local Authority Stop Smoking Service) to receive behavioural support alongside pharmacotherapy for their quit attempt. All existing SSS protocols will be maintained. Patients are considered 3 times more likely to achieve a quit with support from a SSS.

#### Current procedure for administering treatment by Thrive Tribe

Thrive Tribe uses a range of stop smoking medications which are provided for different lengths of time depending on the regional service. All products must be given out as per their SPC (summary of product characteristics). The SPC and full info for each product can be found here [Stop smoking medications \(ncsct.co.uk\)](https://ncsct.co.uk). All clients should be advised to check the Patient Information Leaflet of their products, to be aware of any contraindications with their current list of medications and to seek the advice of their GP if they have any concerns.

At the first appointment advisors will discuss with the client all the available nicotine replacement therapy options, including medication and e-cigarettes. Recommendations will be made based on the clients' smoking habits and any medical history the client discloses which may lead to contraindications. It is noted that OYS do not have access to patient records.

#### **Medication**

It is not compulsory for clients to use medication as part of their quit journey. Each service is unique in what they can offer in terms of products and quantity. Follow the guidance below for more information.

- Ask the client if they have an idea of what support / medication they would like on their quit journey.
- Be aware that Champix is no longer available and Zyban is not available in all areas. Cytisine is a new drug that is currently not available in any Thrive Tribe service.
- If a client does not wish to use medication/NRT/e-cigs, ask them to explain why and give the benefits of using medication along with behavioural support.
- Refer to appendix C for a list of prescribed NRT and e-cigarettes for your service and the usage guide (attached below) for information of how much NRT should be prescribed based on level of nicotine dependency.

### Drug Interactions

- It is important to be aware of the impact stopping smoking can have on other prescribed medications. All advisors are provided with a training pack which lists common medications and the effect on the body by stopping smoking and starting smoking. As a result, the client's GP should be informed of the client's choice to start a quit journey. It is the responsibility of the advisor to assess whether the client can be relied upon to update their GP, and the advisor should inform the GP themselves if necessary.



NRT guidelines how much per week (2).pd

GP Prescription request used by One You Surrey for bupropion



Zyban Prescription Request OYS.pdf

## Evidence review



AWMSG May 24 ESR  
Cytisine 3708 Website

### Evidence review for All Wales Medicines Strategy Group:

#### WHO 2024<sup>2</sup>

A systematic review of 14 studies commissioned by WHO showed that participants who received cytisine were significantly more likely to quit smoking for at least 6 months than those who received placebo/no intervention/usual care (RR: 2.61; 95% CI: 1.50–4.67; 6 trials; 5194 participants) and significantly more likely to have higher long-term abstinence rates than participants who received NRT (RR: 1.36; 95% CI: 1.06–1.73; 2 trials; 1511 participants). There was no significant difference in the likelihood of quitting tobacco use between participants taking cytisine and varenicline (RR: 0.96; 95% CI: 0.63–1.45; 3 trials; 2127 participants). Two trials that examined the impact of longer versus shorter treatment durations of cytisine found high abstinence rates with longer treatment (RR: 1.29; 95% CI: 1.02–1.63; 1009 participants).

While seven studies reported more adverse events among those receiving cytisine compared with those who received placebo, NRT or counselling, there was little evidence of serious adverse events associated with cytisine use.

**Livingstone-Banks et al 2023** undertook a Cochrane Review to assess the effectiveness of nicotine receptor partial agonists, including varenicline and cytisine, for smoking cessation<sup>8</sup>. Eight studies were included that assessed the efficacy of cytisine for smoking cessation in adults. Four studies comparing cytisine to placebo showed that cytisine helped people to quit smoking, with a moderate-certainty of

evidence (risk ratio [RR] 1.30, 95% confidence interval [CI] 1.15 to 1.47). A further two studies reporting cytisine versus varenicline showed that more people in the varenicline arm quit smoking (RR 0.83, 95% CI 0.66 to 1.05). This showed a moderate-certainty of evidence, limited by the fact that the confidence intervals incorporated the potential for benefit from either cytisine or varenicline. One study compared cytisine to NRT and found that more people in the cytisine arm successfully quit than in the NRT arm (RR 1.43, 95% CI 1.13 to 1.80). The final study compared 40 days and 84 days of cytisine, and found that more people successfully quit on the longer treatment, however both durations are longer than the MHRA licensed duration of 25 days<sup>8</sup>.

**Lindson et al 2023** used the data from the Livingstone-Banks et al review to conduct a component network meta-analysis (NMA) to investigate the comparative benefits, harms and tolerability of different smoking cessation pharmacotherapies and e-cigarettes, when used to help people stop smoking tobacco<sup>9</sup>. Cochrane methods were used to select randomised control studies (RCTs) of smoking cessation, measured at six months or longer, using nicotine and non-nicotine e-cigarettes, cytisine, varenicline, NRT, bupropion, and nortriptyline versus no intervention, placebo or another approved pharmacotherapy. The number of RCTs included in the study was 319. The authors concluded that the most effective interventions were nicotine e-cigarettes, varenicline and cytisine (all with high-certainty). The results showed cytisine was associated with higher quit rates than control (odds ratio [OR] 2.21, 95% credibility intervals (CrI) 1.66 to 2.97; based on 7 RCTs, 3,848 participants)<sup>9</sup>

#### **NICE exceptional review of the evidence:**

The final decision by NICE is as follows:

“After considering the available evidence and the impact on current recommendations, we decided that an update of recommendations 1.12.2, 1.12.7, 1.12.8 and 1.12.9 (in NICE NG209) is required.

The change in the availability of cytisine in the UK means that it should be considered alongside other interventions for smoking cessation. Given the evidence provided in the Cochrane review and more recently published trials, it is apparent that cytisine should be listed in the medicinally licensed product recommendations as an option for people who smoke.

There is evidence that the level of adverse events is less than those reported for varenicline and the costs of cytisine do not appear to be prohibitive to the recommendation.

Topic expertise is required on whether cytisine is recommended to people who smoke as a product that is 'more likely to result in them successfully stopping smoking' (recommendation 1.12.7) or 'less likely to result in them successfully stopping smoking' (recommendation 1.12.8)”.

The guideline currently states that varenicline, nicotine-containing e-cigarettes and nicotine replacement therapies (NRT) are more likely to result in people successfully stopping smoking. The available evidence confirms that cytisine has a comparable effect, safety and cost to these recommended products<sup>1</sup>.

[N.B. To clarify, an option that NICE categorises as 'less likely' would still be more likely to achieve success than behavioural support alone].

#### **Safety**

Previous experience and results from clinical studies indicate a good tolerability of cytisine. Cytisine has been used in Europe by several million people who smoke, and up to January 2024 there has been no evidence of any serious adverse events<sup>13</sup>. The proportion of people who discontinued treatment because of adverse reactions was 6 – 15.5% and in controlled studies it was comparable to the proportion of people who discontinued treatment in the placebo group<sup>1</sup>. The Livingstone-Banks Cochrane analysis of 3 studies showed no evidence of a difference in the number of cytisine -treated people versus those treated with placebo reporting serious adverse events (RR 1.04, 95% CI 0.78 to 1.37)<sup>8</sup>. Meta-analysis of two RCTs showed more people treated with varenicline versus those treated



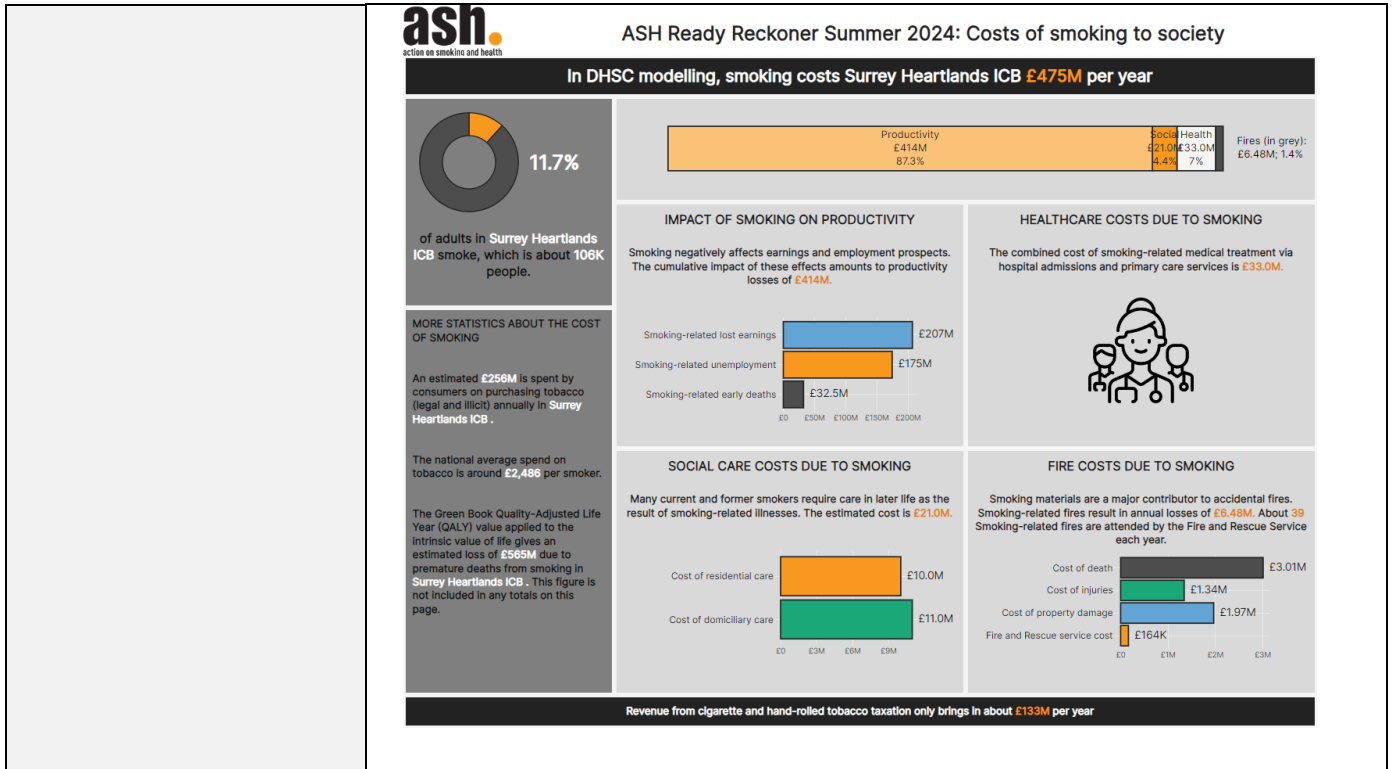
with cytisine reported serious adverse events (RR 0.67, 95% CI 0.44 to 1.03)<sup>9</sup>.

This dosing regimen has not changed since the first introduction of cytisine and has been questioned by some experts, with some studies reporting low adherence to this quite complex regimen, reducing treatment success, and others noting that other smoking cessation treatments would typically be used for longer durations with less frequent dosing. It should also be noted that patients in RCTs tend to adhere to treatment regimes much better than in the real world.

<b>Equity / Stakeholder views</b> (if relevant)	
<b>Decisions of local Trusts DTCs and neighbouring APCs</b>	<p>Not on formulary in South West London, South East London, Sussex, Buckinghamshire, Oxfordshire, North West London</p> <p><b>Frimley ICS:</b> Amber without shared care, that can be prescribed in primary care, on specialist advice without the need for a formal shared care agreement. Added to the formulary while varenicline and bupropion are unavailable. Once supply problems with these products resolve then the formulary position of cytisinicline will be reviewed. Only prescribe if it is recommended by a smoking cessation service and when the service is providing ongoing support.</p> <p><b>West Kent Formulary:</b> Green For use in community, not for secondary care initiation.</p> <p><b>East Kent Formulary:</b> Green. Stop smoking services to develop a PGD. Hampshire and Isle of Wight Formulary: Green. Local public health advise GPs may initiate cytisine, but only:</p> <ul style="list-style-type: none"> <li>• as a second line treatment for people who have already tried NRT with behavioural support</li> <li>• alongside the provision of specialist behavioural support by a smoking cessation service</li> <li>• as a course of treatment for 25 days (as per product licence)</li> </ul>
<b>Recommendations from national / regional decision making groups</b>	<p><b>All Wales Medicines Strategy Group Recommendation<sup>6</sup></b> Cytisinicline (cytisine) is recommended as an option for use within NHS Wales for smoking cessation and reduction of nicotine cravings in smokers who are willing to stop smoking.</p> <p>Additional note(s):</p> <ul style="list-style-type: none"> <li>• cytisinicline (cytisine) should normally be prescribed only as part of a programme of behavioural support.</li> </ul> <p><b>WHO Clinical Treatment Guideline for tobacco cessation in adults:</b> WHO recommends varenicline, NRT, bupropion and cytisine as pharmacological treatment options for tobacco users who smoke and are interested in quitting. Varenicline, NRT or bupropion are recommended as first-line options; combination NRT is an option for tobacco users interested in quitting who will use NRT.</p>
<b>Stakeholder views</b>	No comments were received during APC consultation.
<b>CCG priorities</b>	The <u>Surrey Heartlands Joint Forward Plan</u> sets out how the local NHS, partner local authorities, voluntary, community and social enterprise (VCSE)

	<p>sector, Places and Neighbourhoods will deliver their Integrated Care Strategies and NHS Long Term Plan commitments for the local population. Smoking is specifically mentioned in sections on cardiovascular disease, respiratory, and maternity, including the commitment to reduce the prevalence of smoking in Surrey.</p> <p>The <u>Surrey Tobacco Control Strategy 2023-26</u> was published in Autumn 2023. The strategy sets out why and how Surrey needs to work together to reduce the harmful effects of tobacco. Delivering a high quality, specialist stop smoking service is included in one of the five local priorities.</p> <p>Surrey's <u>Health and Wellbeing Strategy 2022</u> specifically addresses smoking under priority one 'Supporting people to lead healthy lives by preventing physical ill health and promoting physical well-being', with a key outcome to ensure substance misuse is low, including smoking.</p>
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<b>Health economic considerations</b>	
<b>Cost per year per patient</b>	Cytisine 1.5mg tablets 100 x costs £115 (complete 25-day treatment course)
<b>Alternative treatments cost per patient per year</b>	<p>Bupropion cost of 9 week treatment course is £83.52</p> <p>Varenicline previously cost for 12 week course £164 (generic varenicline will become available later in 2024, possibly at lower cost)</p> <p>NRT patch costs of 12 weeks is ~£121</p> <p>NRT patch plus inhalator for 12 weeks is ~£350</p> <p>NRT patch plus gum for 12 weeks is ~£270</p> <p>Note cost of NRT treatment can vary depending on the level of NRT usage.</p>
<b>Other financial considerations (if relevant)</b>	<p>The average cost per service user using an e-cigarette is £40.30.</p> <p>Total spend for E-cigarettes in 23/24 was £24,784 (funded by public health)</p>
<b>Health economic data (if available)</b>	<p>Smoking has a significant financial burden therefore reducing prevalence will lead to cost savings.</p> <p>Smoking increases multimorbidity, leading to over 6000 hospital admissions per year in Surrey.</p> <p>The cost of smoking to the NHS in England is estimated to be £21.8b per year (£475m for Surrey Heartlands ICB). The dashboard below shows the overall estimate costs of smoking to Surrey Heartlands ICB.</p> <p>In addition to cost to the ICB, the cost to the individual patient is significant. In Surrey smokers are spending £256m on tobacco (both legal and illegal), and this works out at £2,486 per smoker per year.</p>



## References

- 2024 exceptional surveillance of tobacco: preventing uptake, promoting quitting and treating dependence (NICE guideline NG209)
- WHO clinical treatment guideline for tobacco cessation in adults. Geneva: World Health Organization; 2024. Licence: CC BY-NC-SA 3.0 IGO.
- All Wales Therapeutics and Toxicology Centre Evidence Summary Report. Cytisine 3708
- Drug and Therapeutics Bulletin: Cytisine for smoking cessation. May 2024, Vol 62, no. 5
- [NG92 Evidence review B behavioural support and pharmacotherapy \(nice.org.uk\)](https://www.nice.org.uk/guidance/ng92/evidence-review-b-behavioural-support-and-pharmacotherapy)
- All Wales Medicines Strategy Group Final Appraisal Recommendation – 0424: cytinicline (cytisine) 1.5 mg tablets July 2024
- National Centre for Smoking Cessation and Training, 2024. Cytisine briefing.
- Livingstone-Banks J, Fanshawe TR, Thomas KH et al. Nicotine receptor partial agonists for smoking cessation. *Cochrane Database of Systematic Reviews*. 2023(5).
- Lindson N, Theodoulou A, Ordóñez-Mena JM et al. Pharmacological and electronic cigarette interventions for smoking cessation in adults: component network meta-analyses. *Cochrane Database of Systematic Reviews*. 2023(9).

## Equality Impact Assessment

Protected characteristics <u>Protected Characteristics - Information</u>	Describe any considerations or concerns for each group.	Describe suggested mitigations to reduce inequalities.
Age	Cytisine is not licensed for people less than 18 years or over 65 years old. This is because no evidence was submitted for these age groups at the time of the original license.	The Summary of Product Characteristics criteria specify which people are excluded from treatment due to the associated risks.
Disability	The summary of product characteristics contradicts use in those with a history of recent myocardial infarction, clinically significant arrhythmias, a history of recent stroke or pregnant	N/A

	or breastfeeding. It is not recommended for those with renal or hepatic impairment.	
Gender reassignment	We do not expect a potential negative, or unequal, impact on people based on their gender, or on people undergoing gender reassignment.	N/A
Marriage and civil partnership	We do not expect a potential negative, or unequal, impact on people based on their marital status or being in a civil partnership.	N/A
Pregnancy & maternity	Cytisine is not recommended for women who are pregnant or who want to become pregnant. Please refer to the SmPC.	The SmPC criteria specify which people are excluded from treatment due to the associated risks of treatment.
Race	We do not expect a potential negative, or unequal, impact on people due to their race.	N/A
Religion and belief	We do not expect a potential negative, or unequal, impact on people who have a religion or belief, or people with no religion of belief.  Some medicines are made from certain animal products and people might not want to take them because of religion or belief.	N/A
Sex	Cytisine is not recommended for females who are of childbearing age or want to become pregnant.	N/A
Sexual orientation	We do not expect a potential negative, or unequal, impact on people based on who they are attracted to.	N/A
Impact on any other vulnerable groups?	Cytisine provides an option for smoking cessation for those with nicotine addiction..	N/A

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Declaration of Interest:

n/a

Date: 9<sup>th</sup> August 2024

**Reviewed by:**

Helen Marlow, Lead Respiratory Specialist Pharmacist, Surrey Heartlands ICB

Declaration of Interest:

None

Date: 9<sup>th</sup> August 2024

## VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
v.1	01.08.2024	Emma Jones	draft	
v.1.1	07.08.2024	Helen Marlow	Draft	Reviewed draft.
V2	09.08.2024	EJ and HM	Final consultation	Draft for consultation
FINAL	28.08.2024	EJ and HM	Final for APC	

## Comments on Evidence review for Area Prescribing Committee (APC)

<b>Medicine and proposed indication</b>	
<b>Comments</b> by	No comments received during consultation
<b>Comments on evidence review</b>	
<b>Additional evidence and references for consideration</b>	
<b>Specific clinical questions</b>	
<b>Other colleagues who should be contacted</b>	